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INHOUD

GOVERNMENT NOTICE
GOEWERMENTSKENNISGEWING

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 553 **30 April 2004**

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

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

The Minister of Health has, on the recommendations of the Pricing Committee, and in terms of the Medicines and Related Substances Act, 1965 (Act No 101 of 1965) made the regulations in the Schedule, commencing on 02 May 2004.

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 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 shall 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 using the average of the total rand value of sales less the total rand value of the discounts for the period for which the medicine was sold 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 Director-General 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 Director-General, 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 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, after consultation with 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 or Scheduled Substance 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. The appropriate dispensing fee as contemplated in section 22G(2)(b) of the Act to be charged by pharmacists must be calculated as follows:

(1) With regard to medicines and scheduled substances falling into Schedules 1 and 2 of the Act, in the absence of a prescription the dispensing fee, exclusive of VAT, must not exceed -

(a) 16% of the single exit price of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is less than one hundred rands;

(b) sixteen rands in respect of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is greater than or equal to one hundred rands.

(2) With regard to medicines and scheduled substances falling into Schedules 3, 4, 5, 6, 7, and 8 of the Act, and medicines and Scheduled substances falling into Schedules 1 and 2 of the Act in respect of which a prescription has been written, the dispensing fee, exclusive of VAT, must not exceed -

(a) 26% of the single exit price in respect of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is less than one hundred rands;

(b) twenty six rands in respect of a medicine or Scheduled substance where the single exit price of that medicine or Scheduled substance is greater than or equal to one hundred rands.

(3) The provisions of this regulation 10 must be reviewed annually by the Minister with regard to the CPI, the PPI, and the need to ensure the availability, affordability and quality of medicines and Scheduled substances in the Republic.

11. Where a medicine or Scheduled substance is dispensed in terms of a prescription written for a person who has been admitted as an inpatient the dispensing fee shall be calculated in terms of regulation 10 in respect of the entire quantity of the medicine or Scheduled substance reflected on such prescription, irrespective of whether the medicine or Scheduled

substance is issued from the stock of the pharmacy or from ward or theatre stock.

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 availability, affordability and quality of medicines and Scheduled substances in the Republic.

13. The appropriate fee to be charged by any person, other than a wholesaler or distributor, in respect of Schedule 0 medicines shall not exceed the percentage mark-up in respect of that medicine or Scheduled substance that was applied at the date of commencement of these regulations.

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 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 parity 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.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH
DATE:

APPENDIX A

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

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

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

No. R. 553 **30 April 2004**

WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET NO 101 VAN 1965)

REGULASIES RAKENDE 'N DEURSIGTIGE PRYSSTELSEL VIR MEDISYNE EN GELYSTE STOWWE

Die Minister van Gesondheid het, op aanbeveling van die Pryskomitee en kragtens die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No 101 van 1965), die regulasies in die Bylae uitgevaardig, wat op 02 Mei 2004 in werking tree.

BYLAE

1. Die verkoop van medisyne en gelyste stowwe in die Republiek van Suid-Afrika is onderhewig aan die voorwaardes in hierdie regulasies uiteengesit.

Woordomskrywing

2. In hierdie Regulasies het enige woord of uitdrukking wat in die Wet omskryf is en nie hierin omskryf is nie, dieselfde betekenis as in die Wet, en tensy dit uit die samehang anders blyk, beteken –

"aanbodketting" ook enige twee of meer van die volgende:
(a) 'n vervaardiger;
(b) 'n invoerder;
(c) 'n uitvoerder;
(d) 'n groothandelaar;
(e) 'n verspreider;
(f) 'n kleinhandelaar;
(g) 'n persoon wat ingevolge artikel 22C(1)(a) van die Wet gelisensieer is;
(h) die gebruiker van 'n medisyne;

"BTW" belasting op toegevoegde waarde soos bedoel in die Wet op Belasting op Toegevoegde Waarde, 1991 (Wet No 89 van 1991);

"datum van inwerkingtreding" 02 Mei 2004;

"die Wet" die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No 101 van 1965), soos gewysig, en ook die Algemene Regulasies daarkragtens uitgevaardig;

"enkele afsetprys" die prys wat ingevolge hierdie regulasies deur die vervaardiger of invoerder van 'n medisyne of gelyste stof gestel is, gekombineer met die logistiekgelde en BTW, en is die prys van die laagste eenheid van die medisyne of gelyste stof binne 'n pak vermenigvuldig met die getal eenhede in die pak;

"gebruiker" 'n natuurlike persoon aan wie 'n medisyne of gelyste stof verkoop word vir gebruik, maar met uitsluiting van 'n vervaardiger, invoerder, uitvoerder, groothandelaar, verspreider, kleinhandelaar en enige ander persoon wat medisyne of gelyste stowwe in die Republiek verkoop;

"Grondwet" die Grondwet van die Republiek van Suid-Afrika, No 108 van 1996;

