Author:

Bettina Taylor[i]

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Rationing of Medicines and Health Care Technology

Abstract

Rationing of medicines and health care technologies has become an important topic globally. Health care budgets are pressurised inter alia by the 'so-called' enhanced capabilities of medicine. As health care technology advances, more patients can potentially benefit from known therapies. Given the inability of any health care system to increase its health care budget indefinitely, choices regarding the allocation of funds have become inevitable. To achieve the best clinical outcomes with available funds, the efficacy, safety and quality of technologies, including medicines, must be ensured, their prices optimised and their appropriate use encouraged.

This chapter not only provides an outline of the processes in South Africa that determine allocation of resources towards such interventions, but based on international experience, it also examines some of the advantages and disadvantages of national drug and technology appraisal systems whose functions extend beyond that of marketing approval agencies. Relevant developments in government policy and legislation as they relate to the establishment of a more efficient and egalitarian health care system is reviewed and considerations for future health care reform are proposed.

i Medscheme Health Risk Solutions

Introduction

It is generally accepted that advances in health care contribute significantly to medical inflation worldwide.[1] Estimates suggest that in the United States of America's (USA) medical sector, half of the real health expenditure growth is attributable to medical technology.[2] Whilst some developments may reduce overall costs of diagnosis and treatment, most are associated with incremental costs to the health care system. As technology advances, more patients can benefit from therapy. Potential quality of care is improved as current capabilities are refined; patients who previously exhausted all therapeutic options may be offered alternatives as novel treatments for previously untreatable conditions (e.g. AIDS and end-stage renal disease) have evolved. Such increases in health care spending are thus a product of what has been alluded to as the 'enhanced capabilities of medicine' that may be associated with technological change.[3]

However, not all proposed technological advancements translate into improved clinical care and often potential benefits are only marginal. Also, health care budgets cannot be increased indefinitely. For these reasons, rationing of medical technology is an important topic globally. The realisation that not all potentially beneficial health care interventions can be funded from community-rated third-party health care funds is no longer confined to poorer societies. Even in the most affluent countries, governments are grappling with decisions on how to best allocate finite budgets (i.e. which medicines and technologies to include and exclude from societal funding).

In South Africa, policymakers have the additional challenge of redressing the inequality in access to health care services between the public and the private sector.[4] Although it is difficult to quantify such inequalities as they relate to health care technologies, the different levels of funding and the skewed distribution of health care personnel between these two sectors are indicators of significant differences in access to the former. Of the total South African population of almost 48 million, approximately 7 million (15%) are beneficiaries of private medical schemes.[5] In 2006, R57.6 billion was channelled through medical schemes compared to an estimated R59 billion administered by public financing intermediaries.[6,7] Although human resources figures may be somewhat outdated, it has been reported that for those health care professionals registered with their respective professional Councils in South Africa, only 11% of pharmacists, <50% of nurses and approximately 25% of doctors service the public sector.[8,9]

It is against this background that a system of Social Health Insurance (SHI) has been proposed. The objectives of this financing reform are explored in detail in the Chapter on Social or National Health Insurance. Other than promoting more equitable access to important health care interventions, such reform is also aimed at improving efficiency in service delivery. Instead of private funders competing on the basis of low risk pools in an effort to keep contributions affordable, it is government's intention for them to compete on the basis of efficiencies by providing incentives to ensure economical use of health care services, including drugs and technologies. Relevant legislation supports medical schemes in such endeavours by allowing for the application of formularies and clinical reimbursement protocols that take into consideration evidence-based medicine, cost-effectiveness and affordability, as well as the appointment of designated service providers.[a]

Prioritisation of medicines and health care technology

Levels of decision making in the use of health care technologies and pharmaceuticals

There are typically three levels in the health care chain where decisions relating to use of and access to health care interventions are made namely, the macro, meso and micro levels. An outline of the various levels as they apply in South Africa is provided.

Macro level

The Department of Health (DoH) defines the types of interventions that are included and excluded from statutory health care packages and guides prioritisation of services within public health facilities. In the private sector, the minimum package that has to be funded by all medical scheme options without financial limit, in at least one provider network, is

a Regulations in terms of the Medical Schemes Act (Act 131 of 1998).

defined in terms of the Prescribed Minimum Benefits (PMBs).[b]

This contrasts with the core packages applicable in the public sector which include the Primary Health Care Package (PHCP)[c] and the Essential Drug List (EDL).[d] Contrary to the PMBs, neither package defines a legal entitlement to care. Instead they are guidelines to serve as a foundation for the establishment of high quality services in public health facilities.

Meso level

Benefit design of private medical schemes, which are voluntary not-for-profit community funds is an important determinant of access to medicines and technologies in the private sector. At a minimum, member contributions must cover the requirements of the PMBs. However, as PMBs have not been designed as a stand-alone package that is marketable on its own, additional benefits are also offered. Such benefits are influenced to varying degrees by schemes' desire to attract younger and healthier members. As a result, payment for less debilitating conditions such as allergic rhinitis and attention deficit hyperactivity disorder may be made available on certain benefit options in preference of treatments for more severe and disabling diseases.

In line with central government's social and political objectives of health, provincial budgets are increasingly channelled towards primary and secondary care facilities. Within such facilities, the use of specific health care interventions is not only guided by the PHCP and the EDL, but also by individual doctor behaviour and opinion. The latter is particularly marked within the tertiary and quaternary sectors of service delivery where various clinical specialties compete for a dedicated portion of available funds.

