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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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INHOUD

GOVERNMENT NOTICE
GOEWERMENTSKENNISGEWING

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 539 **25 April 2003**

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

REGULATIONS RELATING TO FEES PAYABLE TO THE REGISTRAR

The Minister of Health has, in consultation with the Medicines Control Council, in terms of section 35(1) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), made the regulations in the Schedule.

SCHEDULE

Definitions

1. In this Schedule "the Regulations" means the regulations published under Government Notice No. R 352 of 21 February 1975, as amended.

Fees

2. The following fees shall be payable to the Registrar:

Category A medicines

(1) 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 or highly technological products, which have been processed by the abbreviated registration process (first strength, first dosage form): R30 000 per application;

(ii) strengths and dosage forms other than those referred to in sub-paragraph (i): R15 000 per application;

(iii) new chemical entities, including highly technological products, (first strength, first dosage form): R30 000 per application;

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

(v) Biological products (pharmaceutical, analytical and bioavailability evaluated): R30 000 per application;

(vi) Generic products (pharmaceutical, analytical and bioavailability evaluated) and all other dental and radio pharmaceutical products (first strength, first dosage form): R12 500 per application;

(vii) Strengths and dosage forms other than those referred to in sub-paragraph (vi): R6 500 per application;

(b) 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): R550: 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).

Category C medicines

(2) Veterinary medicines, including Biologicals, whether compounded in the RSA or not and for which Council has determined by resolution that such medicines are registrable-

(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): R3 800 per application;

(ii) Generic products (pharmaceutical, analytical and bioavailability evaluated): R3 800 per application;

(b) 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: R600 for each registration.

(c) 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): R350: Provided that this provision shall come into effect one year after the date on which the registration of such 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).

Amendment of entries in the register

(3) 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, and the name of the applicant: R220 per application.

Transfer of certificates of registration

(4) In respect of an application in terms of section 15B: registered name, approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine, dosage form, conditions under which the medicine is registered; and name of applicant: R400 per application.

Replacement of regulation 35 of the regulations

3. These regulations replace regulation 35 of the regulations.

Commencement

4. These regulations come into operation on **2 May 2003.**

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

No. R. 539 25 April 2003

WET OP MEDISYNE EN VERWANTE STOWWE, 1965 (WET 101 VAN 1965)

REGULASIES BETREFFENDE GELDE BETAALBAAR AAN DIE REGISTRATEUR

Die Minister van Gesondheid, in oorleg met die Medisynebeheerraad, het kragtens artikel 35 van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), die regulasies in die bylae uitgevaardig.

BYLAE

Woordomskrywings

1. In hierdie Bylae beteken "die Regulasies" die regulasies gepubliseer by Goewermentskennisgewing No. R. 352 van 21 Februarie 1975, soos gewysig.

Gelde

2. Die volgende gelde sal aan die Registrateur betaalbaar wees.

Kategorie A medisyne

(1) Menslike medisyne, insluitend Biologiese middels, saamgestel in sy geheel in die RSA of nie, waarvoor 'n aansoek vir registrasie ingedien is soos beoog word in artikel 15 van die Wet-

(a) met betrekking tot die indiening van 'n aansoek vir registrasie van:

(i) nuwe chemiese entiteite of hoogs tegnologiese produkte, wat deur die verkorte registrasie prosedure verwerk is (eerste sterkte, eerste doseringsvorm): R30 000 per aansoek;

(ii) sterktes en doseervorme anders as die' in subparagraaf (i) bedoel: R15 000 per aansoek;

(iii) nuwe chemiese entiteite, insluitend hoogs tegnologiese produkte, (eerste sterkte, eerste doseervorm): R30 000 per aansoek;

(iv) sterktes en doseervorme anders as die' in sub-paragraaf (iii) bedoel: R20 000 per aansoek;

(v) Biologiese produkte (farmaseuties, analities en biobeskikbaarheid geëvalueerd): R30 000 per aansoek;

(vi) generiese produkte (farmaseuties, analities en biobeskikbaarheid geëvalueerd) en alle ander tandheelkundige en radiofarmaseutiese produkte (eerste sterkte, eerste doseringsvorm): R12 500 per aansoek;

(vii) sterktes en doseervorme ander as die' in sub-paragraaf (vi) bedoel: R6 500 per aansoek.

