

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 912

31 AUGUST 2018

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 South African Health Products Regulatory Authority, in terms of Section 35(1)(xxxi) and (xxxii) read together with Section 35(4) of the Medicines and Related Substances, intends to make the Regulations in the Schedule.

This Schedule intends to amend the Schedules as published in Government Notice Government Gazette No 39154 Notice R 784 (Medicines and Related Substances Act, 1965 (Act 101 of 1965) 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. Vaccines: R65 000, indicate insertions and replacement of the current fee in the Schedule.

Interested persons are invited to submit, within three month of publication of this notice, comments on the proposed Regulations to the South African Health-Products Regulatory Authority, for the attention of the Chief Executive Officer, Private Bag X828, Pretoria, 0001

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 Chief Executive Officer or the Director General as the case may be:

1 Category A medicines

Human medicines, including Biologicals, for which an application for registration is 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 [AMRP] (first strength, first dosage form): **[R49 000]** R 53 900 per application;

- (ii) Strengths and dosage forms other than those referred to in subparagraph (i): **[R21 000]** R 23 100 per application;
- (iii) New Chemical Entities, including highly technological products, other than vaccines (first strength, first dosage form): **[R54 000]** R59 400 per application;
- (iv) Strengths and dosage forms other than those referred to in subparagraph (iii): **[R27 000]** R29 700 per application;
- (v) Biological products e.g. vaccines and biosimilars (excluding new biotherapeutics): **[R43 000]** R47 300 per application;
- (vi) Strengths and dosage forms other than those referred to in subparagraph (v): **[R13 500]** R14 850 per application;
- (vii) Generic products (pharmaceutical, analytical and bioavailability evaluated) including generic dental and radio-pharmaceutical products (first strength, first dosage form): **[R27 000]** R29 700 per application;
- (viii) Strengths and dosage forms other than those referred to in subparagraph (ix): **[R9 500]** R10 450;
- (ix) Generic products with clinical data: **[R44 000]** R48 400;
- (x) Strengths and dosage forms other than those referred to in subparagraph (xi): **[R13 500]** R14 850 per application;
- (xi) Screening fee on receipt of a Common Technical Document (CTD) format application: **[R1 600]** R1 760;
- (xii) Screening fee on receipt of an electronic Common Technical Document (eCTD) format application: R1 760 per sequence;
- (xiv) Evaluation of additional submitted clinical data (pre-registration): **[R2 700]** R2 970;
- (xv) An application in terms of Section 15C of the Act: **[R32 700]** R35 970;
- (b) An application for priority review: R25 000;
- (c) 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]** R1 760 for each registration;

- (ii) Evaluation of request for rescheduling of products: **[R5 400]** R15 000
- (iii) Evaluation of request to amend package insert and Patient Information Leaflets in respect of which data relating to safety must be evaluated (post registration): **[R3 500]** R3 850;

Evaluation of request to amend package insert and Patient Information Leaflets in respect of which clinical data relating to safety and efficacy must be evaluated (post registration): **[R3 500]** R15 000;

- (iv) Evaluation of request to amend the Generic medicine package inserts and Patient Information Leaflet where clinical data are not required (post registration): R2 500;
- (v) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration): R15 000;
- (vi) Evaluation of requests for approval of once-off deviations from registered requirements: R5 000;
- (vii) Evaluation of requests for exemption from registered post-importation testing requirements per product: R5 000;
- (viii) 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]** R5 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).

- (d) In respect of the testing of a biological medicine for purposes of batch release by the National Control Laboratory: R22 000 per batch;