Micro level

The use of drugs and technologies is ultimately determined by health care providers at the point of service. It is the day-to-day clinical decision making by doctors that eventually decides how much is spent on whom within the constraints of institutional or scheme rules. Although this applies to both the private, as well as the public sector, institutional rules in the public sector are significantly more visible to the doctor than rules of individual schemes (especially in the setting of day-to-day care and non-elective treatment).

Within public sector health care facilities, specific pharmaceuticals and medical devices may not be available. Alternatively, the use of restricted items is managed carefully by means of administrative procedures. Doctors thus practice within the constraints of their respective institutions.

In contrast, private sector service providers are largely detached from the applicable third-party funding system that determines the level of payment of specific interventions, with the patient constituting the formal link between the meso and micro level of resource allocation. However, patients are often poorly informed of the specific benefits their scheme has to offer. As patients themselves are ultimately responsible for the payment of services rendered, some providers opt to ignore third-party funding limitations altogether. These dynamics limit the ability of schemes to influence the use of various items effectively, especially in day-to-day and emergency care.

Drug and technology appraisal by regulatory authorities as a basis for prioritisation: International experience

Although governments have historically only focused on ensuring the clinical quality of pharmaceuticals and technologies, there is increased interest in the relative clinical and financial value of interventions, as well as their budgetary impact. This is due to the fact that continuous expansion of any national health care package, even in the most affluent countries, is unsustainable.

As such, governments have introduced processes that formally adjudicate one or both of these entities beyond safety and efficacy assessments conducted by marketing approval authorities (e.g. National Institute of Health and Clinical Excellence [NICE] in the United Kingdom, Institut für Qualität und Wirtschaftlichkeit im Gesundsheitswesen [IQWiG] in Germany, Pharmaceutical Management Agency [PHARMAC] in New Zealand, Pharmaceutical Benefits Scheme [PBS] in Australia). Although these authorities have different mandates, they are concerned to varying degrees with the optimisation of drug prices, as well as the appropriateness of inclusion of a given intervention within a state-subsidised health care package. For this, they may compare the clinical

b The current PMBs include all emergency-related care, together with hospital-based care and / or ambulatory care for 271 Diagnosis-Treatment Pairs (DTPs), as well as comprehensive care for some 26 chronic diseases listed on the Chronic Disease List (CDL) and that includes chronic medication as defined in statutory treatment algorithms.

c The PHCP is expressed in terms of norms and standards and defines goals that all clinics delivering primary care services in the public sector should achieve. Standards tend to reflect infrastructural requirements, including staff training and availability of medicines, whereas norms tend to identify care targets.

d The EDL is not only central to the PHCP, but it also guides service delivery at secondary and tertiary care institutions. It identifies which drugs should be procured for common conditions at the various levels of the health care system and describes how these drugs should be used.

and financial value of competing services, plus estimate the potential budgetary impact relating to specific interventions

This approach has potential advantages. The health care system which lacks normal market dynamics that tend to control prices of goods takes on the role of informed, discerning purchaser of health care. This pressurises pharmaceutical and technology companies to price their products appropriately. The rationale for inclusion and exclusion of care within a national health package is in the public domain and can be debated.

However, this type of approach is also fraught with problems and complexities. Although drug and technology appraisals are guided by scientific and economic rationale, final decisions are not immune to external political, media and emotional hyperbole. Pressures experienced by those tasked with decision making at a national level in relation to funding of health care can prove immense.

Not only is comprehensive adjudication of medicines and technologies a lengthy process that is prone to derailment, (especially where patient lives are claimed to be threatened as a result of the delay) but there is no technical formula on which an emphatic recommendation can be based. Instead, decisions ultimately rely on value judgements. Such value judgements are based on confidence in the scientific and economic data submitted, magnitude of proposed clinical benefits, gravity of condition to be treated, financial calculations such as incremental cost-effectiveness, as well as social values reflected in the institutional framework of decision making.[10,11] For example, German authorities have cautioned against the use of cost-utility analyses, for the reason that studies have shown that distribution of resources on the basis of aggregated quality-adjusted life years (QALYs) is not accepted by the population as it does not reduce inequality and it discriminates against the elderly, disabled and chronically ill. As such, it is contrary to the country's social values that support equity of accessibility and allocation.

Restrictions imposed on the public distribution of 'commercial-in-confidence' data can also act as an impediment to national health authorities in successfully defending negative decisions and countering political and emotive pressures.

Given the size of the pharmaceutical and health technology sectors, they have an impact on a country's economic well-being and as a result a country's interests relating to trade and industry may come into conflict with its intentions of providing universal health care coverage. This may provide a platform on which powerful companies aim to undermine national health agencies. In Australia, the PBS became a key factor in free trade negotiations between the USA and Australia.[12]

