GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 510 **6 July 2012**

MEDICINES AND RELATED SUBSTANCES ACT (No. 101 OF 1965)

THE REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: AMENDMENT

The Minister of Health, on recommendation of the Pricing Committee, in terms of section 22G of the Medicines and Related Substances Act (No. 101 of 1965), intends to amend the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances as in the Schedule.

Interested persons should submit substantiated comments or representations on the proposed amendments in writing, on a compact disc and hard copy within two months of publication of this notice to:

The Director-General: Health (Attention to the Director: Pharmaceutical Economic Evaluations)
Room 2610 South Tower
Civitas Building
Cnr Andries and Bloed Streets
Pretoria
0001

SCHEDULE

Definitions

1. In these regulations **"the Regulations"** means the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances as published under Government Notice No. R.1102 of 11 November 2005, as amended.

Amendment of Regulation 2 of the Regulations

2. Regulation 2 of the Regulations is hereby amended by—

(a) the insertion of the following definitions after the definition of the Act;

""**Bonus system, rebate system or any other incentive scheme**" means:

(a) unacceptable advertising fees;
(b) unacceptable credit payments;
(c) unacceptable data fees;
(d) unacceptable fees paid to induce and/or encourage biased sale of a particular medicine or scheduled product;
(e) discounts;
(f) formulary listing payments;
(g) kickbacks and perverse incentives;
(h) loyalty fees or similar fees or prizes or rewards;
(i) unacceptable marketing fees and/or co-marketing fees;
(j) shelf space fees;
(k) 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

(l) 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;

"Business enterprise" means businesses operating within the healthcare sector and includes, but is not limited to administrators, managed care companies, management entities, agencies, utility entities, procurement entities and suppliers of services or goods;".

(b) the substitution of the definition of "discounts" for the following definition;

""**discounts"** means any reduction in the price of a medicine that is not recorded as the official SEP and includes, but is not limited to:

(a) volume or 'bulk purchase' reductions below the official selling price (SEP) and other trade reductions below the regulated selling price (SEP)including reductions below the regulated selling price (SEP) given to customers off the manufacturer or importer's published selling price (SEP) at the date of the sale, due to 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 reductions below the regulated selling price (SEP) and rebates, including payments made to purchasers after the date of sale for achieving certain sales targets, or for any other reasons that relate to influencing the procurement or sale of a medicine;

(d) formulary listing payments including payments made by a manufacturer and/or importer to:

(i) private hospitals, pharmacists, dispensing doctors and other dispensing practitioners registered in terms of Section 22C (1) (a) of the Act, independent practitioner associations, provider networks; or

(ii) medical schemes, managed healthcare organizations and administrators of medical schemes as defined or contemplated in the Medical Schemes Act 1998 (Act no 131 of 1998) including the regulations thereto; or

(iii) any other person or organization including vendors or operators of electronic ordering groups, logistics service providers who may be wholesalers or distributors that are logistics service providers, independent pharmacies, pharmacy groups and any other individual or organization purchasing, supplying, selling, prescribing, dispensing, funding or recommending the use of medicines with the purpose of ensuring that a particular medicine or scheduled substance of a particular manufacturer and/or importer is included on the relevant formulary used or recommended by any of the persons or organizations listed in (i) – (iii);

(e) other allowances and fees that are aimed to influence the procurement or sale of a medicine 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 scheduled substances;

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

(h) contributions by manufacturers or importers to salaries or other recurrent expenditure or any other form of payment or

inducement or gift to any person or organization selling medicines that is aimed to influence the procurement or sale of a particular medicine or groups of medicines of that manufacturer and/or importer;"

(c) the insertion of the following definitions after the definition of "distributor;

"**end dispensers**" means all pharmacists and persons licensed in terms of section 22C (1) (a) of the Medicines and Related Substances Act (No. 101 of 1965) that dispense medicines or scheduled substances to end users as defined herein;

"**end user**" means all patients and related persons who are the ultimate consumers of the medicine or scheduled substance;

"**ex-manufacturer price**"; means the price that a manufacturer, licensed in terms of section 22C (1) (b) sets to produce a medicine or scheduled substance for consumption and includes costs incurred in releasing a final pack of a medicine or scheduled substance ready for distribution by persons registered in terms of conditions set in section 22H of the Act and who are logistics service providers. The Ex-Manufacturer Price is a VAT exclusive component of the single exit price of a medicine or scheduled substance;".

