The Minister of Health has published certain proposed amendments to the so-called Medicine Pricing Regulations for public comment in the Government Gazette on 6 July 2012. The amendments are primarily designed to amend the Regulations dealing with the single exit prices applicable to medicines and Scheduled substances in the Republic. The current set of regulations is available for public comment until 6 September 2012 – a period of two months.

Regulations may be published by the Minister of Health in terms of section 22G of the Medicines and Related Substances Act No. 101 of 1965, as amended ("the Medicines Act") in order to control the prices of medicines and Scheduled substances. These Regulations, when initially published, were challenged in the courts but ultimately have prevailed. The amendments that are now proposed to the single exit pricing regulations are designed to address primarily the meaning, scope, ambit and content of the prohibition contained in section 18A of the Medicines Act concerning the supply of medicines in terms of a rebate system or any other incentive scheme. The provisions of section 18A of the Medicines Act contain various terms that are not defined in either the Medicines Act or in regulations pursuant to the Medicines Act. Simply put, section 18A provides that: "No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme."

Conceivably, the provisions of section 18A are very broad and may apply to a number of arrangements or transactions currently in place in the market place. However section 18A is tethered, by its own language, to the supply of medicine. Therefore, the number of transactions to which section 18A may be applicable may be limited as such transactions, when they have nothing to do with the supply of medicine, fall outside of the provisions of section 18A. All of that, however, is about to change.

The amendments that are proposed to the single exit pricing regulations expand significantly the provisions of section 18A by adding content to the terms in section 18A such as “bonus system”, “rebate system”, “discounts” and “other incentive scheme”. Careful consideration will therefore have to be given to existing transactions within the context of the amendments proposed to the single exit price regulations on the assumption that these amendments will eventually pass, as they currently stand, into law. One of the most important amendments that is proposed in the draft regulations deals with the issue of a definition of “[b]onus system, rebate system or any other incentive scheme”. This definition means any one of:

- unacceptable advertising fees;
- unacceptable credit payment;
- unacceptable data fees;
- unacceptable fees paid to induce and/or
encourage biased sale of a particular medicine or schedule product;
- discounts;
- formulary listing payments;
- kickbacks and perverse incentives;
- loyalty fees or similar fees or prizes or rewards;
- unacceptable marketing fees and/or co-marketing fees;
- shelf space fees;
- directors’ fees, honoraria and similar compensation paid to a healthcare professional or any person who is in a position to potentially influence medicine choice, where such professional or other person actually do not perform any services or work for which s/he is purportedly being remunerated; and/or fees, enrichment of or benefit provided to a healthcare professional, administrative staff or any business enterprise or healthcare establishment in the healthcare sector which fee, enrichment or benefit is provided on the understanding that the health establishment or professional will give preference to, or encourage the purchase, sale, prescription, dispensing, use or recommendation of a particular medicine or medicines in return for such fee, enrichment or benefit.

The abovementioned definition forms the heart of the amendments proposed in the draft regulations. A number of secondary definitions are also included in the proposed amendments including “[b]usiness enterprise” and a lengthy definition concerning what is or is not a “discount”.

The amendments also intend to introduce specific definitions for the terms “end dispensers”, “end user”, “logistical services” and “logistics fee cap”. These definitions are important in light of the introduction of a proposed revised definition of “Single Exit Price”, which shifts from the current definition concerning the application of a logistics fee and a price determined by the manufacturer or importer of a medicine to the “ex-manufacturer price determined 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. The Director-General must confirm the correctness of the SEP calculation prior to communication to the public.”

The reference in the proposed definition of “Single Exit Price” to the logistics fee must now be understood with reference to what services are intended to be included in the calculation of the logistics fee – bearing in mind that the logistics fee is also redefined with reference to three components that now form the single exit price of a medicine. These components are the price determined by the manufacturer, the logistics fee “which is determined through negotiation between the manufacturer or importer and the logistics service provider of their medicines or scheduled substances” and value added tax.