Unless approval of new expensive interventions is supported by appropriate funding or associated with formal exclusion of existing services, there is likely to be a negative impact on overall service delivery as highlighted by doctors in the National Health System (NHS) recently. In the NHS, the Primary Care Trusts (PCTs) act as the principal fund holder that commissions health care from hospitals, general practitioners (GPs) and other health care providers. Once they have received their budgets (calculated on the basis of a population-based formula) they must ensure that they do not show a deficit at the end of each financial year. Given this, positive NICE guidance which has been legally-binding in both England and Wales since January 2005, is proving problematic. Following the approval of Herceptin for early breast cancer, the Norfolk and Norwich University Hospital NHS Trust estimated that such guidance would cost their fund £1.9 million per annum in drug costs alone and to balance the books other treatment would have to be dropped, leading to haphazard withdrawal of care.[13] As such, NICE is not achieving its objective of defusing the so-called post-code lottery system of health care in England and Wales, where availability of care is claimed to depend on the NHS Trust area in which a patient lives. This has prompted the British Medical Association (BMA) to call for a basic basket of NHS services that all patients within the NHS would be entitled to.[14]

Review of relevant policy and legislation

For the South African government to achieve its objective of equitable access to health care, legislative reform in the private sector has focused on three areas:

1. medical scheme reform to facilitate a system of social health insurance;
2. transparency in and reduction of medicine prices; and
3. licensing of health care technology.

Medical scheme legislation

Medical Schemes Act (Act 131 of 1998)[15]

To allow for the roll-out of a system of SHI, enabling legislation was first implemented in 2000 with the coming into effect of the Medical Schemes Act (Act 131 of 1998) and its subsequent Regulations. This legislation allowed for open enrolment, community-rating and a minimum set of health care benefits (PMBs) that have to be paid in full within at least one designated provider network by all medical schemes, irrespective of the option to which members are contracted. This means that any drug and technology-related care deemed to be included in such a package should be accessible to all contributing to private health care insurance.

A detailed historic review of the development of the PMBs has been reported by Taylor et al.[16] The cost of the PMBs has been identified as an important barrier to expanding medical scheme growth. As medical scheme membership has been static for many years, a Ministerial Task Team on SHI invited industry stakeholders to make proposals in relation to the establishment of medical schemes catering specifically for low income earners (also known as Low Income Medical Schemes or LIMS). Emanating from this process was a stakeholder proposal for an alternative set of basic benefits that would be specific to LIMS schemes.

Contrary to the PMBs that provide comprehensive cover for specific diseases, especially those where severity may necessitate hospitalisation, where treatment is regarded as non-discretionary and / or where chronic medication is indicated, the proposed LIMS package would be defined in terms of specific benefits that include GP and dental visits, formularies, radiology and pathology lists, emergency transport and optometry entitlement (see Table 1). Of note is the absence of specialised services and hospital-based care within the private health sector.[17] However, such exclusion is accompanied by a recommendation that all user fees at public hospitals should be eliminated for those earning below the proposed LIMS threshold, thus making these services freely available within State institutions. To date, the LIMS proposals have not been endorsed by government.

At a similar time that a restricted statutory minimum package was being proposed, another task team advising government on aspects of social health reform advised on expansion of the PMBs. The report to the South African Risk Equalization Task Group by the International Review Panel recommended inclusion of all care that is usually delivered by primary care physicians. Reasons cited for such expansion include inter alia that primary care plays a pivotal role in the realisation of efficiency gains within a framework of SHI and that the current PMBs are not marketable on their own.[18] Such expanded PMBs are commonly referred to as the basic benefit package (BBP).

It is important to note that in an environment of SHI a minimum set of benefits that has to be paid by all medical scheme options is the platform on which income cross-subsidisation in support of low income earners occurs (i.e. for the 'same' benefit package, there would be a sliding scale of medical scheme contributions based on income). The proposal for a parallel development of two sets of minimum benefits, based on level of income, is thus contrary to this goal and blurs the government's policy directive on future financing of health care, including medicines and technology.

Table 1: Difference between PMBs and the proposed LIMS package

	Prescribed Minimum Benefits (PMBs)	Low Income Medical Scheme benefits (LIMS)
Definition of package	Package defined in terms of diseases and related care	Package defined in terms of benefits
Access to day-to-day care delivered by general practitioners and paramedical service providers	Limited to specific diseases; cover for undifferentiated illness and non-listed diseases as per individual medical scheme option	Limited on the basis of total visits and specific service restrictions (e.g. formularies, pathology lists)
Access to specialised services, including hospital-based care	'Entitlement' to specialised services where disease is defined as a PMB; cover for non-PMB diseases as per specific medical scheme option	Access to specialised services in the public sector on the basis of a 'waiting system', irrespective of underlying condition; no entitlement to any particular care
Standard of care	'Inconsistent' standard for level of care, ranging from public sector to 'best practice' standards	Level of care defined in terms of 'public' sector standards

Source: Developed by author.

Medicine legislation

Medicines and Related Substances Control Amendment Act (Act 90 of 1997)[19]

A key piece of legislation to make health care in South Africa more affordable has been the Medicines and Related Substances Control Amendment Act (Act 90 of 1997) together with the Regulations relating to a transparent pricing system for medicines and scheduled substances. Government's battle since 1997 to introduce this legislation has been fraught with legal challenges that have been outlined extensively in previous editions of the South African Health Review.[20,21]

Dispensing fees

Although a Single Exit Price (SEP) has been implemented successfully, there is ongoing disagreement on an appropriate dispensing fee. Without finalisation of such a fee which is critical in determining the consumer price of medicines, variance in end-user acquisition cost of pharmaceuticals is likely to continue. After the Constitutional Court judgment in September 2005 that the original dispensing fee for pharmacists was not appropriate (given the evidence that it threatened the viability of many pharmacies and with that, accessibility to medicines) it was more than a year before a new fee was proposed. The original dispensing fee of 16% of the SEP with a cap of R16 for all schedule 1 and 2 medicines sold without a prescription, and 26% with a cap of R26 for all schedule 3-6 medicines, as well as schedule 1 and 2 medicines sold with a prescription was replaced with the following new Regulations published in the Government Gazette on 1 December 2006:

