DEPARTMENT OF HEALTH

NO. 659 **12 JUNE 2020**

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

REGULATIONS REGARDING FEES PAYABLE IN TERMS OF THE PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

The Minister of Health intends, 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, to make the Regulations in the Schedule.

Interested persons are invited to submit any substantiated comments on the proposed Regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 for the attention of the Director: Public Entities, Ms M Mushwana, mihloti.mushwana@health.gov.za within two months of this Notice

SCHEDULE

Definitions

1. In these Regulations, "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 1 of 1965).

Fees

2. The following fees shall be payable to the Chief Executive Officer or the Director General as the case may be:

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, which have

been processed by the abbreviated registration process [AMRP] (first strength, first dosage form): R111 000 per application;

(ii) Strengths and dosage forms other than those referred to in sub- paragraph (i): R 44 000 per application;

(iii) New Chemical Entities, new biotherapeutics other than vaccines (first strength, first dosage form): R208 400 per application;

(iv) Strengths and dosage forms other than those referred to in sub- paragraph (iii): R 82 000 per application

(v) Biological products e.g. vaccines (excluding new biotherapeutics): R177 000 per application;

(vi) Biological products e.g. biosimilars (excluding new biotherapeutics): R173 000 per application;

(vii) Strengths and dosage forms other than "those referred to in sub- paragraph (vi): R55 000 per application;

(viii) Generic products (pharmaceutical, analytical and bioavailability evaluated) including generic dental and radio-pharmaceutical products (first strength, first dosage form): R84 000 per application;

(ix) Strengths and dosage forms other than those referred to in sub- paragraph (vii): R27 000;

(x) Generic products with clinical data: R84 000;

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

(xii) Evaluation of additional submitted clinical data (pre-registration): R5 000; and

(xiii) An application in terms of Section 15C of the Act: R37 800.

(b) Any medicine, the registration of which has been approved by the Authority 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 Authority 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: R2 000 for each registration;

(ii) Evaluation of request for rescheduling of products: R16 000;

(iii) Evaluation of request to amend Professional Information and Patient Information Leaflets in respect of which data relating to safety must be evaluated (post registration): R15 600;

Evaluation of request to amend Professional Information and Patient Information Leaflets in respect of which clinical data relating to safety and efficacy must be evaluated (post registration): R15 600;

(iv) Evaluation of request to amend the Generic medicine package insert and Patient Information Leaflet where clinical data are not required (post registration): R2 600;

(v) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type II Level 1: R28 500;

(vi) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type II Level 2: R13 300;

(vii) Evaluation of request for major technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type II Level 3: R4 400;

(viii) Evaluation of request for minor technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type IA: R3 300;

(ix) Evaluation of request for minor technical amendments in respect of which data relating to quality must be evaluated (post registration) – Type IB: R5 400;

(x) Evaluation of requests for approval of once-off deviations from registered requirements: R5 300;

(xi) Evaluation of requests for exemption from registered post-importation testing requirements per product: R5 300;

(xii) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): 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 Authority 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).

(c) In respect of the testing of a human vaccine for purposes of batch release by the National Control Laboratory: R23 100 per batch.

Category C medicines

Veterinary medicines, including Biologicals, for which Authority has determined by resolution that they are registerable:

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

(i) New Chemical Entities, including highly technological products, (first strength, first dosage form): R13 900 per application;

(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): R12 700 per application;

(iii) Generic products with clinical data: R13 900;

(iv) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii), (iii): R4 400;

(v) Screening fee on receipt of the application: R1 800;

(vi) Evaluation of additional submitted clinical data (pre-registration): R2 800.

(e) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3):

(i) In respect of the registration of any medicine, the registration of which has been approved by the Authority 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 800 for each registration;

(ii) Evaluation of request for rescheduling of products: R6 200;

(iii) Evaluation of request to amend Professional Information in respect of which clinical data relating to safety and efficacy must be evaluated: R4 000;

(iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): 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 Authority 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).

Category D medicines (Human medicines)

Human medicines for which an application for registration has been submitted as contemplated in Section 15 of the Act,

(f) 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): R14 300 per application;

(ii) Strengths and dosage forms other than those referred to in sub-paragraph (i): R4 500 per application;

(iii) Products submitted with no clinical or toxicology data (first strength, first dosage form): R6 400 per application;

(iv) Strengths and dosage forms other than those referred to in sub-paragraph (iii): R2 100;

(v) Screening fee on receipt of an application: R1 800;

(vi) Evaluation of additional submitted clinical data (pre-registration):R2 900;

(vii) An application in terms of Section 15C of the Act: R34 700;

(g) Any medicine, the registration of which has been approved by the Authority 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 Authority in terms of Section 15(3) of the Act and in respect of which an application fee has been paid: R1 800 for each registration;

(ii) Evaluation of request for rescheduling of products: R5 800;

(iii) Evaluation of request to amend Professional Information 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 Authority in terms

of Section 15(3): R1 800: 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 Authority 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).

