Government Gazette

REPUBLIC OF SOUTH AFRICA

Regulation Gazette No. 7470

Vol. 448 Pretoria 11 October 2002 **No. 23903**

GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 1230 **11 October 2002**

REGULATIONS UNDER THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

The Minister of Health on recommendation of the Medicines Control Council, intends, in terms of section 35 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), to make regulations contained in the Schedule.

Interested persons are invited to submit comments or representation on the proposed regulations to the director-General: Health, Private Bag X 828, Pretoria, 0001, within three months of the date of publication of this notice.

SCHEDULE

Definition

1. In this Schedule "the Regulations" means the regulations published by Government Notice No. R 352 of 21 February 1975, as amended.

Substitution of regulation 35 of the Regulations

2. The following is hereby substituted for regulation 35 of the Regulations:

"FEES

35. The following fees shall be payable to the Registrar:

(1) Category A medicines

Human medicines, including Biologicals, compounded in its entirety in the RSA or not, for which an application for registration has been submitted as contemplated in Section 15 of the Act

(i) In respect of the submission of an application for registration of:

(a) A medicine contemplated in Section 14(3) of the Act (hereinafter referred to as an old medicine): R5000 per application;

(b) New Chemical Entities or highly technological products, which have been processed by the abbreviated registration process (first strength, first dosage form): R30 000 per application;

(c) Strengths and dosage forms other than those referred to in sub-paragraph (b): R15 000

(d) New Chemical Entities, including highly technological products, (first strength, first dosage form): R30 000 per application;

(e) Strengths and dosage forms other than those referred to in sub-paragraph (d): R20 000

(f) New chemical Entities, including highly technological products, which will be evaluated by the fast tracking process: An additional R30 000 per application.

(g) Biological products (pharmaceutical, analytical and bioavailability evaluated): R30 000 per application.

(h) Homeopathic products: R3 800 per application.

(i) Generic products (pharmaceutical,

analytical and bioavailability evaluated) all other dental and radio pharmaceutical products: R12 500 per application.

(j) Generic products, which will be evaluated by the fast tracking process: An additional R12 500 per application.

(ii) In respect of the registration of any medicine, the registration of which has been approved by the Council in terms of section 15(3) (in the case of medicines in minute-dose forms; the fee encompasses different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid:

R600 for each registration

(iii) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Council in terms of Section 15(3): R550; Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Council in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration shall be cancelled in terms of Section 16(4).

(2) Category C medicines

Veterinary medicines, including Biologicals, whether compounded in the RSA or not and for which Council has determined by resolution:

(i) In respect of the submission of an application for registration:

(a) A medicine contemplated in Section 14 (3) of the Act (hereinafter referred to as an old medicine): R800 per application:

(b) New Chemical Entities, including highly technological products, (first strength, first dosage form): R3 800 per application;

(c) Generic products (pharmaceutical, analytical and bioavailability evaluated): R3 800 per application;

(d) Homeopathic products: R3 800 per application;

(ii) In respect of the registration of any medicine, the registration of which has been approved by the Council in terms of section 15(3) (in the case of medicines in minute-dose forms; the fee encompasses different dilutions and different volumes, when submitted simultaneously for the same indication or intended use) and in respect of which an application fee has been paid:

R600 for each registration.

(iii) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Council in terms of Section 15(3): R350; Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Council in terms of Section 15(3); Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which

the registration shall be cancelled in terms of Section 16(4).

(3) Amendments

(a) In respect of all application for amendments for any entry in the register, including the transfer of a certificate of registration only:

R220 per application.

(b) Fees in respect of application for technical amendments, which include an amendment of entry in the register:

R600 per amendment.

MANTO TSHABALALA-MSIMANG,
Minister of Health