GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 502 **2 July 2012**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

SCHEDULES

The Minister of Health, in consultation with the Minister of Finance and the Medicines Control Council, in terms of Section 35(1)(xxxi) and (xxxii) read together with Section 35(4) of the Medicines and Related Substances intends to prescribe the following fees.

This Schedule intends to amend the Schedules as published in Government Notice Government Gazette No 24808 Notice R 539 (Medicines and Related Substances Act, 1965 (Act 101 of 1965) and Government Gazette No 25837 Notice R 1807 using the following convention:

- Words and figures in square brackets and bold print e.g. **[R30 000]**, indicate an amendment from the Schedules
- Words underlined with a solid line e.g. vaccine, R45 000, indicate insertions and replacement of the current fee in the Schedule.

Interesting parties are invited to comment on the proposed fees within **one month** from the date of publication and furnish the Registrar of Medicines with any comment thereon in regard to the regulation.

All comments may be submitted to the Registrar of Medicines, Private Bag X828, Pretoria, 0001.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

FEES PAYABLE IN TERMS OF THE PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

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,

(a) in respect of the submission of an application for registration of-

(i) New Chemical Entities, including highly technological products, and new biotherapeutics other than vaccines, which have been processed by the abbreviated registration process

(first strength, first dosage form): **[R30 000]** R45 000 per application;

(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i): **[R15 000]** R20 000 per application;

(iii) New Chemical Entities, including highly technological products, and new biotherapeutics other than vaccines (first strength, first dosage form): **[R30 000]** R50 000 per application;

(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii): **[R20 000]** R25 000 per application;

(v) Biological products e.g. (vaccines and biosimilars), excluding new biotherapeutics: **[R30 000]** R40 000 per application;

(vi) Generic products (pharmaceutical, analytical and bioavailability evaluated) and all other dental and radio pharmaceutical products (first strength, first dosage form): **[R12 500]** R25 000 per application;

(vii) Generic products with clinical data: R40 000

(viii) Strengths and dosage forms other than those referred to in sub-paragraph (vi): **[R6 500]** R8 500;

(ix) Screening fee on receipt of an application: **[R1 050]** R1 500;

(x) Evaluation of additional submitted clinical data (pre-registration): **[R1 900]** R2 500;

(xi) An application in terms of Section 15C of the Act: **[R12 500]** R30 000.

(xii) Of any medicine in accordance with an expedited registration procedure in terms of section 15(2)(b) of the Act:**[R5 000]** R9 000

(b) Any medicine, the registration of which has been approved by the Council in terms of section 15(3) of the Act:

(i) In respect of registration of any medicine, the registration of which has been approved by the Council in terms of section 15(3) of the Act (in the case of medicines in minute-dose form; 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]** R1 500 for each registration.

(ii) Evaluation of request for rescheduling of products: **[R1 900]** R5 000;

(iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated (post registration): **[R2 100]** R3 000.

(iv) 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]** R1 000: 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 may 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 that they are registerable:

(a) In respect of the submission of an application for registration of-

(i) New Chemical Entities, including highly technological products, (first strength, first dosage form): **[R3 800]** R11 000 per application;

(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): **[R3 800]** R10 000 per application;

(iii) Generic products with clinical data: R11 000

(iv) Screening fee on receipt of the application: **[R1 050]** R1 500;

(v) Evaluation of additional submitted clinical data (pre-registration): **[R1 900]** R2 200

(b) Any medicine, the registration of which has been approved by the Council in terms of section 15(3):

(i) 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]** R900 for each registration.

(ii) evaluation of request for rescheduling of products: **[R1 900]** R5 000;

(iii) evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: **[R2 100]** R3 000."

(iv) 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]** R800: 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 may be cancelled in terms of Section 16(4).

3 Use of unregistered medicines

(a) In respect of the submission of an application for the **authorization of the use of an unregistered medicine**:

(i) clinical trials (Companies): **[R6 300]** R8 000;

(ii) clinical trials (Institutions): **[R3 100]** R4 000;

(iii) any other clinical trial: **[R1 075]** R2 000;

(iv) any other application except for the purpose of performing a clinical trial: **[R200]** R250.

(b) In respect of **clinical trials amendments**:

(i) fees in respect of an application for technical amendments: **[R1 050]** R2 000 per amendment;

(ii) fees in respect of an application for administrative amendment: **[R320]** R550 per amendment.

4 In respect of licences

(a) an application for a new licence in terms of section 22C(1)(b) of the Act:

(i) Manufacture: **[R3 500]** R20 000;

(ii) Distribution: **[R2 400]** R12 000;

(iii) Wholesale: **[R2 400]** R12 000;

(iv) Import: **[R2 400]** R12 000 (Holder of certificate of registration);

(v) Export: **[R2 400]** R12 000 (Holder of certificate of registration)

(b) an application for the renewal of a licence in terms of section 22D of the Act, the licensing of which has been approved by the Council in terms of section 22C(1)(b) of the Act:

(i) Manufacture: **[R3 500]** R17 500;

(ii) Distribution: **[R2 400]** R10 000;

(iii) Wholesale: **[R2 400]** R10 000;

(iv) Import: **[R2 400]** R7 500 (Holder of certificate of registration)

(v) Export: **[R2 400]** R7 500 (Holder of certificate of registration)

(c) Annually, in respect of the retention of a licence issued in terms of section 22C(1)(b) of the Act: R2 700 **[R600]**, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled;

(d) licensing for any manufacture, distribution, wholesale, import or export, the licence of which has been approved by the Council in terms of Section 22(1)(b) of the Act: R2 700 **[R600]**.

5 Inspections to assess the quality of medicines

In respect of performance of inspections to assess the quality of medicines:

(a) Local manufacturing sites: **[R160]** R600 per hour;

(b) International manufacturing sites: **[R400]** R3 600 per hour;

(c) Wholesale sites: **[R800]** R5 000 per site;

(d) Distributor sites: **[R800]** R5 000 per site.

6 Permits and Certificates

In respect of the issuing of a permit or a certificate:

(a) Certificate: **[R525]** R1 050; (Certificate of a Pharmaceutical Product (WHO), Good Manufacturing Practice (GMP) Certificate, Certificate of Free Sale)

(b) Import permit: **[R500]** R750 (Holder of certificate of registration);

(c) Export permit: **[R300]** R725 (Holder of certificate of registration);

(d) Any other permit: **[R525]** R755;

(e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: **[R100]** R755.

7 Amendment of entries in register

In respect of all applications for amendments in terms of Section 15A, the name of the medicine approved by the Council under section 15(5), which shall be the proprietary name, the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine, the conditions of registration, **[and]** the name of the applicant, the name and address of the manufacturer, packer, final product release control, final product release responsibility: **[R220]** R600 per application.

8 Transfer of certificates of registration

In respect of an application in terms of Section 15B: **[registered name, approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine, dosage form, conditions under which the medicine is registered; and name of applicant]**: **[R400]** R800per application.

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 19/6/2012