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Achieving meaningful access to medicines: a patient-centric approach – the next healthcare debate

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Access to medicines

Access to medicines may be a challenge for patients requiring access to innovative medicines where the costs of those medicines are either not covered entirely or only partially covered by an insurance product or medical scheme benefit. The situation is exacerbated, ironically, by the provisions of the Medicines & Related Substances Act[1] ("the Medicines Act"), which requires that registered medicines be sold only at a mandatory single exit price or SEP[2] and without any rebate or discount.[3]

Accordingly, should we not be considering a more flexible approach to the pricing and purchasing of medicines in the South African private healthcare sector, where the issues referred to above are most prevalent? This article explores the rise of alternative reimbursement models for medicines in the form of patient access programs ("the programs") and the legal challenges that, in consequence, exist and, perhaps that should be addressed by the regulatory authorities responsible for enforcing the Medicines Act in order to facilitate access to healthcare.

Legal obstacles raised by the Medicines Act

Currently, there is no one defined program that facilitates access to expensive medicines. Accordingly, a number of proposals exist, ranging in type or classes of medicines and diseases or medical conditions, albeit that the persons proposing such programs understand the legal obstacles raised by the Medicines Act to the execution of such programs.

In the main, the programs are designed with the participation of a pharmaceutical manufacturer, a funder such as a medical scheme, a prescriber, a dispenser and a patient but also an intervening funding organisation or IFO. The IFO acts as both the treasurer of funds donated to it to assist with the payment of medicines that patients cannot afford and an assessment body to determine when a patient qualifies for such financial assistance. Most of the programs utilise an IFO as part of their design as an IFO is tasked with objectively identifying needy patients with particular circumstances that deserve financial assistance and where the pharmaceutical manufacturer does not want to be seen as creating outright (and unlawful) incentives in the market for patients to use and prescribers to prescribe particular medicines.

In respect of the programs, the following criteria may be used for selecting patients to receive assistance with the costs of a required medicine:

- the IFO, with the patient's consent, will confirm the patient's diagnosis by conducting or reviewing medical reports, opinions by treating medical practitioners and laboratory tests;
- the referring healthcare practitioner will decide which treatment is appropriate for a patient's condition in conjunction with the patient in terms of the applicable principles of informed consent and section 8 of the National Health Act No. 61 of 2003;
- only in the event that the patient cannot afford the co-payment associated with the treatment referred to above and meets the applicable clinical criteria, may the treating healthcare practitioner apply for assistance from the IFO. With a patient qualifying for financial assistance, the IFO will pay any co-payment levied on the medicine on behalf of the patient;
- in the event that there is uncertainty in respect of whether or not a patient is eligible for assistance from the IFO, the IFO may consult an independent clinical board, which consists of medical practitioners, independent of the parties to the proposed transaction, for advice on whether or not the patient is, in fact, eligible for assistance; and
- the co-payment will be made directly to the dispensing pharmacy by the IFO.

The program may then be used to monitor patients, record and evaluate health-related outcomes and assist in further decisions regarding the patient's care in circumstances where, but for the program, the patient and his or her healthcare provider would have been bereft of possible healthcare alternatives.

The legal position – Provisions of the Medicines Act

For purposes of evaluating the programs from a legal point of view, one is required to consider the provisions of the Medicines Act, the Regulations promulgated in terms of the Medicines Act.[4] ("the Medicines Regulations"), the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances.[5] ("the SEP Regulations") as well as the Medical Schemes Act.[6]

The crisp question that arises is whether or not the programs contravene sections 18A(1) and 22G of the Medicines Act.

