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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 37 **16 January 2004**

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

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES MADE IN TERMS OF SECTION 22G OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO 101 OF 1965)

The Minister of Health intends to make the regulations in the Schedule.

Interested persons are invited to submit written comments or representations on the proposed Regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for attention of the Cluster Manager: Pharmaceutical Policy and Planning), within three months of the date of publication of this Notice.

SCHEDULE

1. The sale of medicines and Scheduled substances in the Republic of South Africa is subject to the conditions stipulated in these regulations made in terms of section 22G of the Medicines and Related Substances Act.

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 101 of 1965), as amended and includes the General Regulations made thereunder;

"Blue Book" means the electronic publication known as the Pharmaceutical Blue Book published by Pharmaceutical Printers and Publishers, a wholly owned subsidiary of Alex White Holdings Limited;

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

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

"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;

"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" includes all costs associated with the manufacture and sale of the medicine or Scheduled substance;

"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;

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 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 category 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;
(f) if the medicine or Scheduled substance is sold in other countries, the price at which it is sold;

4. The label on the immediate container of every medicine or Scheduled substance intended for sale to a user must reflect the single exit price of the medicine or Scheduled substance.

5. Upon commencement of these regulations, the single exit price contemplated in section 22G shall 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, provided that for a period of one year after commencement of these regulations such price shall not be higher than fifty percent of the manufacturer net price (MNP) as reflected in the Blue Book as at the date of publication of these regulations for public comment in the *Gazette*.

6. A manufacturer may not charge any fee or other amount, except 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 and 10, the single exit price of a medicine or Scheduled substance may only be increased by a

manufacturer or importer once a year but may be decreased by the manufacturer or importer at any time.

8. The extent to which the single exit price of a medicine or Scheduled substance may be increased by manufacturers and importers will be determined annually by the Minister, after consultation with the Pricing Committee, by notice in the Gazette with regard to –

(1) the average CPI for the preceding year;

(2) the average PPI for the preceding year;

(3) changes in the rates of foreign exchange and purchasing power parity; and

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

9. A manufacturer or importer may, in exceptional circumstances, apply to the Minister for authorisation to increase the price of a medicine or Scheduled substance by a specified amount greater than that permitted in terms of regulation 8 and the Minister must consider such application with regard to –

(1) the nature and extent of any adverse financial, operational and other consequences for the manufacturer or importer if it is not permitted to increase the single exit price of the relevant medicine by an amount greater than that permitted in terms of regulation 8;

(2) the effect, if any, on the availability of the medicine or Scheduled substance within the Republic should the price not be increased by the amount requested in the application;

(3) 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;

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

(a) should the singe exit price not be increased by the amount requested in the application; and

(b) 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) Where a medicine or Scheduled substance costs less than one hundred rands, the dispensing fee may not exceed twenty four percent of the single exit price in respect of each such medicine or Scheduled substance dispensed;

(2) Where a medicine or Scheduled substance costs one hundred rands or more, the dispensing fee may not exceed twenty four rands in respect of each such medicine or Scheduled substance dispensed.

11. 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) must be calculated as follows:

(1) Where the single exit price of a medicine or Scheduled substance is less than one hundred rands, the dispensing fee may not exceed sixteen percent of the single exit price in respect of each such medicine or Scheduled substance dispensed.

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

12. Subject to the provisions of regulation 14, the appropriate fee as contemplated in section 22G(2)(c) of the Act to be charged by wholesalers must be calculated as follows –

(1) Where the single exit price of a medicine or Scheduled substance is less than forty rands, the fee may not exceed 15% of the single exit price in respect of each pack of medicine or Scheduled substance sold;

(2) Where the single exit price of a medicine or Scheduled substance is forty rands or more, the fee may not exceed six rands in respect of each pack of medicine or Scheduled substance sold.

13. Subject to the provisions or regulation 14, the appropriate fee as contemplated in section 22G(2)(c) of the Act to be charged by distributors must be calculated as follows –

(1) Where the single exit price of a medicine or Scheduled substance is less than forty rands, the fee may not exceed 15% of the single exit price in respect of each pack of medicine or Scheduled substance sold;

(2) Where the single exit price of a medicine or Scheduled substance is forty rands or more, the fee may not exceed six rands in respect of each pack of medicine or Scheduled substance sold.

14. Where a medicine or Scheduled substance is obtained by a wholesaler from a distributor, the maximum fee that may be charged-

(1) by the distributor must be calculated as follows:

(a) where the single exit price of the medicine or Scheduled substance is less than forty rands, the distributor's fee in respect of each pack of medicine or Scheduled substance sold must not exceed two and a half percent of the single exit price;

(b) Where the single exit price of the medicine or Scheduled substance is forty rands or more the distributor's fee in respect of each pack of medicine or Scheduled substance sold must not exceed one rand.