"groothandelaar" 'n handelaar wat medisyne of gelyste stowwe van 'n vervaardiger koop en dit aan 'n kleinhandelaar verkoop, en ook 'n groothandelapteek;

"invoerder" 'n persoon wat medisyne vir die doel van verkoop in die Republiek invoer van 'n vervaardiger of ander persoon buite die Republiek, en ook 'n parallelle invoerder soos in die Wet omskryf;

"jaar" die tydperk van 12 maande wat op 02 Mei begin;

"kleinhandelaar" 'n persoon wat nie 'n groothandelaar, invoerder, uitvoerder, vervaardiger of verspreider is nie wat 'n medisyne of gelyste stof aan 'n gebruiker verkoop, en ook 'n persoon wat ingevolge artikel 22C(1)(a) van die Wet gelisensieer is;

"koopkragpariteit" die vergelykende koopkrag van die geldeenhede van twee lande ten opsigte van 'n voorafbepaalde mandjie goedere en dienste;

"kortings" ook, maar is dit nie beperk nie tot –

(a) volume- of losmaataankopekortings en ander handelskortings, insluitende kortings aan kliënte toegestaan op die vervaardiger of invoerder se gepubliseerde verkoopprys op die verkoopdatum, as gevolg van die koop van groot hoeveelhede, as 'begunstigde' kliënte of om enige ander rede;

(b) bonustransaksies ingevolge waarvan bykomende produkeenhede onder die lysprys of gratis aan kliënte verskaf word;

(c) vereffeningskortings en rabatte, insluitende betalings ná die verkoopdatum aan kopers gedoen vir tydige betaling van rekenings, om sekere verkoopteikens te haal, of om enige ander rede;

(d) formulariumlysbetalings, insluitende betalings gedoen aan –

(i) private hospitale, resepterende dokters, verenigings van onafhanklike praktisyns, verskaffersnetwerke; of

(ii) mediese skemas, organisasies vir bestuurde gesondheidsorg en administrateurs van mediese skemas soos omskryf of beoog in die Wet op Mediese Skemas, 1998 (Wet No 131 van 1998), insluitende die regulasies daarby; of

(iii) enige ander persoon of organisasie met die doel om te verseker dat 'n bepaalde medisyne of gelyste stof ingesluit word by die betrokke formularium wat deur daardie befondser of verskaffer gebruik word;

(e) ander toelaes en gelde, insluitende reklamegelde en gelde vir rakruimte;

(f) gratis dienste deur vervaardigers en invoerders of hulle agente gelewer aan ander persone wat medisyne of gelyste stowwe verkoop;

(g) die koop of die verskaffing van enige toerusting deur vervaardigers of invoerders of hulle agente teen 'n verlaagde koste of gratis aan ander persone wat medisyne of gelyste stowwe verkoop;

(h) bydraes deur vervaardigers of invoerders tot salarisse of ander herhalende uitgawes of enige ander vorm van betaling of oorreding aan enige persoon of organisasie wat medisyne verkoop;

"logistieke dienste" die dienste wat deur verspreiders en groothandelaars gelewer word met betrekking tot 'n medisyne of gelyste stof, insluitende maar nie beperk nie tot pakhuisopberging, inventaris- of

voorraadbeheerbestuur, bestellings- en lotbestellingsverwerking, aflewering, lotsamestelling, opsporing en nasporing, kouekettingberging en -verspreiding;

"logistiekgelde" die gelde wat ten opsigte van logistieke dienste betaalbaar is;

"PPI" die Produksieprysindeks vir farmaseutiese produkte soos van tyd tot tyd deur Statistieke SA bepaal en gepubliseer;

"Pryskomitee" die Pryskomitee ingevolge artikel 22G van die Wet deur die Minister aangestel;

"uitvoerder" 'n persoon binne die Republiek wat medisyne aan 'n persoon buite die Republiek verkoop;

"verspreider" 'n ander persoon as 'n vervaardiger, groothandelaar of kleinhandelaar, wat 'n medisyne of gelyste stof aan 'n kleinhandelaar of 'n groothandelaar verskaf;

"VPI" die Verbruikersprysindeks soos van tyd tot tyd deur Statistieke SA bepaal en gepubliseer.

3. Om deursigtigheid by die prysbepaling van medisyne en gelyste stowwe in die Republiek te bevorder, moet 'n vervaardiger of, waar die vervaardiger van die medisyne of gelyste stof buite die Republiek is, die invoerder van 'n medisyne of gelyste stof, waar toepaslik die volgende inligting op sodanige wyse en in sodanige formaat, met sodanige tussenpose, op sodanige voorwaardes en in sodanige media publiseer as wat die Direkteur-generaal van tyd tot tyd by kennisgewing in die *Staatskoerant* bepaal:

   (a) die eiendomsnaam van die medisyne of gelyste stof;
   (b) die generiese of goedgekeurde naam van die medisyne of gelyste stof;
   (c) die hoeveelheid van elke aktiewe bestanddeel in die medisyne of gelyste stof;
   (d) die terapeutiese kategorie, bylae en farmakologiese klas waarin die medisyne of gelyste stof ingevolge die Wet val;
   (e) die enkele afsetprys van die medisyne of gelyste stof in die Republiek.

