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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 1102 11 November *2005*

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO 101 OF 1965)

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

In compliance with the order of the Constitutional Court in case number CCT 59/04 made on the 30 September 2005 the Minister of Health hereby republishes the abovementioned regulations duly amended as required.

SCHEDULE

1. The sale of medicines and Scheduled substances in the Republic of South Africa is subject to the conditions stipulated in these regulations.

Definitions

2. In these Regulations, any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and, unless the context otherwise indicates, in these Regulations –

"the Act" means the Medicines and Related Substances Act, 1965 (Act No 101 of 1965) as amended and includes the General Regulations made thereunder;

"Constitution" means the Constitution of the Republic of South Africa Act No 108 of 1996;

"CPI" means the Consumer Price Index as determined and published by Statistics South Africa from time to time;

"date of commencement" means 02 May 2004;

"discounts" includes but is not limited to –

(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 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 targets, 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 health care organisations 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 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 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;

(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;

"distributor" means a person, other than a manufacturer, wholesaler or retailer, who supplies a medicine or Scheduled Substance to a retailer or a wholesaler;

"exporter" means a person within the Republic who sells medicines to a person outside of the Republic;

"importer" means a person importing medicines for the purpose of sale in the Republic from a manufacturer or other person outside of the Republic and includes a parallel importer as defined in the Act;

"logistics fee" means the fee that is payable in respect of logistical services;

"logistical services" means those services provided by distributors and wholesalers in relation to a medicine or Scheduled substance including but not limited to warehousing, inventory or stock control management, order and batch order processing, delivery, batching, tracking and tracing, cold chain storage and distribution;

"PPI" means the Production Price Index for pharmaceutical products as determined and published by Statistics South Africa from time to time;

"Pricing Committee" means the Pricing Committee appointed by the Minister in terms of section 22G of the Act;

"purchasing power parity" means the comparative purchasing power of the currencies of two countries with respect to a predetermined basket of goods and services;

"retailer" means a person who is not a wholesaler, importer, exporter, manufacturer or distributor who sells a medicine or Scheduled substance to a user and includes a person licensed in terms of section 22C(1)(a) of the Act;

"single exit price" means 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;

"supply chain" includes any two or more of the following-

(a) a manufacturer;
(b) an importer;
(c) an exporter;
(d) a wholesaler;
(e) a distributor;
(f) a retailer;
(g) a person licensed in terms of section 22C(1)(a) of the Act;
(h) the user of a medicine

"user" means a natural person to whom a medicine or Scheduled substance is sold for use and excludes a manufacturer, importer, exporter,

wholesaler, distributor, retailer and any other person selling medicines or Scheduled substances in the Republic;

"wholesaler" means a dealer who purchases medicines or Scheduled substances from a manufacturer and sells them to a retailer and includes a wholesale pharmacy;

"VAT" means value added tax as contemplated in the Value Added Tax Act, **1991** (Act No **89** of **1991);**

"year" means the period of **12** months beginning on **02** May.

3. In order to promote transparency in the pricing of medicines and Scheduled substances in the Republic, a manufacturer or where the manufacturer of the medicine or Scheduled substance is outside of the Republic, the importer of a medicine or Scheduled substance shall publish, where applicable, the following information in such manner and format, at such time intervals, upon such conditions and in such media as may be determined by the Director-General from time to time by notice in the Gazette:

(a) the proprietary name of the medicine or Scheduled substance;
(b) the generic or approved name of the medicine or Scheduled substance;
(c) the quantity of each active ingredient in the medicine or Scheduled substance;
(d) the therapeutic category, Schedule and pharmacological class into which the medicine or Scheduled substance falls in terms of the Act;
(e) the single exit price of the medicine or Scheduled substance in the Republic.

4. The single exit price must be clearly and legibly reflected on the package or the immediate container within which a medicine or Scheduled substance is sold to a user.

5. (1) Upon commencement of these regulations the price of a medicine or Scheduled substance must be set by the manufacturer, or where the medicine or Scheduled substance is imported by a person other than the manufacturer, the importer of the relevant medicine or Scheduled substance, and combined with the logistics fee and VAT in order to arrive at a single exit price for the relevant medicine or Scheduled substance.