(d) the substitution of the definition of "logistics fee" for the following definition;

""**logistics fee**" is one of the three components that form the Single Exit Price, which are: (i) the ex-manufacturer price, which is determined by the manufacturer, (ii) 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 (iii) VAT. The logistics fee means the fee that is paid directly by manufacturers to logistics service providers exclusively for the provision of logistical services in respect of medicines or scheduled

substances distributed from the manufacturer or importer's premises to end dispensers. This fee may be paid by manufacturers to their in-house logistics-service-provider division;

(e) the substitution of the definition of "logistical services" for the following definition;"

""**logistical services**" means those services provided by logistics service providers, for the distribution of medicines or scheduled substances to end-dispensers and comprises of the following activities in relation to medicines or scheduled substances:

(a) Receiving of medicines or scheduled substances;

(b) Warehousing of medicines or scheduled substances;

(c) Proper inventory control and rotation;

(d) Taking orders from end dispensers;

(e) Delivery of orders to end dispensers;

(f) Provision of emergency deliveries to end dispensers where required;

(g) Proper record keeping;

(h) Batch tracking and tracing;

(i) Ability to maintain cold chain storage and distribution where necessary;

(j) Returning products to manufacturers when required; and

(k) Having and operating a debtor's control system which conforms to accepted accounting norms.

(f) the insertion of following definitions after the definition "logistical services";

""**logistics service provider"** means a person, licensed in terms of section 22C (1) (b) of the Act that performs Logistical Services as defined herein;

"logistics fee cap" means the maximum logistics fee determined for medicines or scheduled substances, above which no logistics fee shall be allowed;".

(g) the substitution of the definition of "single exit price" by the following definition;

""**Single Exit Price (SEP)"** means 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;".

Amendment of Regulation 3

3. Regulation 3 of the Regulations is hereby substituted for the following regulation:

"**3.** In order to promote transparency in the pricing of medicines and scheduled substances in the Republic, a manufacturer or importer of a medicine or scheduled substance shall make applications to Director-General of Health to confirm the correctness of the SEP calculation and or the medicine or scheduled substance details. The Director-General shall from time to time publish the information required to confirm the SEP calculation and or the medicine or scheduled substance details in the media and manner for publication of the SEP by notice in the Gazette:

(a) the proprietary name of the medicine or scheduled substance;

(b) the medicines registration certificate as issued by the Medicines Control Council;

(c) the generic or approved name of the medicine or scheduled substance;

(d) the quantity of each active ingredient in the medicine or scheduled substance;

(e) the therapeutic category, schedule and pharmacological class into which the medicine or scheduled substance falls in terms of the Act;

(f) the single exit price and/or related price components of the medicine or scheduled substance in the Republic;

(g) the license number of the applicant of a medicine or scheduled substance as issued by the Medicines Control Council;

(h) the applicant name for the medicine or scheduled substance;

(i) all other details of the medicine or scheduled substance deemed necessary by the Director-General".

Amendment of Regulation 4:

4. Regulation 4 of the Regulations is hereby substituted for the following regulation:

"**4.** The manufacturer, or where the medicine or Scheduled substance is imported by a person other than the manufacturer, the importer of a medicine or Scheduled substance must clearly and legibly reflect the single exit price of that medicine or scheduled substance on the original package or the immediate container within which that medicine or Scheduled substance is sold to a user. Where the medicine is dispensed in the original container, the dispenser must clearly reflect the SEP on the label of any other container."

Amendment of Regulation 7

5. Regulation 7 of the Regulations is hereby substituted for the following regulation:

"**7.** (1) Subject to the provisions of regulations 5, 8 and 9, the single exit price of a medicine or Scheduled substance may only be adjusted once a year by the independent reviews of the ex-manufacturer or logistics fee components of the single exit price;

(2) Subject to the review contemplated in sub-regulation 7(1), the manufacturer and/or importer of a medicine or scheduled substance may not interchange amounts between the ex-manufacturer and logistics fee component of the single exit price, regardless of the change or lack thereof in the single exit price;

(3) Amounts of the ex-manufacturer and logistics fee component of the single exit price of a medicine or scheduled substance can only be amended by means provided for in these Regulations".