4. Die enkele afsetprys moet duidelik en leesbaar getoon word op die pakket of die onmiddellike houer waarin 'n medisyne of gelyste stof aan 'n gebruiker verkoop word.

5. (1) Met die inwerkingtreding van hierdie regulasies moet die prys van 'n medisyne of gelyste stof deur die vervaardiger, of waar die medisyne of gelyste stof deur 'n ander persoon as die vervaardiger ingevoer word, deur die invoerder van die betrokke medisyne of gelyste stof gestel word en met die logistiekgelde gekombineer word ten einde 'n enkele afsetprys vir die betrokke medisyne of gelyste stof te bepaal.

(2) Die enkele afsetprys moet in ooreenstemming met die volgende bepalings gestel word:

(a) Vir 'n tydperk van een jaar na die inwerkingtreding van hierdie regulasies mag die enkele afsetprys nie verhoog word nie.

(b) Behoudens subregulasie 5(2)(a) mag die enkele afsetprys ingevolge regulasie 8 van hierdie regulasies verhoog word.

(c) Die prys van elke medisyne of gelyste stof wat op die datum van inwerkingtreding van hierdie regulasies deur die vervaardiger of invoerder gestel moet word, mag nie hoër wees nie as –

(i) ten opsigte van 'n gelyste stof wat nie 'n medisyne is nie, die geweegde gemiddelde netto verkoopprys per eenheid van elke gelyste stof vir die kalenderjaar 2003: Met dien verstande dat waar verkope van die gelyste stof aan die begin van Januarie 2004 of daarna begin het, die prys van sodanige stof bereken moet word deur die gemiddelde van die totale randwaarde van verkope minus die totale randwaarde van die kortings vir die tydperk waarvoor die gelyste stof verkoop is, te gebruik, en met verwysing na die prys van daardie gelyste stof in ander lande waar die pryse van medisyne en gelyste stowwe gereguleer en gepubliseer word;

(ii) ten opsigte van 'n medisyne, die geweegde gemiddelde netto verkoopprys van die medisyne, wat bereken moet word deur die volgende formule te gebruik:

"S gedeel deur die totale getal laagste eenhede (bv 'n tablet) vir al die pakke van dieselfde dosissterkte van die medisyne wat in die jaar 2003 verkoop is",

waar S = die totale randwaarde van die netto verkope (naamlik verkope minus kortings) vir alle pakke van dieselfde dosissterkte van die medisyne wat in die jaar verkoop is:

Met dien verstande dat waar die verkope van die medisyne aan die begin van Januarie 2004 of daarna begin het, die prys van die medisyne bereken moet word deur die gemiddelde van die totale randwaarde van verkope minus die totale randwaarde van die kortings vir die tydperk waarvoor die medisyne verkoop is, te gebruik, en met verwysing na die prys van daardie medisyne in ander lande waar die pryse van medisyne en gelyste stowwe gereguleer en gepubliseer word.

(Opmerking: Voorbeelde van die wyse waarop die geweegde gemiddelde netto verkoopprys bereken moet word, verskyn in Aanhangsel A by hierdie regulasies.)

(d) Die enkele afsetprys vir 'n pak is die produk van die prys van elke eenheid en die getal eenhede in die pak.

(e) Die Direkteur-generaal moet 'n metodologie vir voldoening aan internasionale norme bepaal en in die *Staatskoerant* publiseer, met inagneming van die prys, en faktore wat prys beïnvloed, waarteen die medisyne of gelyste stof, of 'n medisyne of gelyste stof wat deur die Direkteur-generaal as gelykwaardig beskou word, in ander lande verkoop word waar die pryse van medisyne of gelyste stowwe gereguleer en gepubliseer word, en die enkele afsetprys van elke medisyne of gelyste stof moet binne drie maande na die publikasie van sodanige metodologie in die *Staatskoerant* aan internasionale norme voldoen in ooreenstemming met sodanige metodologie.

(f) Behoudens regulasie 5(2)(g) moet die logistiekgelde bepaal word deur ooreenkoms tussen die verskaffer van logistieke dienste en die vervaardiger of invoerder.

(g) Die Minister moet maksimum logistiekgelde bepaal waar so 'n bepaling na die Minister se mening nodig is om die publiek se belange te bevorder of te beskerm –

(i) ten einde redelike toegang tot beskikbare medisyne te verseker;

(ii) ter verwesenliking van die grondwetlike reg op toegang tot gesondheidsorgdienste in artikel 27 van die Grondwet beoog;

(iii) vir die doeltreffende en doelmatige verspreiding van medisyne en gelyste stowwe dwarsdeur die Republiek.