Section 18A(1) of the Medicines Act provides, *inter alia*, that no person is entitled to supply any medicine "according to a bonus system, rebate system or any other incentive scheme". In this regard, the wording of section 18A(1) is peremptory and, thus, imposes a strict and absolute prohibition on the supply of any medicine according to a "bonus system", "rebate system" or any other "incentive scheme" – terms which are not defined in the Medicines Act.[7]

The undefined terms that appear in section 18A(1) of the Medicines Act broaden the scope and ambit of the application of the terms which, in turn, arguably quash as many possible types of incentives pertaining to the supply of medicines as possible, including the programs. This is due to the fact that the undefined terms contained in section 18A may include any reduction in costs of a medicine, which would amount to a discount in the hands of the patient and a departure from the "single exit price" applicable to that medicine (a term which is discussed below in further detail).

In so far as the purpose of section 18A(1) is concerned, Chaskalson J remarked as follows in the case of the *Minister of Health and Another NO v New Clicks & Others* (*Treatment Action Campaign and Another as Amici Curiae*).[8] ("the *New Clicks* case"), at paragraph 206 –

> *"No doubt the prohibition of discounts and bonuses and the mandated element of transparency … are likely to create market conditions more conducive to competition than those that previously existed. But these are not the only measures by which the price of medicines can be lowered. Sections 15C, 18A, 22F, 22G and 22H [of the Medicines Act], read together, contain a regulatory framework, partly in the Medicines Act and partly in regulations to be made under section 22G, designed to contribute to the lowering of the cost of medicines [footnotes omitted]".*

Section 18A(1) should, therefore, arguably be interpreted within the context of the remarks made by Chaskalson J in the *New Clicks* case – namely that the purpose of section 18A(1) is to create transparency and affordability in the pricing of medicines by eliminating the need to increase the price of medicines in order to compensate for discounts, rebates and the cost of other incentives.

In light of what is set out above, and in the context of section 18A of the Medicines Act –

- the terms "bonus", and "incentive scheme" may be interpreted to refer to a plan implemented for the payment of a sum of money or a payment made to a person with the intention of inducing or encouraging that person to act in a certain manner; and
- the term "rebate" may be considered to include deductions or discounts made on a sum due in respect of the purchase of medicines within a supply chain.

Arguably, therefore, any activity that falls within the transactions listed in the definitions is prohibited outright in terms of section 18A(1) of the Medicines Act.

Notably, the term "discount" is defined in the SEP Regulations in relatively broad terms as follows –

"(a) volume or 'bulk purchase' discounts and other trade discounts including discounts given to customers off the manufacturer or importer's published selling price at the date of the sale, due to the purchase of large quantities, as 'favoured' customers or for any other reason";

(b) bonus deals in terms of which additional product units are supplied to customers below the list price or free of charge;

(c) settlement discounts and rebates including payments made to purchasers after the date of sale for timeous payment of accounts, for achieving certain sales target, or for any other reason;

(d) formulary listing payments including payments made to –

(i) private hospitals, dispensing doctors, independent practitioner associations, provider networks; or

(ii) medical schemes, managed healthcare organisations and administrators of medical schemes as defined or contemplated in the Medical Schemes Act … including the regulations thereto;

(iii) any other person or organisation with the purpose of ensuring that a particular medicine or scheduled substance is included on the relevant formulary used by that funder or provider;

(e) other allowances and fees including advertising fees and fees for shelf space;

(f) free services rendered by manufacturers and importers or their agents to other persons selling medicines or Schedules substances;

(g) the purchase or the provision of any equipment by manufacturers or importers of their agents at a reduced cost or free to other persons selling medicines or Scheduled substances;

(h) contributions by manufacturers or importers to salaries or other recurrent expenditure or any other form of payment or inducement to any person or organisation selling medicines".

Section 22G of the Medicines Act

Section 22G of the Medicines Act, in turn, empowers the Minister of Health to make regulations governing the single exit price of medicines and related substances. In this regard, the term "single exit price" is defined in the SEP Regulations as "the price set by the manufacturer or importer of a medicine or Scheduled substance in terms of these regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or Scheduled substance within a pack multiplied by the number of units in the pack".