(b) Jaarliks, ten opsigte van die retensie van die registrasie van 'n medisyne, waar die registrasie deur die Raad goedkeur is kragtens artikel 15(3): R550 per aansoek: Met dien verstaande dat hierdie bepaling een jaar na die datum waarop die registrasie van genoemde medisyne deur die Raad goedgekeur is ooreenkomstig artikel 15(3) in werking sal tree: Met dien verstaande verder dat genoemde gelde wat gedurende 'n bepaalde kalenderjaar betaalbaar is op of voor die laaste werksdag van Junie van sodanige jaar betaalbaar sal wees, by gebreke waarvan die registrasie gekanselleeer mag word ooreenkomstig artikel 16(4).

Kategorie C medisyne

(2) Veterinêre medisyne, insluitend Biologiese middels, hetsy saamgestel in die RSA of nie en waarvoor die Raad by resolusie besluit het dat sodanige medisyne registreerbaar is :

(a) Met betrekking tot die indiening van 'n aansoek vir registrasie van:

(i) nuwe chemiese entiteite, insluitend hoogs tegnologiese produkte, (eerste sterkte, eerste doseringsvorm): R3 800 per aansoek;

(ii) generiese produkte (farmaseuties, analities en biobeskikbaarheid geëvalueerd): R3 800 per aansoek;

(b) Met betrekking tot die registrasie van enige medisyne, waar die registrasie deur die Raad goedkeur is kragtens artikel 15(3) (in die geval van medisyne in klein doseervorme; word verskillende verdunnings en verskillende volumes deur die gelde ingesluit, waneer gelyktydig ingedien word vir dieselfde indikasie of voorgenome gebruik) en ten opsigte waarvan aansoekgelde betaal is: R600 vir elke registrasie.

(c) Jaarliks, ten opsigte van die retensie van die registrasie van 'n medisyne, waar die registrasie deur die Raad goedkeur is kragtens artikel 15(3): R350 per aansoek: Met dien verstaande dat hierdie bepaling een jaar na die datum waarop die registrasie van sodanige medisyne deur die Raad goedgekeur is kragtens artikel 15(3), in werking sal tree: Met dien verstaande verder dat sodanige gelde wat gedurende 'n bepaalde kalenderjaar betaalbaar is, betaalbaar wees op of voor die laaste werksdag van Junie van daardie die jaar, by gebreke waar die registrasie kragtens Artikel 16(4) gekanselleeer sal word.

Wysigings van inskrywings in die register

(3) Ten opsigte van alle aansoeke vir wysigings kragtens artikel 15A, die naam van die medisyne soos goedgekeur deur die Raad kragtens artikel 15(5), wat die eiendomsnaam sal wees, die goedgekeurde naam van elke aktiewe bestanddeel van die medisyne en die hoeveelheid daarvan per dosiseenheid of per geskikte massa of volume of eenheid van die medisyne, die voorwaardes van registrasie, en die naam van die applikant: R220 per aansoek.

Oordrag van sertifikate van registrasie

(4) Ten opsigte van 'n aansoek kragtens artikel 15B: geregistreerde naam, goedgekeurde naam van elke aktiewe bestanddeel en hoeveelhede daarvan per dosiseenheid of per geskikte massa of volume of eenheid van die medisyne, dosseervorm, voorwaardes waaronder die medisyne geregistreer is; en naam van applikant: R400 per aansoek."