(3) Minstens twee maande voor 'n bepaling ingevolge regulasie 5(2)(g) moet die Minister 'n kennisgewing in die *Staatskoerant* publiseer waarin sy of haar voorneme verklaar word om daardie bepaling te maak en belanghebbende persone genooi word om hom of haar skriftelik te voorsien van enige kommentaar daaroor of enige vertoë wat hulle in verband daarmee wil rig.

(4) Vir doeleindes van regulasie 5(2)(c) beteken "eenheid" die pak waarin die medisyne of gelyste stof verkoop word.

6. 'n Vervaardiger, invoerder, verspreider of groothandelaar mag geen ander gelde of bedrag as die enkele afsetprys hef nie ten opsigte van die verkoop van 'n medisyne of gelyste stof aan 'n ander persoon as die Staat.

7. Behoudens die bepalings van regulasies 5, 8 en 9 mag die enkele afsetprys van 'n medisyne of gelyste stof net een keer per jaar verhoog word.

8. (1) Die mate waarin die enkele afsetprys van 'n medisyne of gelyste stof verhoog mag word, sal jaarliks, na oorleg met die Pryskomitee, deur die Minister by kennisgewing in die *Staatskoerant* bepaal word, met inagneming van –

(a) die gemiddelde VPI vir die voorafgaande jaar;

(b) die gemiddelde PPI vir die voorafgaande jaar;

(c) veranderinge in die wisselkoerse en koopkragpariteit;

(d) internasionale prysinligting rakende medisyne en gelyste stowwe;

(e) kommentaar wat ingevolge regulasie 8(2) van belanghebbende persone ontvang is;

(f) die behoefte om die beskikbaarheid, bekostigbaarheid en gehalte van medisyne en gelyste stowwe in die Republiek te verseker.

(2) Minstens drie maande voor 'n bepaling ingevolge regulasie 8(1) moet die Minister 'n kennisgewing in die *Staatskoerant* publiseer waarin sy of haar voorneme verklaar word om daardie bepaling te maak en belanghebbende persone genooi word om hom of haar skriftelik te voorsien van enige kommentaar daaroor of enige vertoë wat hulle in verband daarmee wil rig.

(3) Behoudens die bepalings van regulasie 8(1) mag 'n vervaardiger of invoerder die enkele afsetprys van 'n medisyne of gelyste stof nie meer as een keer per kwartaal binne 'n jaar verhoog nie: Met dien verstande dat –

(i) sodanige verhoging nie die enkele afsetprys van die medisyne of gelyste stof soos eerste ten opsigte van daardie jaar gepubliseer, te bowe mag gaan nie;

(ii) die verhoging in die enkele afsetprys op alle verkope van die medisyne of gelyste stof toegepas word en nie op geselekteerde kategorieë kopers nie;

(iii) die vervaardiger of invoerder die Direkteur-generaal van die verhoging in die enkele afsetprys in kennis stel minstens 48 uur voor die implementering van sodanige verhoging;

(iv) die enkele afsetprys nie soos ingevolge regulasie 8(3) bedoel verhoog mag word nie binne die tydperk van ses maande wat op die datum van inwerkingtreding van hierdie regulasies begin.

9. (1) Die Minister kan in uitsonderlike omstandighede 'n vervaardiger of invoerder, op skriftelike aansoek deur sodanige vervaardiger of invoerder, magtig om die prys van 'n medisyne of gelyste stof met 'n bepaalde bedrag groter as wat ingevolge regulasie 8 toegelaat word, te verhoog.

(2) By die oorweging van 'n aansoek in regulasie 9(1) bedoel, moet die Minister ag slaan op –

(a) die aard en omvang van enige nadelige finansiële, operasionele en ander omstandighede vir die vervaardiger of invoerder indien die aansoek wat ingevolge regulasie 9(1) gedoen is, nie toegestaan word nie;

(b) die uitwerking, indien wel, op die beskikbaarheid van die medisyne of gelyste stof binne die Republiek indien die aansoek wat ingevolge regulasie 9(1) gedoen is, nie toegestaan word nie;

(c) die aard van die gesondheidstoestand waarvoor die medisyne of gelyste stof 'n geregistreerde indikasie binne die Republiek is en die mate waarin die openbare gesondheid nadelig geraak sal word indien die medisyne of gelyste stof onbeskikbaar of onbekostigbaar raak binne die Republiek;

(d) die mate waarin die regte in artikel 27(1)(a) en 27(3) van die Grondwet beoog, nadelig geraak of beperk kan word –

(i) indien die enkele afsetprys nie met die bedrag wat in die aansoek versoek word, verhoog word nie; en

(ii) indien die medisyne of gelyste stof onbeskikbaar of onbekostigbaar raak binne die Republiek.