Amendment of Regulation 8:

6. Regulation 8 of the Regulations is hereby substituted for the following regulation:

(1)"**8.** The Minister may, by notice in the gazette, on recommendation of the Pricing Committee, annually review the ex-manufacturer price and/ or logistics fee of a medicine or Scheduled substance. In this review the Minister may have regard to the following:

(a) the average CPI for the preceding year (s);
(b) the average PPI for the preceding year (s);
(c) changes in the rates of foreign exchange and purchasing power parity;
(d) international pricing information relating to medicines and scheduled substances;

(e) comments received from interested persons in terms of regulation 8 (2); and

(f) the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic.

(2)Not less than three months before the review contemplated in terms of regulation 8 (1), the Minister must publish a notice in the Gazette declaring his or her intention to make that review and inviting interested persons to furnish him or her in writing with any comments thereon or any representations they may wish to make in regard thereto

(3)Subject to the provisions of regulation 8 (1), a manufacturer or importer may no more than once a quarter increase the ex-manufacturer price and/or the logistics fee of a medicine within a year provided that—

(i) such increase does not exceed the ex-manufacturer price and/or logistics fee of the medicine or scheduled substance as first published in respect of that year;

(ii) the increase in ex-manufacturer price and/or logistics fee is applied to all sales of the medicine or Scheduled substance and not to selected categories of purchasers;

(iii) the manufacturer or importer notifies the Director-General in a manner determined appropriate by the Director-General, of the increase in the ex-manufacturer price and/or logistics fee at least 30 working days prior to the implementation of such increase;

(iv) the Single Exit Price may not be increased as contemplated in terms of regulation 8 (3) within the period of six months beginning from the date of commencement of these amended regulations".

Amendment of Regulation 9:

7. Regulation 9 of the Regulations is hereby substituted for the following regulation:

"**9. (1)** The Minister may, in exceptional circumstances, authorise a manufacturer or importer, on written application by such manufacturer or importer, to increase the ex-manufacturer price and/or logistics fee of a medicine or Scheduled substance by a specified amount greater than that permitted in terms of regulation 8 and regulation 5 (2) (g).

(2)In considering an application as contemplated in regulation 9 (1) the Minister must take into account—

(a) the nature and extent of any adverse financial, operational and other circumstances for the manufacturer or importer if the application made in terms of regulation 9 (1) is not approved;

(b) the effect, if any, on the availability of the medicine or Scheduled substance within the Republic if the application made in terms of regulation 9 (1) is not approved;

(c) the nature of the health condition for which the medicine or Scheduled substance is a registered indication within the Republic and the extent to which public health would be adversely affected should the medicine or Scheduled substance become unavailable or unaffordable within the Republic;

(d) the extent to which the rights contemplated in section 27 (1) (a) and 27 (3) of the Constitution may be adversely affected or limited—

(i) should the ex-manufacturer price and/or logistics fee not be increased by the amount requested in the application; and

(ii) the medicine or Scheduled substance becomes unavailable or unaffordable within the Republic".

Amendment of Regulation 14:

8. Regulation 14 of the Regulations is hereby substituted for the following regulation:

"**14.** (1) The Director-General may in writing request from a manufacturer, importer, exporter, wholesaler, distributor, logistics service provider, pharmacist, person licensed in terms of section 22C(1) (a), or any other person selling a medicine or Scheduled substance in the Republic, information or documentation relating to one or more of the following—

(a) the approved name and the proprietary name of a medicine or Scheduled substance and details as to the nature of its composition, including active and other ingredients;
(b) the price at which the medicine is being sold in any market in the Republic or in any other country specified by the Director-General;
(c) the volume or quantity and total value of sales of such medicine or Scheduled substance in respect of categories of purchasers;
(d) the method and cost of distribution within the Republic of the medicine or Scheduled substance including details of the supply chain by means of which the medicine or Scheduled substance will be made accessible to users;
(e) details as to the comparative efficacy, safety and cost effectiveness of the medicine or Scheduled substance relative to that of other medicines or Scheduled Substances in the same therapeutic class compiled in a manner consistent with guidelines published by the Director-General in the Gazette from time to time.

(2) Where the information as contemplated in regulation 14 (1) is not consistent or does not comply with the requirements as specified, the Director-General may, in writing, not approve the submitted documentation and or content thereof."