The logistics services that are to be taken into account are proposed as an exhaustive list - contained in an amended definition of “logistical services”. The services refer to expressly in the proposed amendments are the following:
- Receiving of medicines or scheduled substances;
- Warehousing of medicines or scheduled substances;
- Proper inventory control and rotation;
- Taking orders from end dispensers;
- Delivery of orders to end dispensers;
- Provision of emergency deliveries to end dispensers where required;
- Proper record keeping;
- Batch tracking and tracing;
- Ability to maintain cold chain storage and distribution where necessary;
- Returning products to manufacturers when required; and
- Having and operating a debtor’s control system which conforms to accepted accounting norms.”

The provision of logistical services also has to be considered in light of the definitions of rebate, incentive and discount schemes that are identified in the proposed regulations. In addition, logistical services may only be provided by logistics service providers who, in turn, must be licensed to provide such services in terms of section 22C of the Medicines Act.

Subsequent proposed amendments to the regulations also deal with:
- the manner in which the Single Exit Price for medicines is to be reflected on medicine containers;
- the adjustment of the single exit price in terms of independent reviews of the prices determined by the manufacturer or logistics fee components of the single exit price by the regulatory authorities;
- the increase of the single exit price annually, more particularly, the criteria that the Minister of Health is to take into account before allowing any increases to a single exit price. Those criteria include the average consumer price index for the preceding year, foreign exchange rates, “international pricing information”, comments from interested and affected parties and “the need to insure the availability, affordability and quality of medicines and scheduled substances in the Republic.”;
- exemptions and exclusions to the increase of the single exit price which are intended to be provided only with reference to the criteria that the Minister may use to determine such an exemption or exclusion; and
- powers afforded to the Director-General of the Department of Health to obtain, from a range of persons concerned with the supply of medicine, information relating to the pricing of that medicine. This is an important change in the powers afforded to the Director-General especially in relation to the amendment of the definitions and introduction of the definition of “bonus system, rebate system or any other incentive scheme” as the power to police the introduction of such schemes is now afforded to the Director-General within the context of the single exit price regulations – a power that rests within the amendments proposed to regulation 22 of the single exit price regulations.

The one difficulty faced by the proposed amendments, as they currently stand, more particularly, the definitions of “bonus system, rebate system or any other incentive scheme” and “discounts” is the infection of these definitions by vague terms and rambling sentences that ultimately cause more problems from an interpretation point of view than legislative solutions. Consequently, the proposed amendments may be too vague to pass constitutional challenge and may have to be revisited in their entirety before they are introduced into law. This having been said, in so far as the public remain passive about the issues contained in the draft regulations, then there is no reason why the regulations should not pass into law in their current format.

One aspect of the proposed regulations is clear: the end to transactions, currently in place, dealing with any particular aspect otherwise affected by the regulations. The full extent of the effect of the regulations, as amended, especially within the context of the Medical Schemes Act No. 131 of 1998, as amended (“the MSA”), will have to be seen and tested. Unfortunately, the writer’s view remains that the proposed amendments to the single exit price regulations are too broad and too vague to be enforced especially within a medicines and Scheduled substances environment that is fundamentally split between two economic realities: the one is the manner in which medicines and Scheduled substances move through the supply chain
when medical schemes and associated parties are involved and the other when these commodities move through ordinary supply chains without the interference of the provisions of the MSA such as formulary listings, managed healthcare principles and applicable treatment protocols and algorithms. Unfortunately, medical schemes only derive savings from the supply of medicines by the application of principles especially created in terms of the MSA to allow medical schemes to control costs of medicines and the supply of Scheduled substances. With the invasion of the single exit price regulations into the medical schemes arena, many of the managed healthcare principles that are currently applicable to the supply of medicines may possibly be compromised and struck down by the amendments. Therefore, the proposed amendment may operate to render medicines, supplied within the medical schemes environment, susceptible to increases, alternatively, falling off medical scheme formularies to the disadvantage of medical scheme members.

As with any aspect of healthcare regulation, the debate about whether or not intensive regulation is preferable to promote the interests of the South African healthcare consumer, is contentious - especially in so far as the costs of medicines and the current structuring of the medicines supply chain in the Republic are concerned.

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