10. Die gepaste resepteringsgeld soos in artikel 22G(2)(b) van die Wet bedoel wat deur aptekers gehef moet word, moet soos volg bereken word:

(1) Met betrekking tot die medisyne en gelyste stowwe wat binne Bylaes 1 en 2 van die Wet val, by ontstentenis van 'n voorskrif, mag die resepteringsgelde, BTW uitgesluit, nie meer wees nie as –

(a) 16% van die enkele afsetprys van 'n medisyne of gelyste stof waar die enkele afsetprys van daardie medisyne of gelyste stof minder as een honderd rand is;

(b) sestien rand ten opsigte van 'n medisyne of gelyste stof waar die enkele afsetprys van daardie medisyne of gelyste stof groter as of gelyk aan een honderd rand is.

(2) Met betrekking tot medisyne en gelyste stowwe wat in Bylaes 3, 4, 5, 6, 7 en 8 van die Wet val, en medisyne en gelyste stowwe wat in Bylaes 1 en 2 van die Wet val ten opsigte waarvan 'n voorskrif uitgeskryf is, mag die resepteringsgelde, BTW uitgesluit, nie meer wees nie as –

(a) 26% van die enkele afsetprys ten opsigte van 'n medisyne of gelyste stof waar die enkele afsetprys van daardie medisyne of gelyste stof minder as een honderd rand is;

(b) ses en twintig rand ten opsigte van 'n medisyne of gelyste stof waar die enkele afsetprys van daardie medisyne of gelyste stof groter as of gelyk aan een honderd rand is.

(3) Die bepalings van hierdie regulasie moet jaarliks deur die Minister hersien word met betrekking tot die VPI, die PPI en die behoefte om die beskikbaarheid, bekostigbaarheid en gehalte van medisyne en gelyste stowwe in die Republiek te verseker.

11. Waar 'n medisyne of gelyste stof geresepteer word ingevolge 'n voorskrif uitgeskryf vir 'n persoon wat as 'n binnepasiënt opgeneem is, moet die resepteringsgeld ingevolge regulasie 10 bereken word ten opsigte van die hele hoeveelheid van die medisyne of gelyste stof wat op sodanige voorskrif weerspieël word, ongeag of die medisyne of gelyste stof uit die apteek se voorraad of uit saal- of teatervoorrade kom.

12. Die gepaste resepteringsgeld soos in artikel 22G(2)(b) van die Wet beoog, wat gehef moet word deur persone wat ingevolge artikel 22C(1)(a) van die Wet gelisensieer is, moet soos volg bereken word, BTW uitgesluit:

(1) Waar die enkele afsetprys van 'n medisyne of gelyste stof minder as een honderd rand is, mag die resepteringsgeld nie meer as 16% van die enkele afsetprys ten opsigte van daardie medisyne of gelyste stof wees nie.

(2) Waar die enkele afsetprys van 'n medisyne of gelyste stof een honderd rand of meer is, mag die resepteringsgeld nie meer as sestien rand ten opsigte van daardie medisyne of gelyste stof wees nie.

(3) Die bepalings van hierdie regulasie moet jaarliks deur die Minister hersien word met betrekking tot die VPI, die PPI en die behoefte om die beskikbaarheid, bekostigbaarheid en gehalte van medisyne en gelyste stowwe in die Republiek te verseker.

13. Die gepaste gelde wat deur enige ander persoon as 'n groothandelaar of verspreider gehef mag word ten opsigte van Bylae O-medisyne, mag nie meer wees nie as die persentasie marge ten opsigte van daardie medisyne of gelyste stof wat op die datum van inwerkingtreding van hierdie regulasies van toepassing was.

14. Die Direkteur-generaal kan inligting of dokumentasie rakende een of meer van die volgende skriftelik versoek van 'n vervaardiger, invoerder, uitvoerder, groothandelaar, verspreider, apteker, persoon wat ingevolge

artikel 22C(1)(a) gelisensieer is of enige ander persoon wat 'n medisyne of gelyste stof in die Republiek verkoop:

(1) die goedgekeurde naam en die eiendomsnaam van 'n medisyne of gelyste stof en besonderhede van die aard van die samestelling daarvan, insluitende aktiewe en ander bestanddele;

(2) die prys waarteen die medisyne in enige mark in die Republiek of in enige ander land deur die Direkteur-generaal bepaal, verkoop word;

(3) die volume of hoeveelheid en totale waarde van verkope van sodanige medisyne of gelyste stof ten opsigte van kategorieë kopers;

(4) die metode en koste van verspreiding van die medisyne of gelyste stof binne die Republiek, insluitende besonderhede van die aanbodketting deur middel waarvan die medisyne of gelyste stof vir gebruikers toeganklik gemaak sal word;

(5) besonderhede rakende die vergelykende doelmatigheid, veiligheid en kostedoeltreffendheid van die medisyne of gelyste stof relatief tot dié van ander medisyne of gelyste stowwe in dieselfde terapeutiese klas, saamgestel op 'n wyse in ooreenstemming met riglyne wat van tyd tot tyd deur die Direkteur-generaal in die *Staatskoerant* gepubliseer word.