Amendment of *Regulation 19:*

9. Regulation 19 of the Regulations is hereby substituted for the following regulation:

"**19.** An applicant must, for registration of a single exit price of a medicine or scheduled substance that is registered in terms of section 15 of the Act, 30 working days before the commencement of the sale of the medicine submit an application with all of the relevant information (as published in the guidelines) required for approval of the requested single exit price to the Director General, but not limited to—

(1) The proprietary name, brand name or trade name under which it is intended to sell the medicine or Scheduled substance in the Republic;

(2) The nature of its composition including active and other ingredients;

(3) The ex-manufacturer price and logistics fee at which the applicant proposes to sell the medicine or Scheduled substance in the Republic in conformity with international benchmarks using a methodology as determined and published by the Director-General in the Gazette taking into account the price, and factors that influence price, at which the medicine or Scheduled substance, or a medicine or Scheduled substance that is deemed equivalent by the Director-General, is sold in all other countries in which the prices of medicines and Scheduled substances are regulated and published;

(4) The price at which the medicine or Scheduled substance is currently being sold in all other countries by the applicant;

(5) The intended method and cost of distribution of the medicine or Scheduled substance in the Republic, including details of the supply chain by means of which the medicine will be made accessible to users;

(6) The following information in relation to the medicine or Scheduled substance:

(a) The nature of the disease or condition in respect of which the medicine or Scheduled substance will be used in the Republic;

(b) The prevalence of the disease or condition as established by the applicant;

(7) Details as to the efficacy, safety and cost-effectiveness of the medicine or Scheduled substance compared to other medicines or Scheduled Substances in the same therapeutic class;

(8) All other information deemed necessary as compiled in a manner consistent with guidelines and templates published by the Director-General from time to time".

Amendment of Regulation 20:

10. Regulation 20 of the Regulations is hereby substituted for the following regulation:

"**20.** Where any of the information specified in regulation 19 is not within the knowledge, possession or control of the applicant, the applicant shall inform the Director-General to this effect and reasoning in writing in an affidavit sworn to by a commissioner of oaths."

Amendment of Regulation 21:

11. Regulation 21 of the Regulations is hereby substituted for the following regulation:

"**21.** The Director-General shall, and in the case of the information referred to in regulation 21 (2) (d), publish or otherwise communicate, or require manufacturers, importers, wholesalers or distributors that are logistics service providers, pharmacists or persons licensed in terms of section 22C(1) (a) of the Act to publish or otherwise communicate in such manner and format as he or she may by notice in the Gazette determine, information in relation to a particular medicine or Scheduled substance or class or category of medicines or Scheduled substances or the sale of a medicine or Scheduled substance for the purpose of—

(1) informing the public of—

(a) the therapeutic value of a medicine or Scheduled substance relative to the single exit price set by the manufacturer;

(b) the single exit price, strength, dosage form and pack size of a medicine or Scheduled substance;

(c) the risks associated with a particular medicine or Scheduled substance relative to the single exit price of that medicine or Scheduled substance;

(2) informing the public on the following matters—

(a) the availability of a medicine or Scheduled substance;

(b) the pricing system contemplated in section 22G of the Act;

(c) the supply chain for a medicine or Scheduled substance;

(d) the fees charged by wholesalers, distributors, retailers and other persons selling medicines or Scheduled substances;

(e) the country from which a medicine or Scheduled substance is sourced.

(3) Where the Director-General requires persons who sell medicines or Scheduled substances to publish information in terms of this regulation, such persons may only be required to publish information in respect of the medicines or Scheduled substances that they sell.

(4) Nothing in this regulation must be interpreted to mean that the Director-General may publish or communicate, or compel any other person to publish or communicate, information where there is a ground for refusal of access to a record containing such information in terms of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000)".

Amendment of Regulation 22:

12. Regulation 22 of the Regulations is hereby substituted for the following regulation:

"**22.**(1) The Director-General may determine that the ex-manufacturer price and/or logistics fee of a medicine or Scheduled substance is unreasonable and communicate to the relevant manufacturer,

importer, wholesaler or distributor that is a logistics service provider, in a manner which he or she deems appropriate, such determination together with the basis upon which the determination has been made.

(2) With regard to the determination contemplated in regulation 22 (1), the Director-General must consult with the relevant member of the supply chain and consider any representations made by that member concerning the reasonableness of the single exit price and or components of the Single Exit Price.

(3) Where the Director-General is not convinced, after the consultation and representations contemplated in regulation 22 (2), that the single exit price and or components of the single exit price is (are) reasonable, he or she may publish a notice in the Gazette to the effect that in the opinion of the Director-General, the single exit price and or components of the single exit price is (are) unreasonable and must state the reasons for such opinion".

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 4/6/2012