(2) The single exit price must be set in accordance with the following provisions –

(a) for a period of one year after commencement of these regulations the single exit price shalt not be increased;

(b) subject to sub-regulation 5(2)(a) the single exit price may be increased in terms of regulation 8 of these regulations;

(c) the price of each medicine or Scheduled substance to be set upon the date of commencement of these regulations by the manufacturer or importer must not be higher -

(i) in respect of a Scheduled substance that is not a medicine, than the weighted average net selling price per unit of each Scheduled substance for the calendar year 2003: provided that where sales of the Scheduled substance commenced at the beginning of January 2004 or thereafter, the price of such substance must be calculated using the average of the total rand value of sales less the total rand value of the discounts for the period for which the Scheduled substance was sold and with reference to the price of

that Scheduled substance in other countries in which the prices of medicines and Scheduled substances are regulated and published;

(ii) in respect of a medicine, than the weighted average net selling price of the medicine which must be calculated using the formula:

"S divided by the total number of lowest units (eg a tablet) for all of the packs of the same dosage strength of the medicine sold in the year 2003"

Where S = the total rand value of net sales (being sales less discounts) for all packs of the same dosage strength of the medicine sold in the year:

provided that where sales of the medicine commenced at the beginning of January 2004 or thereafter, the price of the medicine must be calculated and with reference to the price of that medicine in other countries in which prices of medicines and Scheduled substances are regulated and published.

(Note: Examples of the manner in which the weighted average net selling price must be calculated are cited in Appendix A of these regulations.)

(d) the single exit price for a pack is the product of the price of each unit and the number of units in the pack.

(e) The Minister on the recommendation of the Pricing Committee must determine and publish in the Gazette a methodology for conforming with international benchmarks, 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 Minister on the recommendation of the Pricing Committee, is sold in other countries in which the prices of medicines and Scheduled substances are regulated and published and the single exit price of each medicine or Scheduled substance must,

within 3 months of publication of such methodology in the Gazette conform with international benchmarks in accordance with such methodology;

(f) Subject to regulation 5(2)(g), the logistics fee must be determined by agreement between the provider of logistical services and the manufacturer or importer.

(g) The Minister, on the recommendation of the Pricing Committee, must determine a maximum logistics fee where, in the opinion of the Minister, such a determination is necessary to promote or protect the interests of the public in -

(i) ensuring reasonable access to affordable medicines;

(ii) the realization of the constitutional right of access to health care services contemplated in section 27 of the Constitution;

(iii) the efficient and effective distribution of medicines and Scheduled substances throughout the Republic.

(3) Not less than two months before making a determination in terms of regulation 5(2)(g), the Minister must publish a notice in the Gazette declaring his or her intention to make that determination 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.

(4) For the purpose of regulation 5(2)(c), 'unit' means the pack in which the medicine or Scheduled substance is sold.

6. 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.

7. Subject to the provisions of regulations 5, 8 and 9, the single exit price of a medicine or Scheduled substance may only be increased once a year.

8. (1) The extent to which the single exit price of a medicine or Scheduled substance may be increased will be determined annually by the Minister, on the recommendation of the Pricing Committee, by notice in the Gazette with regard to –

(a) the average CPI for the preceding year;

(b) the average PPI for the preceding year;

(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 making a determination in terms of regulation 8(1), the Minister must publish a notice in the Gazette declaring his or her intention to make that determination 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 single exit price of a medicine within a year provided that -

(i) such increase does not exceed the single exit price of the medicine or scheduled substance as first published in respect of that year;

(ii) the increase in the single exit price 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 of the increase in the single exit price at least 48 hours prior to the implementation of such increase;

(iv) the single exit price may not be increased as contemplated in terms of this regulation 8(3) within the period of six months beginning from the date of commencement of these regulations .

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

(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 single exit price not be increased by the amount requested in the application; and

(ii) should the medicine or Scheduled substance become unavailable or unaffordable within the Republic.

