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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. 918 **7 November 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 made the regulations in the Schedule.

SCHEDULE

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

The following fees shall be payable to the Registrar or the Director General as the case may be:

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): R45 000 per application;

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

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

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

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

(vi) Strengths and dosage forms other than those referred to in sub-paragraph (v): R12 500 per application;

(vii) Generic products (pharmaceutical, analytical and bioavailability evaluated) and all other dental and radio pharmaceutical products (first strength, first dosage form): R25 000 per application;

(viii) Strengths and dosage forms other than those referred to in sub-paragraph (vii): R8 500;

(ix) Generic products with clinical data: R40 000

(x) Strengths and dosage forms other than those referred to in sub-paragraph (ix): R12 500 per application;

(xi) Screening fee on receipt of an application: R1 500;

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

(xiii) An application in terms of Section 15C of the Act: R30 000.

(xiv) 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 (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 500 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): 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): R11 000 per application;

(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): R10 000 per application;

(iii) Generic products with clinical data: R11 000

(iv) Strengths and dosage forms other than those referred to in sub-paragraphs (i), (ii), (iii): R3 500

(v) Screening fee on receipt of the application: R1 500;

(vi) Evaluation of additional submitted clinical data (pre-registration): 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: R900 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): 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): R8 000;

(ii) clinical trials (Institutions): R4 000;

(iii) any other clinical trial: R2 000;

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

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

(i) fees in respect of an application for technical amendments: R2 000 per amendment;

(ii) fees in respect of an application for administrative amendment: 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: R20 000;

(ii) Distribution: R12 000;

(iii) Wholesale: R12 000;

(iv) Import: R12 000 (Holder of certificate of registration);

(v) Export: 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: R17 500;

(ii) Distribution: R10 000;

(iii) Wholesale: R10 000;

(iv) Import: R7 500 (Holder of certificate of registration)

(v) Export: 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, 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.

5 Inspections to assess the quality of medicines

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

(a) Local manufacturing sites: R600 per hour;

(b) International manufacturing sites: R3 600 per hour;

(c) Wholesale sites: R5 000 per site;

(d) Distributor sites: R5 000 per site.

6 Permits and Certificates

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

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

(b) Import permit: R750 (Holder of certificate of registration);

(c) Export permit: R725 (Holder of certificate of registration);

(d) Any other permit: R755;

(e) Permits issued by the Director-General in terms of Section 22A of the Act, excluding government departments: 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, the name of the applicant, the name and address of the manufacturer, packer, final product release control, final product release responsibility: R600 per application.

8 Transfer of certificates of registration

In respect of an application in terms of Section 15B: R800 per application.

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 28/10/2012

Comments received on the proposed Amendment to the Medicines and Related Substances Act, 1965: FEES

New Clicks: David Janks – 021 4601471
IMSA (Innovative Medicines SA): Val Beaumont - 011 8804644
PIASA (Pharmaceutical Industry Association of SA): Kirsti Narsai - 011 805 5100 / 011 265 2107
NAPM (National Association of Pharmaceutical Manufacturers) : Mohammad Bodhania – 011 312 6966

Organisation	Section in Act	Comments received	MRA Response
New Clicks	Increase in the registration cost for generic product registration by 100%	Industry will be able to absorb the costs however, need to be accompanied by improved response from MCC on timelines to process amendments and product registrations.	Noted
New Clicks	Increase in the retention fee costs by 81%	Industry will be able to absorb the costs however, need to be accompanied by improved response from MCC on timelines to process amendments and product registrations.	Noted
New Clicks	Increase in the renewal costs for a Manufacturing license by 400%	Industry will be able to absorb the costs however, need to be accompanied by improved response from MCC on timelines to process amendments and product registrations.	Noted
IMSA	Increase in the fees for inspections by 800%	Do not support the increase as an "hourly fee". Suggest charging a single "facility-fee".	Charging a "Facility fee" may be too costly for small manufacturing sites which may require much shorter time to complete the inspection
NAPM	Increase in the fee for inspections	Supports the increase in the hourly fee however requests that the following wording be added to the fee "for the time spent at the site"	MRA is already only charging a fee depending on the times spent at the facility.
NAPM	No fee for inspections of Applicants	Propose to add a fee for the inspection of an Applicant of R3000.00 per inspection	Inspection is done to issue a Wholesale or Manufacture license. Act does not make provision for the inspection of an Applicant.
IMSA	No fees for amendments to the dossier	Propose to add an additional fee Charge a fee of R400.00 for evaluation of amendments made to the medicine dossier to allow for greater efficiency	Act does not make provision to charge for Amendments
IMSA	No fee for service	Propose to add an additional fee for services where 50% is paid upfront and rest paid in increments depending on	Act does not make provision to charge for "Service fee"

Organisation	Section in Act	Comments received	MRA Response
		the specific milestone reached.	
NAPM	No fee for service	Propose to add an additional fee for services where 50% is paid upfront and rest paid in increments depending on the specific milestone reached.	Act does not make provision to charge for "Service fee"
PIASA	All fees	Supported	Noted
NAPM	No fees for different strengths of Biological medicines or Generic medicines with clinical data	For "Biologicals" and "Generic products with clinical data" to allow for a lower fee of R12500 when subsequent strengths and dosage forms are submitted	Agree to add additional fee

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