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IMPORTANT

Information

from Government Printing Works

Dear Valued Customers,

Government Printing Works has implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submits your notice request.

Please take note of these guidelines when completing your form.

GPW Business Rules

1. No hand written notices will be accepted for processing, this includes Adobe forms which have been completed by hand.
2. Notices can only be submitted in Adobe electronic form format to the email submission address submit.egazette@gpw.gov.za. This means that any notice submissions not on an Adobe electronic form that are submitted to this mailbox will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
3. Notices brought into GPW by "walk-in" customers on electronic media can only be submitted in Adobe electronic form format. This means that any notice submissions not on an Adobe electronic form that are submitted by the customer on electronic media will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
4. All customers who walk in to GPW that wish to submit a notice that is not on an electronic Adobe form will be routed to the Contact Centre where the customer will be taken through the completion of the form by a GPW representative. Where a customer walks into GPW with a stack of hard copy notices delivered by a messenger on behalf of a newspaper the messenger must be referred back to the sender as the submission does not adhere to the submission rules.
5. All notice submissions that do not comply with point 2 will be charged full price for the notice submission.
6. The current cut-off of all Gazette's remains unchanged for all channels. (Refer to the GPW website for submission deadlines – www.gpwonline.co.za)
7. Incorrectly completed forms and notices submitted in the wrong format will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za)
8. All re-submissions by customers will be subject to the above cut-off times.
9. All submissions and re-submissions that miss the cut-off will be rejected to the customer to be submitted with a new publication date.
10. Information on forms will be taken as the primary source of the notice to be published. Any instructions that are on the email body or covering letter that contradicts the notice form content will be ignored.

You are therefore advised that effective from **Monday, 18 May 2015** should you not comply with our new rules of engagement, all notice requests will be rejected by our new system.

Furthermore, the fax number **012- 748 6030** will also be **discontinued** from this date and customers will only be able to submit notice requests through the email address submit.egazette@gpw.gov.za.

government printing
Department:
Government Printing Works
REPUBLIC OF SOUTH AFRICA

eGazette

Contents

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

WARNING!!!

To all *suppliers and potential suppliers* of goods to the Government Printing Works

The Government Printing Works would like to warn members of the public against an organised syndicate(s) scamming unsuspecting members of the public and claiming to act on behalf of the Government Printing Works.

One of the ways in which the syndicate operates is by requesting quotations for various goods and services on a quotation form with the logo of the Government Printing Works. Once the official order is placed the syndicate requesting upfront payment before delivery will take place. Once the upfront payment is done the syndicate do not deliver the goods and service provider then expect payment from Government Printing Works.

Government Printing Works condemns such illegal activities and encourages service providers to confirm the legitimacy of purchase orders with GPW SCM, prior to processing and delivery of goods.

To confirm the legitimacy of purchase orders, please contact:

Renny Chetty (012) 748-6375 (Renny.Chetty@gpw.gov.za),

Anna-Marie du Toit (012) 748-6292 (Anna-Marie.DuToit@gpw.gov.za) and

Siraj Rizvi (012) 748-6380 (Siraj.Rizvi@gpw.gov.za)

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