10. ..... *(currently under review by the Pricing Committee)*

11. ..... *(currently under review by the Pricing Committee)*

12. The appropriate dispensing fee as contemplated in section 22G(2)(b) of the Act to be charged by persons licensed in terms of section 22C(1)(a) of the Act must be calculated, exclusive of VAT, as follows:

(1) Where the single exit price of a medicine or Scheduled substance is less than one hundred rands, the dispensing fee must not exceed16% percent of the single exit price in respect of that medicine or Scheduled substance.

(2) Where the single exit price of a medicine or Scheduled substance is one hundred rands or more, the dispensing fee must not exceed sixteen rands in respect of that medicine or Scheduled substance.

(3) The provisions of this regulation 12 must be reviewed annually by the Minister with regard to the CPI, the PPI, and the need to ensure the avaitability, affordability and quality of medicines and Scheduled substances in the Republic.

13. **…….*(currently under review by the Pricing Committee)***

14. The Director-General may in writing request from a manufacturer, importer, exporter, wholesaler, distributor, 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 –

(1) 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;

(2) 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;

(3) the volume or quantity and total value of sales of such medicine or Scheduled substance in respect of categories of purchasers;

(4) 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;

(5) 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.

15. Subject to the provisions of any other law, where the information or documentation requested in terms of regulation 14 is within the knowledge, possession or control of the person from whom it has been requested, such information or documentation must be provided to the Director-General in the specified format within 30 working days of the date of such request, or such other reasonable period as the Director-General may determine.

16. Where the information or documentation requested by the Director-General in terms of regulation 14 is not within the knowledge, possession or control of the person from whom it has been requested, such person shall inform the Director-General to this effect in writing within 14 days of the date of such request.

17. The Director-General may refer the information and documentation contemplated in regulation 14 to the Pricing Committee for the purpose of facilitating the performance by the Pricing Committee of its duties in terms of the Act.

18. The Pricing Committee may, at its discretion, receive written or oral representations from any person concerning the pricing of medicines or

Scheduled substances in the Republic and elsewhere and such person may be required by the chairperson of the Committee, before making any oral representation to take an oath or make an affirmation, which oath or affirmation shall be administered by the chairperson.

19. An applicant for registration of a medicine in terms of section 15 of the Act must, at least one month before the commencement of the sale of the medicine supply the following information to the Director General-

(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 single exit price 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 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 any other country 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 compiled in a manner consistent with guidelines published by the Director-General in the Gazette from time to time.

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 in writing.

21. The Director-General may, and in the case of the information referred to in regulation 21(2)(d) must, publish or otherwise communicate, or require manufacturers, importers, wholesalers, distributors, 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).

22. (1) The Director-General may determine that the single exit- price of a medicine or Scheduled substance is unreasonable and communicate to the relevant manufacturer, importer, wholesaler or distributor, 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.

(3) Where the Director-General is not convinced, after the consultation and representations contemplated in regulation 22(2), that the single exit price is 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 is unreasonable and must state the reasons for such opinion.

23. In determining whether the price of a medicine or Scheduled substance is unreasonable as contemplated in regulation 22, the Director-General must have regard to –

(1) the single exit price at which the medicine or Scheduled substance is being sold in the relevant market;

(2) the single exit prices at which other medicines or Scheduled substances in the same therapeutic class are being sold in the relevant market;

(3) the prices at which the medicine or Scheduled substance and other medicines or Scheduled substances in the same therapeutic class are being sold in countries other than the Republic;

(4) changes in the CPI, the PPI and the relevant rates of foreign exchange;

(5) purchasing power panty with reference to the Republic and any other country in which the medicine or Scheduled substance is sold;

(6) the relative availability within the Republic of medicines or Scheduled substances in the same therapeutic class as the medicine or Scheduled Substance and the safety and efficacy of the medicine or Scheduled substance relative to other medicines or Scheduled substances in the same therapeutic class;

(7) the nature of any indication in respect of which the medicine or Scheduled Substance has been registered in the Republic;

(8) the size of the market for the medicine or Scheduled substance in the Republic relative to that in other countries;

(9) any relevant information provided by the Council for Medical Schemes established in terms of the Medical Schemes Act, 1998 (Act No 131 of 1998);

(10) the size of the obstacle, represented by the single exit price, to access to the medicine or Scheduled substance relative to the public interest in having widespread and general access to the medicine or Scheduled substance;

(11) such other factors which in the view of the Director-General are relevant to the pricing, or the costs of manufacture or sale, of the medicine or Scheduled substance.