- R4 plus 33% of the SEP for medicines less than R75
- R25 plus 6% of the SEP for medicines R75 or more, but less than R250
- R33 plus 3% of the SEP for medicines R250 or more, but less than R1 000
- R50 plus 1.5% of the SEP for medicines R1 000 or more

However, it was again claimed by some pharmacy groups that this would cause the demise of smaller community pharmacies and an urgent application was brought to the Transvaal Provincial Division of the High Court of South Africa, requesting suspension of the dispensing fee Regulations until such time as the matter concerning the lawfulness of the Regulations had been determined by the court.

As a result, the implementation thereof was postponed once more. Although the fee is under review by government, it remains the subject of legal challenge by certain pharmacy groups. At the same time the National Convention on Dispensing (NCD) representing the majority of dispensing doctors in South Africa has also expressed dissatisfaction with its current fees regulated at 16% of the SEP to a maximum of R16 and warned of a legal challenge if such concern is not adequately addressed by government.[e]

Single Exit Price

With regard to ex-manufacturer pricing of medicines, there has been the first opportunity for a price increase (capped at 5.2%) in about three years. Furthermore, draft Regulations for international benchmarking of medicine prices were published in December 2006.[22] In essence, it is proposed that benchmarking for originator products is to be applied at the level of the smallest dosage unit of the same pharmaceutical ingredient as per its International Nonproprietary Name (INN) in the same dosage form. The suggested benchmark price is to be the lowest of the prices in five countries that include Canada, Australia, New Zealand, Spain and South Africa. For generic medicines, the ex-manufacturer price is to be set at least 40% lower than the existing price of the originator product. The price of combination products is proposed to be the sum of the individual active ingredients and as such these products can be subject to both the originator as well as the generic benchmarking processes.

Although multinational manufacturers support international benchmarking of medicine prices in principle, they have expressed a number of concerns, including the selection of New Zealand and Spain as part of the basket of countries (given the heavy-handed price regulatory approaches in those countries). Instead of benchmarking the price against the lowest of the five countries, the industry has proposed that the average price be used. For combination products that include a patent-protected ingredient, it has put forward that the originator pricing methodology should prevail.[f]

Regarding generic medicines, it is argued that prices are best controlled by means of competition and that further ex-manufacturer price regulatory efforts may prove counterproductive in the long-term. Not only are first-to-market generic medicines on average 36% cheaper than originator

e Personal communication, N Mabasa, Chairperson National Convention on Dispensing, August 2007.

f Personal communication, G Goolab, Executive Council, Pharmaceutical Industry Association of South Africa, August 2007.

products at time of launch,[g] but there is a further gradual reduction in price as more direct competitors enter the market (with the ratio of average generic to originator price in South Africa being 0.48).

Concern has been expressed that tighter control of the first generic market entrants could delay their introduction, as the incentive for early launch (which allows for a somewhat higher price) is dampened. This could potentially prolong the time period where originator products remain unchallenged. Proposed price reductions would thus not result in a net gain in savings to health budgets. It has also been argued that cross-subsidy of public and private sector prices may be negatively affected and as a result tender prices to the State could increase.[h] Benchmarking the prices of generics may furthermore compete with industrial goals of the government. Based on recent media reports, the pharmaceutical sector has been identified as a priority sector for government's Accelerated and Shared Growth Initiative (AsGI-SA). However, contrary to other sectors identified, the sector is performing poorly with a trade imbalance of $830 million in 2005, weaker than expected export growth and a critical shortage of skills. Generic manufacturers have warned that further price regulation of generics could threaten the viability of the local industry even more.[23]

Other aspects relating to transparent pricing of medicines

The exclusion of all registered schedule 0 medicines from the operation of section 22G of the Medicines and Related Substances Act (Act 101 of 1965) is of interest as some essential medicines (e.g. paracetamol) have been exempt from price control.[24] The rationale for such a decision is unknown.

Furthermore, a proposal for a maximum logistics fee in terms of Regulation 5.2(g) of the Regulations for a Transparent Pricing System (as per government gazette dated 11 November 2005) has not as yet materialised.[25] Until such time that this and the dispensing fee have been finalised, strict enforcement of section 18A of the Medicines and Related Substances Act that prohibits any type of bonus, rebate or incentive scheme is undermined.

Health technology legislation

Licensing of health technology

Since government's failed attempts to introduce the South African Medicines and Medical Devices Regulatory Authority (SAMMDRA), which aimed at evaluating, regulating and monitoring all medicines, clinical trials and medical devices (and which was to replace the Medicines Control Council) there has been limited progress in regulating medical devices. Medical devices essentially include all devices from disposable items like simple wooden tongue depressors to highly sophisticated computerised equipment for purposes of diagnosing, monitoring and treating disease. The government is pursuing its intentions to control this market, but this has been a slow process. Although draft Regulations relating to the registration of health technology have been published recently, they have not yet been gazetted.[i]

Within such draft Regulations, it is proposed that the intended Medical Devices Regulatory Authority is to form part of the Radiation Control Directorate, which currently issues licenses for electro-medical equipment as required by the Hazardous Substances Act (Act 15 of 1973).[26] The duties of the said authority will be to extend latter function to all medical devices, to withdraw products where use may lead or has led to the health of the public or particular person being placed at risk and to enforce other parts of the Regulations. These include stipulated advertising and labelling practices, maintenance obligations, reporting of adverse events and clinical trials. The intensity and ambit of regulatory control would depend on the risk of the medical device and for these purposes the Global Harmonization Task Force (GHTF) recommendations are to be adopted. The major purpose for registration of low risk devices such as tongue depressors or surgical retractors is to provide for a current and comprehensive data base of suppliers of medical devices in South Africa. For products that are deemed high risk (e.g. implantable items such as heart valves and in-vivo defibrillators), regulation is to extend to maintenance of an auditable repository of information detailing all instances where such devices have been used.