Category D medicines (Veterinary medicine)

Veterinary medicines for which Authority has determined by resolution that they are registerable:

(h) 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 900 per application;

(ii) Products submitted with no clinical or toxicology data (first strength, first dosage form): R2 800 per application;

(iii) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii): R1 600;

(iv) Screening fee on receipt of the application: R1 800;

(v) Evaluation of additional submitted clinical data (pre-registration): R1 500

(i) Any medicine, the registration of which has been approved by the Authority in terms of Section 15(3):

(i) In respect of the registration of any medicine, the registration of which has been approved by the Authority in terms of Section 15(3) and in respect of which an application fee has been paid: R1 800 for each registration;

(ii) Evaluation of request for rescheduling of products: R5 800;

(iii) Evaluation of request to amend Professional Information 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 Authority in terms of Section 15(3): R1 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 Authority 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).

Fees for clinical trials

3. (a) In respect of the submission of an application for the authorisation of the use of an unregistered medicine for clinical trials:

i. Clinical trial application (Safety and efficacy): R32 400.00;

ii. Clinical trial application (Bioequivalence study): R30 400;

iii. Clinical trial application (Postgraduate study): R10 800;

iv. Any other clinical trial application: R5 000;

(b) In respect of clinical trials amendments:

v. Fees in respect of an application for technical amendments: R7 000.00 per amendment;

vi. Fees in respect of an application for administrative amendment: R4 100 per amendment.

Use of unregistered medicines (section 21 applications)

4. Any other application except for the purpose of performing a clinical trial: R350.

Fee for new licences

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

i. Manufacture: R25 200;

ii. Distribute: R15 000 [Holder of certificate of registration (HCR)];

iii. Wholesale: R15 000;

iv. Import: R15 000 (Holder of certificate of registration);

v. Export: R15 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 Authority in terms of Section 22C(1)(b) of the Act:

i. Manufacture: R22 000;

ii. Distribute: R12 600 (Holder of certificate of registration);

iii Wholesale: R12 600;

iv Import: R9 200 (Holder of certificate of registration);

v Export: R9 200 (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: R4 200, 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 manufacturer, distributor, wholesale, import or export, the license of which has been approved by the Authority in terms of Section 22(1)(b) of the Act: R3 400;

(e) Application for the amendment to an existing licence to manufacture, distribute, wholesale, import or export: R5 300.

Fees for inspections to assess the quality, safety and efficacy of medicines or scheduled substances

6. (a) Local manufacturing site: R1 600/h; (Travel time to be charged)

(b) International manufacturing sites: R1 600/h; (Travel time to be charged)

(c) Wholesale sites: R1 600/h;

(d) Distributor sites, Local: R1 600/h;

(e) Clinical trial site; Local: R1 600/h;

(f) International clinical trial site: R1 600/h;

(g) Local pharmacovigilance inspection: R1 600/h; and

(h) International pharmacovigilance inspection: R1 600/h.

(i) Desktop inspection to assess quality, safety and efficacy of medicines or scheduled substances: R2 100

Fees for permits and certificates

7. Fees for 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 400;

(b) Import permit (holder of certificate of registration): R950;

(c) Export permit (holder of certificate of registration): R925;

(d) Any other permit or certificate: R950;

(e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: R950.

Amendment of entries in register

8. Fee for all applications for amendments in terms of Section 15A, the name of the medicine approved by the Authority 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: R800 per application.

Transfer of certificates of registration

9. Fee for an application in terms of Section 158: R1 050 per application.

Appeal against the decision of the Authority

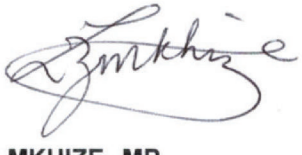
10. Fee for an application in terms of Section 24 (3): R50 000 per application.

Repeal of laws

11. Regulations published in Government Notice Government *Gazette* No 42474 Notice R 695 are hereby repealed.

Short title

12. These Regulations are called Regulations Regarding Fees Payable in terms of the provisions of the Medicines and Related Substances Act, 1965 (act no. 101 of 1965), 2020.



DR ZL MKHIZE, MP

MINISTER OF HEALTH

DATE: 8/4/2020