Veterinary medicines, including Biologicals, 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]** R13 200 per application;
 - (ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): **[R11 000]** R12 100 per application;
 - (iii) Generic products with clinical data: **[R12 000]** R13 200;
 - (iv) Strengths and dosage forms other than those referred to in subparagraphs (i), (ii), (iii): **[R3 800]** R4 180;
 - (v) Screening fee on receipt of the application: **[R1 600]** R1 760;
 - (vi) Evaluation of additional submitted clinical data (pre-registration): **[R2 400]** R2 640.
- (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]** R 1 760 for each registration;
 - (ii) Evaluation of request for rescheduling of products: **[R5 400]** R5 940 ;
 - (iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: **[R3 500]** R3 850 ;
 - (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]** R2 300: 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—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]** R13 640 per application;
 - (ii) Strengths and dosage forms other than those referred to in subparagraph (i): **[R3 900]** R4 290 per application;
 - (iii) Products submitted with no clinical or toxicology data (first strength, first dosage form): **[R5 500]** R6 050 per application;
 - (iv) Strengths and dosage forms other than those referred to in subparagraph (iii): **[R1 800]** R1 980;
 - (v) Screening fee on receipt of an application: **[R1 600]** R1 760;
 - (vi) Evaluation of additional submitted clinical data (pre-registration): **[R2 500]** R2 750;
 - (vii) An application in terms of Section 15C of the Act: **[R30 000]** R33 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]** R1 760 for each registration;
 - (ii) Evaluation of request for rescheduling of products: **[R5 000]** R5 500;
 - (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]** R3 300;
 - (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]** R1 700: 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 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]** R3 740 per application;
 - (ii) Products submitted with no clinical or toxicology data (first strength, first dosage form): **[R2 400]** R2 640 per application;
 - (iii) Strengths and dosage forms other than those referred to in subparagraphs (i), (ii): **[R1 400]** R1 540;
 - (iv) Screening fee on receipt of the application: **[R1 600]** R1 760;
 - (v) Evaluation of additional submitted clinical data (pre-registration): **[R1 300]** R1 430
- (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: R1 760 for each registration;
 - (ii) Evaluation of request for rescheduling of products: **[R5 000]** R5 500;
 - (iii) Evaluation of request to amend package insert in respect of which clinical data relating to safety and efficacy must be evaluated: **[R3 000]** R3 300;
 - (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]** R1 200: 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 **authorisation of the use of an unregistered medicine**:
 - (i) Clinical trial application (Companies): **[R9 000]** R9 900;
 - (ii) Clinical trial application (Institutions): **[R4 500]** R4 950;
 - (iii) Any other clinical trial application: **[R2 200]** R2 420;
 - (iv) Any other application except for the purpose of performing a clinical trial: **[R300]** R330.
- (b) In respect of **clinical trials amendments**:
 - (i) Fees in respect of an application for technical amendments: **[R2 100]** R 2 310 per amendment;
 - (ii) Fees in respect of an application for administrative amendment: **[R650]** R715 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]** R23 980;
 - (ii) Distribute: **[R13 000]** R14 300 [Holder of certificate of registration (HCR)];
 - (iii) Wholesale: **[R13 000]** R14 300;
 - (iv) Import: **[R13 000]** R14 300 (Holder of certificate of registration);
 - (v) Export: **[R13 000]** R14 300 (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]** R20 900
 - (ii) Distribute: **[R10 900]** R11 990 (Holder of certificate of registration);
 - (iii) Wholesale: **[R10 900]** R11 990;
 - (iv) Import: **[R8 000]** R8 800 (Holder of certificate of registration);
 - (v) Export: **[R8 000]** R8 800 (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]** R10 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, distributor, wholesale, import or export, the license of which has been approved by the Council in terms of Section 22(1)(b) of the Act: **[R2 900]** R3 190;
- (e) Application for the amendment to an existing licence to manufacture, distribute, wholesale, import or export: R5 000.

7 Inspections to assess the quality, safety and efficacy of medicines or scheduled substances

- (a) Local manufacturing site **[R650/h]** R715/h;
- (b) International manufacturing sites (excluding Southern Africa Development Community countries): **[R4 000/h]** R4 400/h
- (c) International manufacturing sites in Southern Africa Development Community countries: R2 000/h;
- (d) Wholesale sites **[R5 500]** R6 050;
- (e) Distributor sites **[R5 500]** R6 050;
- (f) Local clinical trial site: R715/h;
- (g) International clinical trial site (excluding Southern Africa Development Community countries): R4 400/h;
- (h) International clinical trial sites in Southern Africa Development Community countries: R2 000/h;
- (i) Local pharmacovigilance inspection: R715/h;
- (j) International pharmacovigilance inspection (excluding Southern Africa Development Community countries): R4 400/h;

- (k) International pharmacovigilance inspection in Southern Africa Development Community countries: R2 000/h.

8 Desktop inspection to assess quality, safety and efficacy of medicines or scheduled substances: R2 000

9 Permits and Certificates

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

- (a) Certificate [Certificate of a Pharmaceutical Product (WHO), Good Manufacturing Practice (GMP) Certificate, Certificate of Free Sale]: **[R1 200]** R1 320;
- (b) Import permit (holder of certificate of registration): **[R800]** R880;
- (c) Export permit (holder of certificate of registration): **[R790]** R869;
- (d) Any other permit or certificate: **[R820]** R902;
- (e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: **[R820]** R902.

10 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]** R770 per application.

11 Transfer of certificates of registration

In respect of an application in terms of Section 15B: **[R900]** R990 per application.

12 Appeal against the decision of the Authority

In respect of an application in terms of Section 24 (3): R50 000 per application.

13 Withdrawal of Notice

Government Notice Government Gazette No 39154 Notice R 784 is hereby withdrawn.



DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE:

5/7/2018