15. Behoudens die bepalings van enige ander wet, waar die inligting of dokumentasie wat ingevolge regulasie 14 aangevra is, in die kennis, besit of beheer is van die persoon van wie dit aangevra is, moet sodanige inligting of dokumentasie in die bepaalde formaat aan die Direkteur-generaal verskaf word binne 30 werkdae na die datum van sodanige versoek, of sodanige ander redelike tydperk as wat die Direkteur-generaal bepaal.

16. Waar die inligting of dokumentasie wat ingevolge regulasie 14 deur die Direkteur-generaal versoek is, nie in die kennis, besit of beheer is nie van die persoon van wie dit versoek is, moet sodanige persoon die Direkteur-generaal skriftelik dienooreenkomstig inlig binne 14 dae na die datum van sodanige versoek.

17. Die Direkteur-generaal kan die inligting en dokumentasie in regulasie 14 bedoel, na die Pryskomitee verwys ten einde die verrigting deur die Pryskomitee van sy pligte ingevolge die Wet te fasiliteer.

18. Die Pryskomitee kan na goeddunke skriftelike of mondelinge vertoë van enige persoon ontvang oor die prys van medisyne of gelyste stowwe in die Republiek en elders, en sodanige persoon kan deur die voorsitter van die Komitee versoek word om, voordat enig mondelinge vertoë gerig word, 'n eed of plegtige verklaring af te lê, welke eed of plegtige verklaring deur die voorsitter afgeneem moet word.

19. 'n Applikant vir registrasie van 'n medisyne ingevolge artikel 15 van die Wet moet minstens een maand voor die begin van die verkoop van die medisyne die volgende inligting aan die Direkteur-generaal verstrek:

(1) Die eiendomsnaam of handelsnaam waaronder dit die voorneme is om die medisyne of gelyste stof in die Republiek te verkoop.

(2) Die aard van die samestelling daarvan, insluitende aktiewe en ander bestanddele.

(3) Die enkele afsetprys waarteen die applikant beoog om die medisyne of gelyste stof in die Republiek te verkoop in ooreenstemming met internasionale norme, met gebruik van 'n metodologie soos deur die Direkteur-generaal bepaal en in die *Staatskoerant* gepubliseer, met inagneming van die prys, en faktore wat die prys beïnvloed, waarteen die medisyne of gelyste stof, of 'n medisyne of gelyste stof wat deur die Direkteur-generaal as gelykwaardig beskou word, verkoop word in ander lande waar die pryse van medisyne en gelyste stowwe gereguleer en gepubliseer word.

(4) Die prys waarteen die medisyne of gelyste stof tans deur die applikant in enige ander land verkoop word.

(5) Die voorgenome metode en koste van verspreiding van die medisyne of gelyste stof in die Republiek, insluitende besonderhede van die aanbodketting deur middel waarvan die medisyne vir gebruikers toeganklik gemaak gaan word.

(6) Die volgende inligting met betrekking tot die medisyne of gelyste stof:

(a) Die aard van die siekte of toestand ten opsigte waarvan die medisyne of gelyste stof in die Republiek gebruik gaan word.

(b) Die voorkomssyfer van die siekte of toestand soos deur die applikant vasgestel.

(7) Besonderhede rakende die doelmatigheid, veiligheid en kostedoeltreffendheid van die medisyne of gelyste stof vergeleke met ander medisyne of gelyste stowwe in dieselfde terapeutiese klas, saamgestel op 'n wyse in ooreenstemming met riglyne wat die Direkteur-generaal van tyd tot tyd in die *Staatskoerant* publiseer.

20. Waar enige van die inligting in regulasie 19 vermeld nie in die kennis, besit of beheer van die applikant is nie, moet die applikant die Direkteur-generaal skriftelik daarvan in kennis stel.

21. Die Direkteur-generaal kan inligting met betrekking tot 'n bepaalde medisyne of gelyste stof of klas of kategorie medisyne of gelyste stowwe of die verkoop van 'n medisyne of gelyste stof publiseer of andersins bekend maak, of van vervaardigers, invoerders, groothandelaars, verspreiders, aptekers of persone wat ingevolge artikel 22C(1)(a) van die Wet gelisensieer is, vereis om sodanige inligting te publiseer of andersins bekend te maak op die wyse en in die formaat wat hy of sy by kennisgewing in die *Staatskoerant* bepaal, met die doel om –

(1) die publiek in te lig oor –

(a) die terapeutiese waarde van 'n medisyne of gelyste stof relatief tot die enkele afsetprys wat deur die vervaardiger gestel is;