The fact that these draft Regulations follow the guidelines and principles proposed by the GHTF is likely to expedite acceptance of their content, as well as implementation thereof. The GHTF was founded in 1993 by government as well as industry representatives of Australia, Canada, Japan,

g Medscheme analysis based on SEP of generic medicines in relation to originator product at time of launch and limited to first-to-market, substitutable, non-parenteral generics introduced after regulation of a single SEP.

h Presentation: National Association of Pharmaceutical Manufacturers, Board of Healthcare Funders Annual Conference, July 2007.

i Personal communication, T Dowes. Deputy Director: Health Technology, Department of Health, August 2007.

the European Union and the USA in order to harmonise national regulatory standards and to encourage a convergence in standards and regulatory practices relating to the safety, performance and quality of medical devices.[27] Local licensing could thus follow licensing in any of the GHTF Member States without the need for extensive additional reviews. Proposed regulation of in-vitro diagnostic devices which refers to a medical device to be used in-vitro for the examination of samples or specimens derived from the human body and which includes blood and tissue has nevertheless been excluded from current draft Regulations and at this point remains pending.

Certificate of need

Contrary to the developments regarding licensing of health technology, there have been no visible developments relating to the contentious certificate of need (CoN), which would ensure that health technology is distributed evenly throughout the country to enable equitable access to health services for everyone.

Section 36(1)(b) of the National Health Act stipulates that *"a person may not increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency without being in possession of a certificate of need"*.[28] However, Regulations to bring this section into effect have not been published. One reason for this is the lack of capacity to administer a CoN at this point in time. The Director-General must, in compliance with section 78 of the National Health Act, establish an Office of Standards Compliance, which inter alia must advise the Minister of Health on norms and standards for the CoN processes. Other priorities of the DoH, such as medical scheme reform, are likely to have contributed to the delay in the establishment of such an office. Another possible reason for lack of visible development in this area may also relate to the fact that this type of policy may conflict with the principles of a free market economy, including internationally-binding legal commitments negotiated by the former apartheid regimen under the World Trade Organization's General Agreement on Trade in Services (GATS).[29] In essence, such agreements allow foreigners to invest freely in South Africa and the type of restrictions enlisted by a CoN could thus constitute an illegal barrier to market entry.

Impact of health reform

Given the focus on establishing improved and equitable access to medicines and technologies, some of the positive and negative impacts to date of health reform are reviewed.

Medical scheme membership

Despite a reduction in the price of medicines, as well as legislation aimed at promoting accessibility of private health care funds, the number of medical scheme beneficiaries has fluctuated around the 7 million mark for the past 10 years. Although the most recent report published by the CMS suggests a small increase in insured lives (4.3%), some of this growth is due to the introduction of the Government Employees Medical Scheme (GEMS) which has attracted previously uninsured lives as a result of a generous employer subsidy.[30] The current number of beneficiaries of 7.1[j] million contrasts with 7.0 million reported in 2001.[31] This must be viewed against total population growth in the same period of more than 3 million.[k] This suggests that the number of patients reliant on the State and / or on non-subsidised self-funding have increased significantly in this time period.

Benefit design

An objective of medical scheme reform is the establishment of a more egalitarian health care system. In this regard the disease-based approach of the PMBs, especially relating to chronic illnesses, is proving problematic. Although in 2002 the treatment of the diagnoses listed as part of the 271 Diagnosis Treatment Pairs (DTPs) was extended to include ambulatory care, such care has not been readily funded by medical schemes.[31] Instead, benefit designs have focused on ensuring unlimited cover for the chronic conditions listed as part of the Chronic Disease List (CDL) only.

A reason for such an industry response has been the fact that therapeutic algorithms have not been published for the former, and such expansion is deemed unaffordable. Given such a response, cover for ambulatory care relating to non-CDL diseases has been compromised. For example, after implementation of the CDL, 29.1% of open medical scheme options discontinued chronic medication cover for

j The figures for 2006 excluded membership of bargaining council schemes. Given the lack of inclusion in the report, it is unlikely that such figures are significant.

k StatsSA reported a total population of 44.8 million in 2001, whereas the mid-year estimate for 2007 is 47.9 million.

Table 2: Percentage change in SEP from 2004 to 2005

Period	% change in SEP		
	Branded products with patent protection	Branded products with expired patents	Generic equivalents
January 2004 to January 2005	-13.9	-15.6	-38.7

Source: Mediscor, 2006.[33]

ailments not listed on the CDL.[32] This has resulted in a situation whereby on many medical scheme options, patients can receive comprehensive medical care for statutory CDL diseases (often pegged against best care, rather than reasonable care as defined on the basis of what is readily available in the State sector), yet any type of ambulatory care for diseases not so listed is excluded altogether. This has resulted in unfair discrimination on the basis of underlying chronic disease.

