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AIDS HELPLINE: 0800-123-22 Prevention is the cure

GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 755 **7 June 2002**

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

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

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:

(a) 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) Application for registration—

(aa) of medicine contemplated in section 15 (hereinafter referred to as an old medicine): R5 000 per application;

(bb) of New Chemical Entities: R30 000 per application;

(cc) of AMRP: R30 000 per application;

(dd) of Fast Track: R30 000 per application;

(ee) of Biological: R30 000 per application;

(ff) of Biological EDL: R12 000 per application;

(gg) of Generic: R12 500 per application;

(hh) of Generic EDL: R10 000 per application;

(ii) of Products containing similar active ingredients: R20 000 per application.

(2) Category C medicines:

(a) Veterinary medicines, including Biologicals, whether compounded in the RSA or not:

(i) Application for registration—

(aa) of medicine in section 14 (3) (hereinafter referred to as an old medicine): R800 per application;

(bb) of New Chemical Entities: R3 800 per application;

(cc) of Generic: R3 800 per application;

(dd) of Homeopathic: R3 800 per application;

(ii) In respect of the registration of a medicine, the registration of which has been approved by the Council in terms of section 15—

(aa) of Old medicines: R600 per application;

(bb) of New Chemical Entities: R600 per application;

(cc) of AMRP: R600 per application;

(dd) of Fast Track: R600 per application;

(ee) of Biological: R600 per application;

(ff) of Biological EDL: R600 per application;

(gg) of Generic: R600 per application;

(hh) of Generic EDL: R600 per application;

(ii) of Products containing similar active ingredients: R600 per application;

(iii) fees for registration of Veterinary medicines, including Biologicals whether compounded in the RSA or not—

(aa) of Old medicines: R600 per application;

(bb) of New Chemical Entities: R600 per application;

(cc) of Generic: R600 per application;

(dd) of Homeopathic: R600 per application;

(iv) Annual fees in respect of the retention of the registration of the medicines, the registration of which has been approved by the Council:

(aa) of Old medicines: R550;

(bb) New Chemical Entities: R550;

(cc) AMRP: R550;

(dd) Fast Track: R550;

(ee) Biological: R550;

(ff) Biological EDL: R550;

(gg) Generic: R550;

(hh) Generic EDL: R550;

(ii) Products containing similar active ingredients: R550;

(v) Annual fees in respect of the retention of the registration of the veterinary medicines, the registration of which has been approved by the Council—

(aa) Old medicines: R350;

(bb) New Chemical Entities: R350;

(cc) Generic: R350;

(dd) Homeopathic: R120;

Amendments

(vi) Fees in respect of application for administrative amendments which include an amendment of an entry in the register, and transfer of the certificate of registration—

(aa) Administrative: R220;

(vii) Fees in respect of application for technical amendments which include an amendment of entry in the register, and transfer of the certificate of registration—

(aa) Technical: R600;

Other fees

(viii) Newly created fees for services rendered for which no fees were charged—

(aa) Screening fee: R1 050;

(bb) Clinical trial (C): R6 300;

(cc) Clinical Trial (N): R3 150;

(dd) Clinical Trial (A): R1 050;

(ee) Clinical Trial (T): R320;

(ff) Any other clinical trial: R1 075;

(gg) Pakage Insert amendment: R2 100;

(hh) Rescheduling: R1 900;

(ii) Resubmission Clinical data: R1 900;

(ix) Newly created fees for which permits and certificates were issued and no fees were charged—

(aa) WHO Certificates: R525;

(bb) Free Sale Certificates: R265;

(cc) GMP Certificates: R525;

(dd) Import Permit: R315;

(ee) Export Permit: R315;

(ff) Narcotic Permit: R525;

(x) Fees created for services for which no fees were charged—inspections—

(aa) Pre-approval inspections—Super site: R160 per hour;

(bb) Pre-approval inspection—Major site: R140 per hour;
(cc) Pre-approval inspection—Standard: R120 per hour;
(dd) Pre-approval inspection—Minor: R110 per hour;
(ee) Follow-up inspection—Super site: R110 per hour;
(ff) Follow-up inspection—Major site: R90 per hour;
(gg) Follow-up inspection—Standard: R60 per hour;
(hh) Follow-up inspections—Minor site: R50 per hour.

The above fees are applicable with effect from the 1st July 2002.

MANTO TSHABALALA-MSIMANG
Minister of Health