(b) die enkele afsetprys, sterkte, dosisvorm en pakgrootte van 'n medisyne of gelyste stof;

(c) die risiko's verbonde aan 'n bepaalde medisyne of gelyste stof relatief tot die enkele afsetprys van daardie medisyne of gelyste stof;

(2) die publiek in te lig oor die volgende aangeleenthede:

(a) die beskikbaarheid van 'n medisyne of gelyste stof;

(b) die prysstelsel in artikel 22G van die Wet beoog;

(c) die aanbodketting vir 'n medisyne of gelyste stof;

(d) die gelde wat gehef word deur groothandelaars, verspreiders, kleinhandelaars en ander persone wat medisyne of gelyste stowwe verkoop;

(e) die land waaruit 'n medisyne of gelyste stof verkry word.

(3) Waar die Direkteur-generaal van persone wat medisyne of gelyste stowwe verkoop, vereis om inligting ingevolge hierdie regulasie te publiseer, mag daar van sulke persone vereis word net om inligting te publiseer ten opsigte van die medisyne of gelyste stowwe wat hulle verkoop.

(4) Niks in hierdie regulasie moet so uitgelê word dat dit beteken dat die Direkteur-generaal inligting mag publiseer of bekend maak of enige ander persoon mag dwing om dit te publiseer of bekend te maak nie, waar daar 'n rede is om toegang tot 'n rekord wat sodanige inligting bevat, te weier ingevolge die Wet op die Bevordering van Toegang tot Inligting, 2000 (Wet No 2 van 2000).

22. (1) Die Direkteur-generaal kan bepaal dat die enkele afsetprys van 'n medisyne of gelyste stof onredelik is en kan sodanige bepaling, tesame met die basis waarop die bepaling gemaak is, aan die betrokke vervaardiger, invoerder, groothandelaar of verspreider meedeel op 'n wyse wat hy of sy gepas ag.

(2) Met betrekking tot die bepaling in regulasie 22(1) bedoel, moet die Direkteur-generaal met die betrokke lid van die aanbodketting oorleg pleeg en enige vertoë oorweeg wat deur daardie lid gerig is met betrekking tot die redelikheid van die enkele afsetprys.

(3) Waar die Direkteur-generaal na die oorleg en vertoë in regulasie 22(2) beoog nie oortuig is dat die enkele afsetprys redelik is nie, kan hy of sy 'n kennisgewing in die *Staatskoerant* publiseer ten effekte dat die enkele afsetprys na die mening van die Direkteur-generaal onredelik is, met vermelding van die redes vir sodanige mening.

23. By die bepaling of die prys van 'n medisyne of gelyste stof onredelik is soos in regulasie 22 beoog, moet die Direkteur-generaal ag slaan op –

(1) die enkele afsetprys waarteen die medisyne of gelyste stof in die betrokke mark verkoop word;

(2) die enkele afsetprys waarteen ander medisyne of gelyste stowwe in dieselfde terapeutiese klas in die betrokke mark verkoop word;

(3) die pryse waarteen die medisyne of gelyste stof en ander medisyne of gelyste stowwe in dieselfde terapeutiese klas in ander lande as die Republiek verkoop word;

(4) veranderinge in die VPI, die PPI en die betrokke wisselkoerse;

(5) koopkragpariteit met betrekking tot die Republiek en enige ander land waar die medisyne of gelyste stof verkoop word;

(6) die relatiewe beskikbaarheid in die Republiek van medisyne of gelyste stowwe in dieselfde terapeutiese klas as die medisyne of gelyste stof en die veiligheid en doelmatigheid van die medisyne of gelyste stof relatief tot ander medisyne of gelyste stowwe in dieselfde terapeutiese klas;

(7) die aard van enige indikasie ten opsigte waarvan die medisyne of gelyste stof in die Republiek geregistreer is;

(8) die grootte van die mark vir die medisyne of gelyste stof in die Republiek relatief tot dié in ander lande;

(9) enige tersaaklike inligting verstrek deur die Raad vir Mediese Skemas ingestel ingevolge die Wet op Mediese Skemas, 1998 (Wet No 131 van 1998);

(10) die grootte van die hindernis, verteenwoordig deur die enkele afsetprys, vir toegang tot die medisyne of gelyste stof relatief tot die openbare belang om wydverspreide en algemene toegang tot die medisyne of gelyste stof te hê;

(11) sodanige ander faktore as wat na die mening van die Direkteur-generaal tersaaklik is vir die prysbepaling, of die koste van vervaardiging of verkoop, van die medisyne of gelyste stof.