Reduction in medicine prices

The introduction of a SEP (based on phasing out of inflationary practices such as discounting and rebating) resulted in a definite reduction in the published ex-manufacturer prices of medicines and was most marked for generic medicines (see Table 2). Overall, government has reported a 19% reduction in prices[l]

The extent to which this change translated into direct savings for consumers and third-party funders has varied for the following reasons:

- The dispensing fee for pharmacists has remained unfixed and has been inconsistent for the period under review. However, where third-party funders adopted a dispensing fee of 26% (to a maximum of R26 per item) for this group of service providers, net medicine price of out-of-hospital medicines was reduced significantly from their perspective. For example, for Medscheme-administered schemes, this was estimated to be 24.3% on average.[m] Nevertheless, the mix of medicines as well as the dispensing type would affect such an analysis. Furthermore, this does not reflect out-of-pocket spending by consumers.
- Various provider groups re-negotiated their third-party reimbursement structures. In the past these groups generated significant revenue from the sale of medicines as a result of mark-ups, rebates, discounts, as well as bonuses provided by the pharmaceutical industry. This revenue was used, in part, to subsidise the provision of other services, facilities and staff. In order to offset loss of income that would result from the implementation of a SEP plus a professional fee, a different tariff structure and / or an adjustment of existing tariffs was introduced.

Private hospitals transferred their profits from pharmaceutical rebates into tariff items such as ward fees and theatre fees. The extent to which this practice influenced total health care costs is not in the public domain.

Specialist groups that represented providers who commonly dispensed pharmaceuticals and which included the Radiological Society of South Africa and the South African Oncology Consortium (SAOC) introduced new tariff codes. For example, a fee for the administration of chemotherapy, as well as use of facilities, was introduced for oncologists in lieu of the previous percentage-based mark-up on pharmaceuticals dispensed. A Medscheme analysis[n] revealed that prior to the introduction of the SEP and new tariff codes, the average cost of treating a patient with chemotherapy was R4 530 per month, whereas it was R4 626 per month for the same period in the subsequent year. This reflects a 2.1% increase in cost. Although changing utilisation of medicines may have contributed towards such an upward trend, it is apparent that the new pricing legislation did not introduce overall cost-savings to consumer or payers as reflected in overall costs of chemotherapy.

l Available at: http://www.doh.gov.za/docs/presentation/faq.html

m Medscheme is the largest multi-scheme administrator in South Africa. The analysis was based on re-pricing of all acute and chronic ambulatory medicines claims for the time period January to April 2004 using the SEP published in August 2004, together with a dispensing fee of 26%/R26 for pharmacists and 16%/R16 for doctors.

n The findings are based on an analysis of all oncology-related medicine claims as pre-authorised by the Medscheme oncology management programme between January-April 2004 and January-April 2005.

Utilisation of medicines

Total medicine use

Decreased expenditure on medication by third-party payors as a result of the reduction in the SEP was further partially offset by increased utilisation of medicines. A review published by Mediscor[o] shows that despite a fairly constant percentage of beneficiaries claiming medicines, there has been a steady increase in the intensity of ambulatory medicine use, with the existing pool of patients using more medicines year-on-year (see Table 3).

Table 3: Utilisation of ambulatory medicines based on medical scheme data, 2004-2006

Measure	2004	2005	2006
Utilising beneficiaries as percentage of total beneficiaries	87	87	87
Average number of items per utilising beneficiary	19	21	22

Source: Mediscor, 2006.[33]

The increased utilisation of medicines is supported by wholesale pharmaceutical data depicting constant growth in the volume of medicine sales in the private sector (see Table 4).

Table 4: Average monthly unit sales of prescription medicines in the private sector, 2005-2007

	2005	2006	2007
Volume (average monthly units x 1 000)	6 686	7 414	8 295
Year-on-year growth (%)		10.9	11.9

Source: IMS data.[p]

Factors contributing to the trend of increasing utilisation of medicines include:

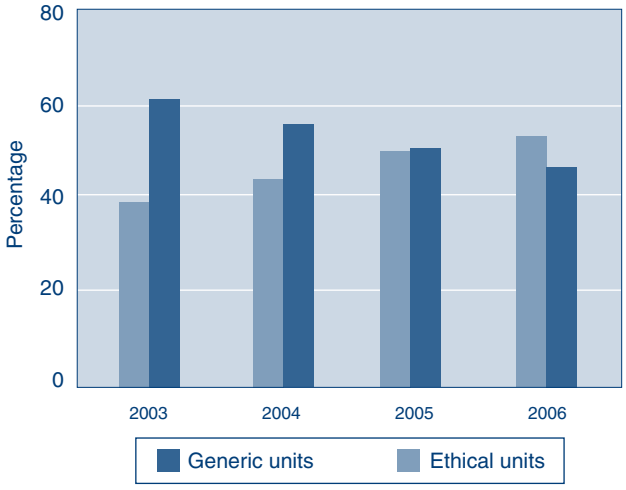
- the unlimited medical scheme benefits for care, including chronic medicines, defined within the therapeutic algorithms of the CDL;
- increased access to acute medicines as day-to-day benefits do not have to be exhausted by chronic medicines; and
- a shift towards use of cheaper medicines, allowing more medicine use within the available benefit limits.