24. (1) Manufacturers and importers must, within one month of the date of commencement of these regulations –

(a) submit to the Director-General a schedule reflecting the single exit price of a pack of each medicine or Scheduled substance **sold** by them, including the pack size, dosage form and strength of the medicine or Scheduled substance;

(b) supply to the Director-General the following information -

(i) the total sales value of each medicine or Scheduled substance sold in the year 2003;

(ii) the total value of discounts in respect of the sale of each medicine or Scheduled substance in the year 2003;

(iii) the total number of packs of each medicine or Scheduled substance sold in the year 2003.

(2) Within 3 months of the date of commencement of these regulations manufacturers and importers must, at the expense of the manufacturer or importer concerned, submit to the Director-General a report and audit certificate compiled by independent auditors who are not the current auditors of the manufacturer or importer verifying the information supplied in terms of regulation 24(1) and detailing, where applicable, any variances in such information.

(3) To the extent that the audit certificate indicates that the information supplied in the schedule contemplated in section 24(1)(a) is inaccurate, the manufacturer or importer must, within 14 days of receipt of the audit certificate, revise that schedule to the reasonable satisfaction of the auditors to reflect an initial single exit price which in

the reasonable opinion of the auditors fairly reflects the single exit price of the medicine or Scheduled substance concerned and the auditors must then issue a revised audit certificate which must be submitted to the Director-General together with the schedule as revised in terms of regulation 24(2).

(4) Manufacturers and importers must, with effect from the date one month after the date of commencement of these regulations, sell medicines and Scheduled substances only in accordance with the provisions of these regulations.

(5) Wholesalers, distributors and retailers must, with effect from the date 3 months after the date of commencement of these regulations, sell medicines and Scheduled substances only in accordance with the provisions of these regulations.

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ME TSHABALALA-MSIMANG
MINISTER OF HEALTH
DATE: 26-10-2005

APPENDIX A

EXAMPLES OF THE MANNER IN WHICH THE WEIGHTED AVERAGE NET SELLING PRICE MUST BE CALCULATED

Calculation of the price for solid dosage form where this is available in different pack sizes

Example 1: 2 pack sizes (50 tablets and 500 tablets) of a 500 mg strength of a medicine

Average 2003 price of 50 tablet pack = 50 Rands
Average 2003 price of 500 tablet pack = 300 Rands

2003 sales of 50 tablet pack = 100,000 packs
2003 sales of 500 tablet pack = 10,000 packs

Total 2003 discounts for 50 tablet pack sales in 2003 = 500,000 Rands
Total 2003 discounts for 500 tablet pack sales in 2003 = 200,000 Rands

$$\text{Unit price} = \frac{((100000*50)-(500000))+((10000*300)-(200000))}{((100000*50)+(10000*500))}$$

The price of the unit is 0.73 Rand/500mg tablet

The price of the 50 tablet pack is 36.5 Rands
The price of the 500 tablet pack is 365 Rands

Calculation of the price for liquid dosage form where this is available in different pack sizes

Example 2: 2 pack sizes (125 ml bottle and a 500 ml bottle) of a 5mg/ml strength of a medicine

Average 2003 price of 125ml bottle = 50 Rands
Average 2003 price of 500ml bottle = 150 Rands

2003 sales of 125 ml bottles = 10,000 bottles
2003 sales of 500 ml bottles = 5,000 bottles

Total 2003 discounts for sales of 125ml bottles in 2003 = 50,000 Rands
Total 2003 discounts for sales of 500ml bottles in 2003 = 75,000 Rands

$$\text{Unit price} = \frac{((10000*50)-(50000))+((5000*150)-(75000))}{((10000*125)+(5000*500))}$$

The price of the unit is 0.3 Rand/ml

The price of the 125ml bottle is 37.5 Rands
The price of the 500 ml bottle is 150 Rands