24. (1) Vervaardigers en invoerders moet binne een maand na die datum van inwerkingtreding van hierdie regulasies –

(a) 'n lys aan die Direkteur-generaal voorlê wat die enkele afsetprys toon van 'n pak van elke medisyne of gelyste stof wat deur hulle verkoop word, insluitende die pakgrootte, dosisvorm en sterkte van die medisyne of gelyste stof;

(b) die volgende inligting aan die Direkteur-generaal verstrek:

(i) die totale verkoopswaarde van elke medisyne of gelyste stof wat in die jaar 2003 verkoop is;

(ii) die totale waarde van kortings ten opsigte van die verkoop van elke medisyne of gelyste stof in die jaar 2003;

(iii) die totale aantal pakke van elke medisyne of gelyste stof wat in die jaar 2003 verkoop is.

(2) Binne drie maande na die datum van inwerkingtreding van hierdie regulasies moet vervaardigers en invoerders, op die koste van die betrokke vervaardiger of invoerder, aan die Direkteur-generaal voorlê 'n verslag en 'n ouditsertifikaat opgestel deur onafhanklike ouditeure wat nie die huidige ouditeure van die vervaardiger of invoerder is nie, waarin die inligting wat ingevolge regulasie 24(1) verstrek is, geverifieer word en waarin enige verskille in sodanige inligting vermeld word, waar van toepassing.

(3) In soverre die ouditsertifikaat toon dat die inligting verstrek in die lys in artikel 24(1)(a) beoog onakkuraat is, moet die vervaardiger of invoerder binne 14 dae na ontvangs van die ouditsertifikaat daardie lys hersien tot die redelike tevredenheid van die ouditeure om 'n aanvanklike enkele afsetprys te toon wat na die redelike mening van die ouditeure 'n billike weerspieëling van die enkele afsetprys van die betrokke medisyne of gelyste stof is, en die ouditeure moet dan 'n hersiene ouditsertifikaat uitreik wat aan die Direkteur-generaal voorgelê moet word tesame met die lys soos ingevolge regulasie 24(2) hersien.

(4) Vervaardigers en invoerders mag, met ingang van die datum een maand na die datum van inwerkingtreding van hierdie regulasies, die medisyne en gelyste stowwe net in ooreenstemming met die bepalings van hierdie regulasies verkoop.

(5) Groothandelaars, verspreiders en kleinhandelaars mag, met ingang van die datum drie maand na die datum van inwerkingtreding van hierdie regulasies, medisyne en gelyste stowwe net in ooreenstemming met die bepalings van hierdie regulasies verkoop.

ME TSHABALALA-MSIMANG
MINISTER VAN GESONDHEID
DATUM:

AANHANGSEL A

VOORBEELDE VAN DIE WYSE WAAROP DIE GEWEEGDE GEMIDDELDE NETTO VERKOOPPRYS BEREKEN MOET WORD

Berekening van enkele afsetprys vir vaste dosisvorm waar dit in verskillende pakgroottes beskikbaar is

Voorbeeld 1: 2 pakgroottes (50 tablette en 500 tablette) van 'n 500 mg-sterkte van 'n medisyne

Gemiddelde 2003-prys van 'n 50-tabletpak = R50
Gemiddelde 2003-prys van 'n 500-tabletpak = R300

2003-verkope van 'n 50-tabletpak – 100 000 pakke
2003-verkope van 'n 500-tabletpak – 10 000 pakke

Totale 2003-kortings vir verkope van 50-tabletpakke in 2003 = R500 000
Totale 2003-kortings vir verkope van 500-tabletpakke in 2003 = R200 000

$$\text{Eenheidsprys} = \frac{((100\,000 * 50) - (500\,000)) + ((10\,000 * 300) - (200\,000))}{((100\,000 * 50) + (10\,000 * 500))}$$

Die prys van die eenheid is R0,73/500 mg-tablet.

Die enkele afsetprys van die 50-tabletpak is R36,50.
Die enkele afsetprys van die 500-tabletpak is R365.

Berekening van die enkele afsetprys vir vloeistofdosisvorm waar dit in verskillende pakgroottes beskikbaar is

Voorbeeld 2: Twee pakgroottes (125 ml-bottel en 500 ml-bottel) van 'n 5 mg/ml-sterkte van 'n medisyne

Gemiddelde 2003-prys van 'n 125 ml-bottel = R50
Gemiddelde 2003-prys van 'n 500 ml-bottel = R150

2003-verkope van 125 ml-bottels = 10 000 bottels
2003-verkope van 500 ml-bottels = 5 000 bottels

Totale 2003-kortings vir verkope van 125 ml-bottels in 2003 = R50 000
Totale 2003-kortings vir verkope van 500 ml-bottels in 2003 = R75 000

$$\text{Eenheidsprys} = \frac{((10\,000 * 50) - (50\,000)) + ((5\,000 * 150) - (75\,000))}{((10\,000 * 125) + (5\,000 * 500))}$$

Die prys van die eenheid is R0,30/ml.

Die enkele afsetprys van die 125 ml-bottel is R37,50.
Die enkele afsetprys van die 500 ml-bottel is R150.

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