Use of generic medicines as a percentage of total medicine use

The trend towards greater use of cheaper medicines is reflected in the increasing proportion of generic use in the private sector as illustrated in Figure 1. This trend has been influenced by factors such as:

- the mandatory offer of generic substitutes by service providers;
- promotion of generics by medical schemes through increased application of formularies and generic reference pricing systems, as well as financial incentives to providers to prescribe cost-effectively; and
- increased consumer awareness.

Figure 1: Proportional use of generics versus originator products, 2003-2006



Source: Analysis based on IMS and Medikredit data.[q]

Although this trend is positive, generic use of medicines in the private sector has significant potential for further growth, given the utilisation achieved in other countries. For example, the percentage of generic use in Canada based on units dispensed is 77.4%.[r] Factors hampering greater market penetration of generic medicines in South Africa include the lack of confidence in generic medicines by some doctor groups, (especially specialists) and the lack of clarity regarding scientific principles used in the determination of non-substitutable status of medicines.[34]

o The trend analysis only included schemes contracted to the organisation for all 3 years and represents data from ~ 1 million beneficiaries.

p IMS data. Analysis of total Private Market as defined by sales to private retail pharmacies, dispensing doctors, private hospitals and clinics, non-collaborating wholesalers and other private dispensing outlets. Units are reflected at pack size level. Average monthly sales have been calculated on the basis of January-June figures for each year.

q National Association of Pharmaceutical Manufacturers. Independent analysis based on IMS and Medikredit data. Data limited to prescription drugs only. Board of Healthcare Funders annual conference, July 2007

r National Association of Pharmaceutical Manufacturers. Independent international analysis describing generic medicine use.

Table 5: Change in annual admission rate per 1 000 beneficiaries over a 4-year period

	Admissions per 1 000 beneficiaries (annualised)		% change
	January to March 2003	January to March 2007	
Spinal fusion	1.13	1.42	26
Hip arthroplasty	0.67	0.79	18
Knee arthroplasty	0.46	0.89	93
Percutaneous transluminal coronary angioplasty (PTCA)	0.87	1.24	43
Coronary artery bypass procedure	0.53	0.51	-4
All admissions (excluding above, as well as pneumonia, tuberculosis, gastroenteritis, meningitis/encephalitis)	206.21	221.53	7

Source: Derived using Medscheme data.

Use of highly specialised medicines

Amidst this positive shift towards the use of cheaper medicines in the private sector, there is another significant development that is of concern and this relates to the increasing use of very high cost items, typically in oncology and chronic diseases. For example, for medical schemes administered by Medscheme, the use of specialised oncology medicines (defined as monoclonal antibodies and tyrosine kinase inhibitors) has increased by a factor of 2.5 from the first quarter of 2004 to the first quarter of 2007. Although the prevalence of use remains extremely low (at 0.06% of all patients receiving chemotherapy), this trend cannot be ignored given the high cost of these drugs. The average monthly drug cost per Medscheme patient treated in 2007 (January-April) was approximately R22 500.

These utilisation trends are supported by reports in the literature, which describe the increasing focus of pharmaceutical companies on developing specialty pharmaceuticals. These are typically medicines produced via biological processes that structurally mimic compounds found in the body. Although they generally target a relatively small number of patients, these drugs may be used for prolonged periods of time. The potential growth of this market is reflected in the fact that in 2004, 101 unique biopharmaceuticals were in late-stage development (i.e. phase 3 trials), targeting 169 different clinical indications.[35]

Price and utilisation of health care technologies

Although it is known that South African health care technologies have a significant impact on total health care expenditure, trends in prices and the use of health care technologies are difficult to monitor. This is partly due to the fact that the market is unregulated with no established registry of available products, plus that pricing structures are highly variable and generally not in the public domain. Furthermore, the quality of data on medical device use is generally poorer than that for medicines. However, as in other parts of the world, empirical data suggest that health care technology is contributing towards health care inflation (although the extent thereof is difficult to quantify). For example, for procedures where new technologies are evolving rapidly, the rate of hospital admission appears to be increasing at a higher rate than for other admissions (see Table 5).[s] Such increased intervention rates may be due to true enhancements in the ability to treat patients; however, they are also influenced by over-enthusiasm and excess confidence in new technologies.

Unfortunately, the analysis by the CMS aimed at understanding contributors towards hospital inflation which was due in March 2006 has not as yet been released.

s The Medscheme analysis incorporated all beneficiaries managed through its hospital utilisation programme at any point in time and represents actual rather than risk-adjusted data. Common infectious causes for admission were excluded from overall admission rates given that their rates are increasing as a result of the HIV epidemic. Coronary artery bypass procedure rates are shown for purposes of demonstrating that their rate did not decrease significantly as a result of the increased PTCA rates. Annual admission rates were projected on the basis of first quarter admission results.

Way forward

Government has effected some positive change in its endeavours to optimise efficiencies in the delivery of private health services, including the use of drugs and technology. Mandatory offer of generic substitution, phasing out of perverse incentives, the introduction of a SEP for medicines as well as pressure on medical schemes to reduce health care costs have resulted in medicines becoming more affordable. Although there are ongoing hurdles that include finalisation of a fair dispensing, as well as logistics fee, plus optimisation of medicine prices, trends in medicine use and prices have been encouraging.

The proposed licensing of all medical devices is also supported as it not only provides a measure of safety for consumers, but it creates a registry that would allow for the introduction of a transparent pricing system for consumables. As for medicines, transparent pricing is important in order to allow for more accurate assessments of true health care expenditure and to phase out any form of perverse incentives that may be fuelling the inappropriate use of medical devices.

With regard to medical scheme reform, major challenges remain if the country is to achieve its objective of a more egalitarian health care system. To proceed constructively, government should consider directing its focus towards the following critical areas.

Financing reform

Not only has government policy regarding a system of SHI become obscure, but the lack of visible synchronisation of risk and income cross-subsidisation is of concern to the private funding industry. Logic dictates that as risk cross-subsidisation becomes increasingly effective, so medical scheme contributions of the healthy steadily increase and those of the sick decrease. Although the ultimate goal of SHI is for the young and healthy to cross-subsidise care of the sick and elderly, risk cross-subsidisation can prove problematic in a non-mandatory medical scheme environment where willingness to contribute is generally lower for the healthy than for the sick (and as such the healthy are more likely to abandon medical schemes at any given contribution level).

As the cost of entrance-level medical scheme options increases, they become less accessible to low income earners. Thus, as risk cross-subsidisation within the private insurance industry is expanded as a result of a risk equalisation fund and / or an enhanced basic benefit package, provisions for financial subsidies for low income earners must be made (given the increase in the minimum contribution level for some schemes). This necessitates close collaboration between the DoH and National Treasury, as well as the Department of Labour where mandatory contributions become part of the offing. For medical scheme reform to succeed, government must clarify and commit to its health care financing strategies.

Minimum benefits

The most complex aspect of health care reform in South Africa relates to the definition of a minimum level of care. Although the concept of an essential health package for all is appealing, its feasibility has been questioned, given South Africa's heterogeneous health care system, fragmented funding thereof, as well as its highly diverse population with different needs and expectations.[15] Furthermore, the appropriateness of the current PMBs as a platform for social health reform has been challenged and the urgent need for their review has been highlighted. In their re-evaluation, the following is of importance:

- Budgetary boundaries within which the BBP is collated must be defined. This calls for close collaboration between legislators who are tasked with the design of the package and those who determine its financial subsidies.
- Although disease-based prioritisation within a statutory package is not rejected altogether, it is likely to predispose to unfair discrimination and as such should be minimised
- The concept of unlimited benefits as an entitlement fuels demand for and supply of health care services. Lest financial constraints of delivering health care services are visible to providers, rationing of care by doctors is undermined. For example, whereas all head injuries (other than those associated with brain death) can potentially benefit from supportive care, neurosurgeons in the public sector have opted to treat the most severe head injuries conservatively given the limited number of neurosurgical beds and the impact active treatment of the former has on the ability to treat other patients with potentially better outcomes.[36] It is unlikely that such an approach would be accepted where there is no tangible shortage of facilities and other important resources.

New drugs and technologies

Although modern health care innovations are as a rule inflationary to the health care system, they are nevertheless important, both from perspectives of adding potential clinical value, as well as from an economic perspective. Access to first world health care services may be an important consideration for offshore investors, as well as skilled workers who are internationally mobile. Given this, it is important that these products do find a niche within the South African health care system. However, their introduction must be controlled.

Based on the expense of biopharmaceuticals, their projected market growth, as well as the fact that they are often used for prolonged periods, it is unlikely that their meaningful inclusion in a minimum prescribed package in South Africa can be justified at this point in time. Furthermore, the current legislative environment allows for medical scheme members to move relatively freely between different options of their schemes, purchasing care as and when needed. Given this, they can access specific benefits without having cross-subsidized their use. Such practice should be discouraged. The feasibility and appropriateness of introducing demarcated insurance products specifically for purposes of very expensive medicines and technologies should also be investigated.

Regarding technology-based procedures, clinical outcomes are highly dependent on the technical skills of the operator. For this reason it is important that any new medical device is only used by those with the adequate training and expertise. To this end novel technologies should be introduced through Centres of Excellence where accredited providers function as part of a multi-disciplinary team, where there is a system of peer review (ideally in collaboration with academic institutions abroad who have established experience with a new technology), where both private and public sector patients are treated in order to ensure a critical mass of patients for optimisation of clinician expertise and where results are audited. To achieve this, there should be a credentialing system for physicians in South Africa which should ideally be a collaborative initiative between the private funding industry, physician groups, hospitals and the Health Professions Council of South Africa (HPCSA).[t] Innovative public-private partnerships are also called for.

Conclusion

Pharmaceuticals and health care technologies are an integral component of any health care delivery system. However, to be of value and to add to the development of an efficient and equitable system, their quality must be ensured through effective regulatory mechanisms, their prices must be optimised and they must be used appropriately within budgetary constraints.

Given the rapid advances in the realms of health care technology, including drugs, together with burgeoning diseases which include lifestyle-related illnesses, infectious diseases and trauma-related inflictions, pressures on available health care funds are increasing steadily. Not only do more patients require care, but more patients are potentially treatable. It is important that government agrees on clear health care financing strategies and invests resources in defining more appropriate statutory minimum benefits for medical schemes. Visible collaboration between various role players in government is of paramount importance. The Department of Health cannot walk this road alone.

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t A proposal for the establishment of a national independent physician credentialing infrastructure in South Africa has been collated by Dr J Fisher, Health Care Consultant.

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