GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 1210 **1 December 2006**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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

The Minister of Health has, in terms of the Medicines and Related Substances Act No. 101 of 1965, made the Regulations in the Schedule, which shall come into effect on 1 January 2007.

SCHEDULE

The Regulations Relating to a Transparent Pricing System for Medicines, as promulgated in Government Notice No. R 1102 on 11 November 2005, are hereby amended as follows -

1. By the insertion of the following definition after the definition of "discounts" in regulation 1:

""dispense" means:

(1) the application by a health professional, authorised by law to dispense medicines, of his or her mind, in the context of the sale of a particular medicine to an identifiable user, to -
(a) the legality of such sale;
(b) the evaluation of a written prescription if any;
(c) the appropriate dosage of that medicine for that user;
(d) safety issues for that user regarding the use of that medicine;
(e) the pharmaceutical and pharmacological incompatibilities of that medicine with any other medicines being taken by the user;
(f) possible allergies of the user to that medicine;
(g) possible medicine interactions;

(h) the optimal use and duration of use of that medicine with regard to a particular health condition of that user; and

(2) the preparation of a particular medicine for an identifiable user including the reconstitution of a medicine in a non-sterile environment, picking, packaging and labelling of the medicine, checking of expiry dates of the medicine, and keeping of appropriate dispensing records as required by law; and

(3) the handing of a particular medicine to an identifiable user or such user's caregiver with advice or instructions as to its safe and effective use or administration, or the provision of a patient information leaflet or other written material on the safety or efficacy of the medicine;

but excludes the manufacturing, manipulation or compounding of a medicine;"

2. By the insertion of the following definition after the definition of "dispense":

""dispensing fee" means the maximum fee, exclusive of **VAT,** that may be charged to dispense a medicine;"

3. By the substitution of the definition in regulation 2 of the term "logistics fee" with the following:

"logistics fee means the fee, inclusive of **VAT,** that is payable in respect of logistical services;"

4. By the substitution of the definition in regulation 2 of the phrase "logistical services" with the following:

""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, batch tracking and tracing, cold chain storage and distribution;"

5. By the insertion in regulation 3 after (e) of the following:

"(9 the logistics fee."

6. By the substitution of regulation 4 for the following:

" (1) Retailers must ensure that the single exit price is clearly and legibly reflected on the packaging in which the medicine is sold to a user;

(2) Retailers must ensure that at the time of the sale of a medicine to a user, the user is supplied with an invoice that reflects separately the single exit price of the medicine and, if the medicine was dispensed, the dispensing fee."

7. By the substitution of regulation 10 with the following:

"(1) The appropriate dispensing fee as contemplated in section 22G(2)(b) of the Act to be charged by pharmacists must be calculated as follows:

(a) Where the single exit price of a medicine is less than seventy five rands, the dispensing fee, is a total of four rands plus 33% of the single exit price of the medicine;

(b) Where the single exit price of a medicine is seventy five rands or more but is less than two hundred and fifty rands, the dispensing fee is a total of twenty five rands plus 6% of the single exit price of the medicine;

(c) Where the single exit price of a medicine is two hundred and fifty rands or more but less than one thousand rands, the dispensing fee is a total of thirty three rands plus 3% of the single exit price of the medicine:

(d) Where the single exit price of a medicine is one thousand rands or more, the dispensing fee is a total of fifty rands plus 1.5% of the single exit price of the medicine.

(2) **The provisions of this regulation 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."**

M E TSHABALALA-MSIMANG
MINISTER OF HEALTH