DEPARTMENT OF HEALTH

NO. 784 **01 SEPTEMBER 2015**

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

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, makes the Regulations in the Schedule.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 1 of 1965). The following fees shall be payable to the Registrar or the Director General as the case may be:

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): R49 000 per application;

(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i): R21 000 per application;

(iii) New Chemical Entities, including highly technological products, and new biotherapeutics other than vaccines (first strength, first dosage form): R54 000 per application;

(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii): R27 000 per application;

(v) Biological products e.g. (vaccines and biosimilars), excluding new biotherapeutics: R43 000 per application;

(vi) Strengths and dosage forms other than those referred to in sub-paragraph (v): R 13 500 per application;

(vii) Generic products (pharmaceutical, analytical and bioavailability evaluated) and all other dental and radio pharmaceutical products (first strength, first dosage form): R27 000 per application;

(viii) Strengths and dosage forms other than those referred to in sub-paragraph (vii): R9 500;

(ix) Generic products with clinical data: R44 000;

(x) Strengths and dosage forms other than those referred to in sub-paragraph (ix): R13 500 per application;

(xi) Screening fee on receipt of an application: R1 600;

(xii) Evaluation of additional submitted clinical data (pre-registration): R2 700;

(xiii) An application in terms of Section 15C of the Act: R32 700;

(xiv) Of any medicine in accordance with an expedited registration procedure in terms of Section 15(2)(b) of the Act: R9 800.

(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: R1 600 for each registration;

(ii) Evaluation of request for rescheduling of products: R5 400;

(iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated (post registration): R3 500;

(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): R1 100: 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): R12 000 per application;

(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): R11 000 per application;

(iii) Generic products with clinical data: R12 000;

(iv) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii), (iii): R3 800;

(v) Screening fee on receipt of the application: R1 600;

(vi) Evaluation of additional submitted clinical data (pre-registration): R2 400.

(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: R1 000 for each registration;

(ii) evaluation of request for rescheduling of products: R5 400;

(iii) evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: R3 500;

(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): R850: 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 Category D medicines (Human medicines)

Human medicines, 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) Products submitted with clinical and or toxicological data (first strength, first dosage form): R12 400 per application;

(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i): R3 900 per application;

(iii) Products submitted with no clinical or toxicology data (first strength, first dosage form): R5 500 per application;

(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii): R1 800;

(v) Screening fee on receipt of an application: R1 600;

(vi) Evaluation of additional submitted clinical data (pre-registration): R2 500;

(vii) An application in terms of Section 15C of the Act: R30 000;

(viii) Of any medicine in accordance with an expedited registration procedure in terms of Section 15(2)(b) of the Act: 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 and in respect of which an application fee has been paid: R950 for each registration;

(ii) Evaluation of request for rescheduling of products: 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): 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): R650: 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).

4 **Category D medicines (Veterinary medicine)**

Veterinary medicines, 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) Products submitted with clinical and or toxicological data, (first strength, first dosage form): R3 400 per application;

(ii) Products submitted with no clinical or toxicology data (first strength, first dosage form): R2 400 per application;

(iii) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii): R1 400;

(iv) Screening fee on receipt of the application: R1 600;

(v) Evaluation of additional submitted clinical data (pre-registration): R1 300.

(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) and in respect of which an application fee has been paid: R700 for each registration.

(ii) evaluation of request for rescheduling of products: R5 000;

(iii) evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: 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): R430 : 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).

5 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): R9 000;

(ii) clinical trials (Institutions): R4 500;

(iii) any other clinical trial: R2 200;

(iv) any other application except for the purpose of performing a clinical trial: R300.

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

(i) fees in respect of an application for technical amendments: R2 100 per amendment;

(ii) fees in respect of an application for administrative amendment: R600 per amendment.

6 In respect of licences

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

(i) Manufacture: R21 800;

(ii) Distribution: R 13 000;

(iii) Wholesale: R13 000;

(iv) Import: R13 000 (Holder of certificate of registration);

(v) Export: R13 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: R19 000;

(ii Distribution: R 10 900;

(iii) Wholesale: R10 900;

(iv) Import: R8 000 (Holder of certificate of registration);

(v) Export: R8 000 (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: R3 000, 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 900.

7 Inspections to assess the quality of medicines

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

(a) Local manufacturing sites: R650 per hour;

(b) International manufacturing sites: R4 000 per hour;

(c) Wholesale sites: R5 500 per site;

(d) Distributor sites: R5 500 per site.

8 Permits and Certificates

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

(a) Certificate: R1 200; (Certificate of a Pharmaceutical Product (WHO), Good Manufacturing Practice (GMP) Certificate, Certificate of Free Sale);

(b) Import permit: R800 (Holder of certificate of registration);

(c) Export permit: R790 (Holder of certificate of registration);

(d) Any other permit: R820;

(e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: R820.

9 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, the name of the applicant, the name and address of the manufacturer, packer, final product release control, final product release responsibility:R700 per application.

10 Transfer of certificates of registration

In respect of a application in terms of Section 15B: R900 per application.

11 Withdrawal of Notice

Government Notice Government Gazette No 24808 Notice R 539 and Government Gazette No. 35857 Notice R 918 are hereby withdrawn.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 31/8/2015