(2) by the wholesaler must be calculated as follows:

(a) where the single exit price of the medicine or Scheduled substance is less than forty rands, the wholesaler's fee in respect of each pack of medicine or Scheduled substance

sold must not exceed twelve and a half percent of the single exit price;

(b) Where the single exit price of the medicine or Scheduled substance is forty rands or more the wholesaler's fee in respect of each pack of medicine or Scheduled substance must not exceed five rands;

15. Where a Schedule 0 medicine or Scheduled substance is sold at a place other than a pharmacy, a maximum fee of 16% of the single exit price may be charged in respect of the sale of that medicine or Scheduled substance: provided that where the medicine or Scheduled substance is obtained from a wholesaler or a distributor, the fee payable to the wholesaler or distributor may be added to the maximum fee that may be charged in terms of this regulation.

16. 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 or has been sold in any market in the Republic or in any other country;

(3) the costs of manufacturing, selling or marketing the medicine or Scheduled substance in Republic, including the manner in which

such costs are calculated and details of expenses incurred in the course of the manufacture or sale of a medicine or Scheduled substance;

(4) the revenue generated by the sale of a particular medicine or Scheduled substance in the Republic or in any other country, including the volume or quantity and total value of sales of such medicine or Scheduled substance;

(5) details of sources of revenue, whether direct or indirect, involving the sale of a medicine or Scheduled substance in the Republic;

(6) details of expenditure on research and development with respect to a particular medicine or Scheduled substance;

(7) the method of distribution within the Republic of the medicine or Scheduled substance including details of the supply chain by means of which the medicine will be made accessible to users;

(8) the name and address of a person, from or to whom a medicine or Scheduled substance was purchased or sold and the quantity and price at which it was purchased or sold;

(9) 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; and

(10) any other information considered necessary by the Director-General with regard to a matter contemplated in section 22G of the Act.

17. Subject to the provisions of any other law, where the information or documentation requested in terms of regulation 16 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.

18. Where the information or documentation requested by the Director-General in terms of regulation 16 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 or, if so required by the Director-General, by way of an affidavit.

19. The Director-General may refer the information and documentation contemplated in regulation 16 to the Pricing Committee for the purpose of facilitating the performance by the Pricing Committee of its duties in terms of the Act.

20. 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.

21. An applicant for registration of a medicine in terms of section 15 of the Act must, at least six months before 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;

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

(5) The anticipated costs of manufacturing, selling or marketing the medicine or Scheduled substance in Republic, including the manner in which such costs are calculated and details of expenses incurred in the course of research and development, manufacture or sale of the medicine or Scheduled substance;

(6) Whether the medicine or Scheduled substance is being sold by any person other than the applicant in the Republic and if so, the name, and address of such other person;

(7) The intended method 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;

(8) Details of any research findings available to the applicant relating to cost effectiveness of the medicine or Scheduled Substance;

(9) 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;

(c) The names of other manufacturers who sell medicines and scheduled substances and who, in the perception of the applicant, would be in direct or indirect competition with the applicant with respect to the medicine or Scheduled substance;

(d) Such other information as the Director-General may require with regard to any of the matters contemplated in section 22G.

(10) 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.

22. Where any of the information specified in regulation 21 is not within the knowledge, possession or control of the applicant, the applicant shall

inform the Director-General to this effect in writing or, at the request of the Director-General, by way of an affidavit.

23. 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 prices of medicines or Scheduled substances that must be used in conjunction with a particular 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) promoting best practices in the sale of medicines and Scheduled substances throughout the supply chain;

(3) 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) access to a medicine or Scheduled substance within the Republic or elsewhere;

(d) transparency of pricing practices relating to a medicine or Scheduled substance;

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

(f) the fees charged by wholesalers, distributors, retailers and other persons who sell medicines or Scheduled substances;

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

(4) Nothing in this regulation may be interpreted to mean that the Director-General may publish or communicate, or compel anyother 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).

24. The Director-General may determine that the price of a medicine or Scheduled substance is unreasonable and communicate to the relevant manufacturer, importer, wholesaler, distributor or retailer in a manner which he or she deems appropriate, or to consumers by notice in the *Gazette*, such determination together the basis upon which the determination has been made.

25. In determining whether the price of a medicine or Scheduled substance is unreasonable as contemplated in regulation 24, 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.

26. The Director-General may not publish the determination as contemplated in regulation 24 unless he or she has-

(1) at least 60 days before the determination is published, by notice in the *Gazette* published his or her intention to make the declaration and invited interested persons thereby to make written representations regarding the proposed declaration so as to reach him or her within 21 days after the date of publication of that notice;

(2) duly considered any representations that may have been received in response to the notice contemplated in sub-regulation (1).

27. Persons selling medicines or Scheduled substances that were manufactured prior to the date of promulgation of these Regulations shall for a period of forty five days from the date of promulgation of these

Regulations not be required to comply with the requirements of these Regulations with respect to such medicines or Scheduled substances.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH
DATE: