# DEPARTMENT OF HEALTH
# DEPARTEMENT VAN GESONDHEID

No. R. 1096 1 August 2003

## MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

## REGULATIONS RELATING TO FEES PAYABLE TO THE REGISTRAR: AMENDMENT

The Minister of Health, in consultation with the Medicines Control Council, intends, in terms of Section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), to make ~~the regulations in the~~ Schedule.

Interested persons are invited to submit any comments or representations on the proposed regulations to the Director-General: Health, Private Bag X 828, Pretoria, 0001, within three months from the date of publication of this notice.

## SCHEDULE

**Definition**

1. In this Schedule "the Regulations" means the Regulations Relating to Fees Payable to the Registrar, published under Government Notice No. R 539 of 25 April 2003 and "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).

**Amendment of regulation 2 of the Regulations**

2. Regulation 2 of the regulations is hereby amended-

(a) in subregulation (1), by the addition in paragraph (a), of the following subparagraphs:

"(viii) screening fee on receipt of an application: R1 050;
(ix) evaluation of additional submitted clinical data: R1 900;
(x) an application in terms of Section 15C of the Act: R12 500.
(xii) any medicine, the registration of which has been approved by the Council in terms of section 15(3) of the Act:

*(aa)* evaluation of request for rescheduling of medicines or substances: R1 900;

*(bb)* evaluation of request to amend package insert in respect of which clinical data relating to efficacy must be evaluated: R2 100.

(xiii) of any medicine in accordance with an expedited registration procedure in terms of section 15(2)(b) of the Act: R 5 000"

(b) in subsection (1), by the insertion after paragraph (a) of the following paragraph, and the existing paragraph (b) becoming paragraph (c):

"(b) 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: R600 for each registration."

(c) in subregulation (2), by the addition in paragraph (a), of the following subparagraphs:

"(iii) screening fee on receipt of the application: R1 050;

(iv) evaluation of additional submitted clinical data: R1 900

(v) any medicine, the registration of which has been approved by the Council in terms of section 15(3):

*(aa)* evaluation of request for rescheduling of products: R1 900;

*(bb)* evaluation of request to amend package insert in respect of which clinical data relating to efficacy must be evaluated: R2 100."

(d) by the insertion after subsection (2) of the following subsections, the current subsections (3) and (4) becoming subsections (8) and (9) respectively:

"(3) In respect of the submission of an application for the authorization of the use of an unregistered medicine:

(a) clinical trials (Companies): R6 300;

(b) clinical trials (Institutions): R3 100;

(c) any other clinical trial: R1 075;

(d) any other application except for the purpose of performing a clinical trial: R200.

(4) In respect of clinical trials amendments:

(a) fees in respect of an application for technical amendments: R1 050 per amendment;

(b) fees in respect of an application for administrative amendment: R320 per amendment.

(5) In respect of licences:

(a) an application for a license in terms of section 22C(1)(b) of the Act:

(i) Manufacturer: R3 500;

(ii) Distributor: R2 400;

(iii) Wholesaler: R2 400;

(b) an application for the renewal of a license 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) Manufacturers: R3 500;

(ii) Distributors: R2 400;

(iii) Wholesalers: R2 400;

(c) annually, in respect of the retention of a licence issued in terms of section 22C(1)(b) of the Act: R600, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled;

(d) a licence fee in respect of any manufacturer, distributor or wholesaler, the license of which has been approved by the Council in terms of Section 22C(1)(b) of the Act: R600.

(6) In respect of performance of inspections to assess the quality of medicines:

(a) local manufacturing sites: R160 per hour;

(b) international manufacturing sites: R400 per hour.

(7) In respect of the issuing of a permit or a certificate:

(a) a certificate: R525;

(b) an import permit: R500;

(c) an export permit: R300;

(d) any other permit: R525; and

(e) permits issued by the Director-General in terms of Section 22A of the Act: R100."

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**MINISTER OF HEALTH**