GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 647 **23 July 2010**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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

(DISPENSING FEE FOR PHARMACISTS)

The Minister of Health, on recommendation of the Pricing Committee, in terms of section 22G (2) (b) of the Medicine and Related Substances Act, 1965 (Act No. 101 of 1965), intends to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations within one month of publication of this notice to the Minister of Health (for the attention of the Director: Pharmaceutical economic Evaluations, Private Bag X828, Pretoria 0001)

SCHEDULE

Definitions

1. In these regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context indicates otherwise-

   "**dispense**" in relation to a dispensing fee means:

   (a) the application by a health professional, authorized 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-

      (i) the legality of such sale;

      (ii) the evaluation of a written prescription if any;

      (iii) advising the patient of the lowest priced generically equivalent medicine currently available in the market

(iv) the appropriate dosage of that medicine for that user;

(v) safety issues for that user regarding the use of that medicine;

(vi) the pharmaceutical and pharmacological incompatibilities of that medicine with any other medicine being taken by the user;

(vii) possible allergies of the user to that medicine;

(viii) possible medicine interactions;

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

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

(c) the handling of a particular medicine to an identifiable user or someone on behalf of such user with advice or instruction 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;

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

"**the Regulations**" means the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances published under government Notice No. R1102 of November 2005 as amended.

Amendment to Regulation 10

2. The following regulation is hereby substituted for regulation 10 of the regulations:

"10. (1) The appropriate dispensing fee as contemplated in section 22G (2) (b) of the Act to be charged by pharmacist, must:

(a) Where the single exit price of a medicine or scheduled substance is less than seventy five rand, the dispensing fee shall not exceed R6 plus 46 % of the single exit price in respect of that medicine or scheduled substance;

(b) Where the single exit price of a medicine or scheduled substance is greater than or equal to seventy five rand but less than two hundred rand, the dispensing fee shall not exceed R15 plus 33 % of the single exit price in respect of that medicine or scheduled substance;

(c) Where the single exit price of a medicine or scheduled substance is greater than or equal to two hundred rand but less than seven hundred rand, the dispensing fee shall not exceed R51 plus 15 % of the single exit price in respect of that medicine or scheduled substance;

(d) Where the single exit price of a medicine or scheduled substance is greater than or equal to seven hundred rand, the dispensing fee shall not exceed R121 plus 5% of the single exit price in respect of that medicine or scheduled substance.

(2) The provisions of this regulation must be reviewed annually by the Minister after taking into account the information contemplated in regulation 10A(1) and the need to ensure the availability, affordability of quality medicines and scheduled substances in the Republic.

Insertion of Regulations 10A and 10B

3. The following regulations are inserted after regulation 10:

"10A. (1) Every owner of a retail pharmacy must, in respect of his, her or its pharmacy, annually supply the Director-General with the following

information in accordance with guidelines determined by the Director-General:

(a) financial statements (income and expenditure statements and balance sheets);

(b) number of medicines dispensed in the pharmacy and the single exit price for such medicines;

(c) structure of the dispensary relative to the pharmacy size;

(d) turnover of the pharmacy;

(e) location of the pharmacy in relation to other pharmacies in the area; and

(f) services that are offered by the pharmacy;

10B. (1) Every retail pharmacy must, by means of a notice displayed clearly in the dispensary, inform patients of the dispensing fee structure charged by that pharmacy.

(2) The notice contemplated in sub regulation (1) must-

a) be clearly visible to patients and situated in the dispensary area.

b) be printed in bold and not less than 20 point font.

(3) The responsible pharmacist must ensure that every patient is given an invoice that identifies each item dispensed, the single exit price and the dispensing fee.

DR A MOTSOALEDI, MP

MINISTER OF HEALTH