Accordingly, in terms of the SEP Regulations, the price of a medicine must be set by the manufacturer of a medicine, and combined with a logistics fee and VAT in order to arrive at a SEP for the relevant medicine.

Regulation 6 of the SEP Regulations, in turn, states that "[a] manufacturer, importer, distributor or wholesaler *may not* charge any fee or amount other than the single exit price in respect of the sale of a medicine or Scheduled substance to a person other than the State" (emphasis added).

Regulation 7 of the SEP Regulations furthermore states that, subject to the provisions of regulations 5, 8 and 9, the SEP of a medicine may only be increased once a year.

Therefore, the SEP Regulations, read together with section 22G of the Medicines Act, require manufacturers of medicines to determine a SEP, which SEP must then be charged by manufacturers, importers, distributors and wholesalers of the relevant medicine for so long as the SEP applies. No deviation from the SEP is thus allowed.

In their blunt and general application, sections 18A(1) and 22G therefore simply ignore the role that the programs may play in creating access to medicines where such access is desperately needed by patients.

The law and the program

On the basis of what is set out above, and taking into account that any funding provided by a pharmaceutical manufacturer is used only to assist eligible patients (to the exclusion of other patients), one would have to accept that the program could amount to an incentive scheme for purposes section 18A(1) of the Medicines Act. In this regard, as incentives schemes are not defined in the Medicines Act, an incentive scheme may be considered to be any manner of arrangement including the programs especially where the existence of the programs may influence a prescriber to favour prescribing a particular medicine in order to gain access for the patient to such a program.

There is, however, no monetary incentive that accrues directly or indirectly to healthcare practitioners by virtue of prescribing a particular medicine that would contravene the provisions of section 18A(1) of the Medicines Act, which operates to underscore the program falling outside of section 18A(1). However, that is an argument and one with which the regulatory authorities may differ.

Taking into account that a payment is made directly to a dispensing pharmacy by the IFO, section 18A(1) may become a relevant consideration when a pharmaceutical manufacturer sells medicines to pharmacies in order for the medicines to be dispensed to patients.

Arguably, however, the programs will fall outside of the ambit of section 18A(1) of the Medicines Act where –

- the sale of medicines to pharmacies by a pharmaceutical manufacturer –
    - is not a plan implemented for the payment of a sum of money with the intention of inducing or encouraging pharmacies or medical practitioners to act in a certain manner;
    - is not considered to include deductions or discounts made on a sum due in respect of the purchase of medicines;
    - is done in accordance with the SEP Regulations; and
    - the prescriber makes a decision based on the health needs of the patient, as set out in the clinical guidelines determined by IFO, which, in turn, determine what medicine is clinically appropriate for a particular patient.

In the above context, the programs do not operate as an incentive but rather involve the application of a medical mind in the best healthcare interests of the patient. Once again, however, the aforementioned view remains an argument, at best, as the provisions of section 18A(1) are blunt in their scope and application.

Therefore, whilst the assistance offered by the programs is directed at the health of the patient, which dictates the need for access to a particular medicine, the programs depart from the payment of a single exit price by the patient and conceivably provides for a discount on the price of the medicine concerned – in contravention of section 18A(1). The difficulty with which one is faced is that, in order for the programs to function legally, one either has to argue away any possible incentive or discount or seek the approval of the programs from a regulatory authority, an approval not necessarily provided for in law. The result is that the enforcement and application of the provisions of sections 18A(1) and 22G by the Department of Health ultimately have the effect of denying eligible patients to access to otherwise available healthcare, which, in turn, is a departure from the State's obligations in terms of section 27 of the Constitution of the Republic of South Africa, 1996.

The need for creative solutions to facilitating access to innovative medicines are needed now more than ever. Such solutions should, ideally, have their emphasis on improving clinical outcomes in patients taking the medicines in question. Such an emphasis or rationale arguably places the commercial aspects of incentives and medicine costs secondary to the constitutional prerogatives of providing for access to healthcare services and thus improving health outcomes for patients generally. The problem may be usefully stated as follows:

> *"Healthcare is consumed primarily by patients who face heavily subsidised prices, because of the government programs or third-party insurance coverage. Access to healthcare is also tightly controlled by physicians and other providers. Most healthcare providers operate in financial environments that reward them for supplying more medical care. Furthermore, healthcare markets are heavily regulated, licensed, credentialed and restricted. In every country, healthcare satisfies few of the Economics 101 criteria for free market competition. Under these circumstances, the 'invisible hand' ensuring that scarce medical resources are being produced or consumed efficiently is severely atrophied and arthritic."*[9]

An alternative approach may be to rely on the provisions of section 36(2) of the Medicines Act. Section 36(2) provides that "[n]otwithstanding subsection (1) an exclusion of any medicine or Scheduled substance from the operation of sections 18A and 22G shall be effected by the Minister on the recommendation of the Pricing Committee". There may be an argument to the effect that any program that advances access to medicines and, in turn, healthcare, may fall within the provisions of section 36(2) on the basis that if the medicine, around which the program is structured, is exempt from the operation of sections 18A and 22G, on the proviso that the medicine is used within the constructs of the program, the exemption may be applicable to both the medicine and the program. This interpretation is supported by the provisions of section 36(1), which allows the Minister to impose whatever conditions he or she may determine in respect of any exemption granted in terms of the Medicines Act. However, a cautious approach would have to be adopted to the application of section 36 of the Medicines Act in so far as the exemption provisions apply to a particular medicine or Scheduled substance and not, necessarily, to a program and its associated principles and conditions.

Conclusion

We are, therefore, of the view that –

- the programs are relevant in circumstances where the costs of medicines, especially innovative medicines, are increasing along with healthcare costs in general;
- the programs, if implemented correctly, have a role to play in assisting the State with fulfilling its obligations in terms of section 27 of the Constitution of the Republic of South Africa, 1996;

- the overall design and implementation of the programs should be considered in conjunction with the relevant regulatory authorities in order to ensure that the operation of the programs is without legal impediment, fault or challenge;
- the programs represent a creative solution by innovative pharmaceutical manufacturers to the provision of medicines required by ordinary citizens in circumstances where, but for the programs, such medicines may not be readily and commercially available to such persons even with the assistance of medical insurance programs or medical scheme memberships;
- the provisions of sections 36 of the Medicines Act may be made available to the programs but a cautious approach must be adopted to the application of section 36 in so far as the language of section 36 deals only with medicines and Scheduled substances per se, together with medical devices and in vitro devices, and thus not allow the Minister to exempt programs in which medicines or Scheduled substances feature and are used;
- the Minister of Health should be encouraged to take steps in terms of section 18A(2) of the Medicines Act in order to implement regulatory infrastructure to support the programs and potentially limit the absolute and blunt application of section 18A(1) to the overall detriment of the patients who will otherwise clearly benefit, both financially and medically, from access to medicines in terms of the programs.

Read: Current status: National Health Insurance Scheme.

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[1] No. 101 of 165, as amended

[2] Section 22G of the Medicines Act

[3] Section 18A of the Medicines Act

[4] As GNR 859, dated 25 August 2017. No steps have been taken to date by the Minister of Health in terms of section 18A(2)

[5] As GNR1102, dated 11 November 2005, as amended

[6] No. 131 of 1998, as amended

[7] Section 18A currently reads as follows:

"(1) No person shall supply any medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister [of Health] may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G."

[8] 2006 (2) SA 311 (CC)

[9] J W Hay "The Application of Cost-effectiveness and Cost-benefit Analysis to Pharmaceuticals" in M A Santoro and T M Gorrie (eds) *Ethics in the Pharmaceutical Industry* (2005) at page 227.

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