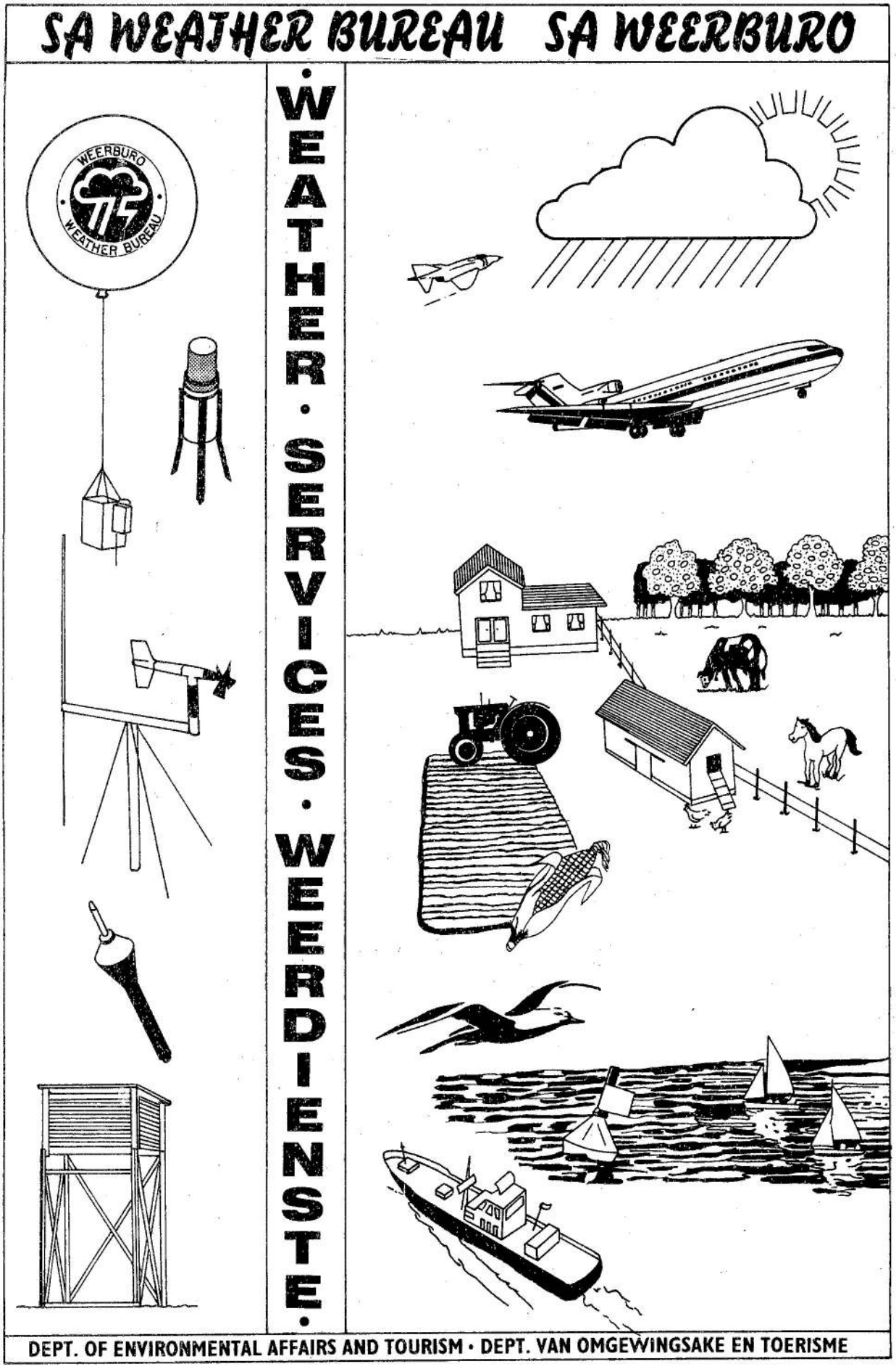
Vervanging van regulasie 35 van die regulasies

3. Hierdie regulasies vervang regulasie 35 van die regulasies.

Inwerkingtreding

4. Hierdie regulasies treë op **2 Mei 2003** in werking.

ME TSHABALALA-MSIMANG
MINISTER VAN GESONDHEID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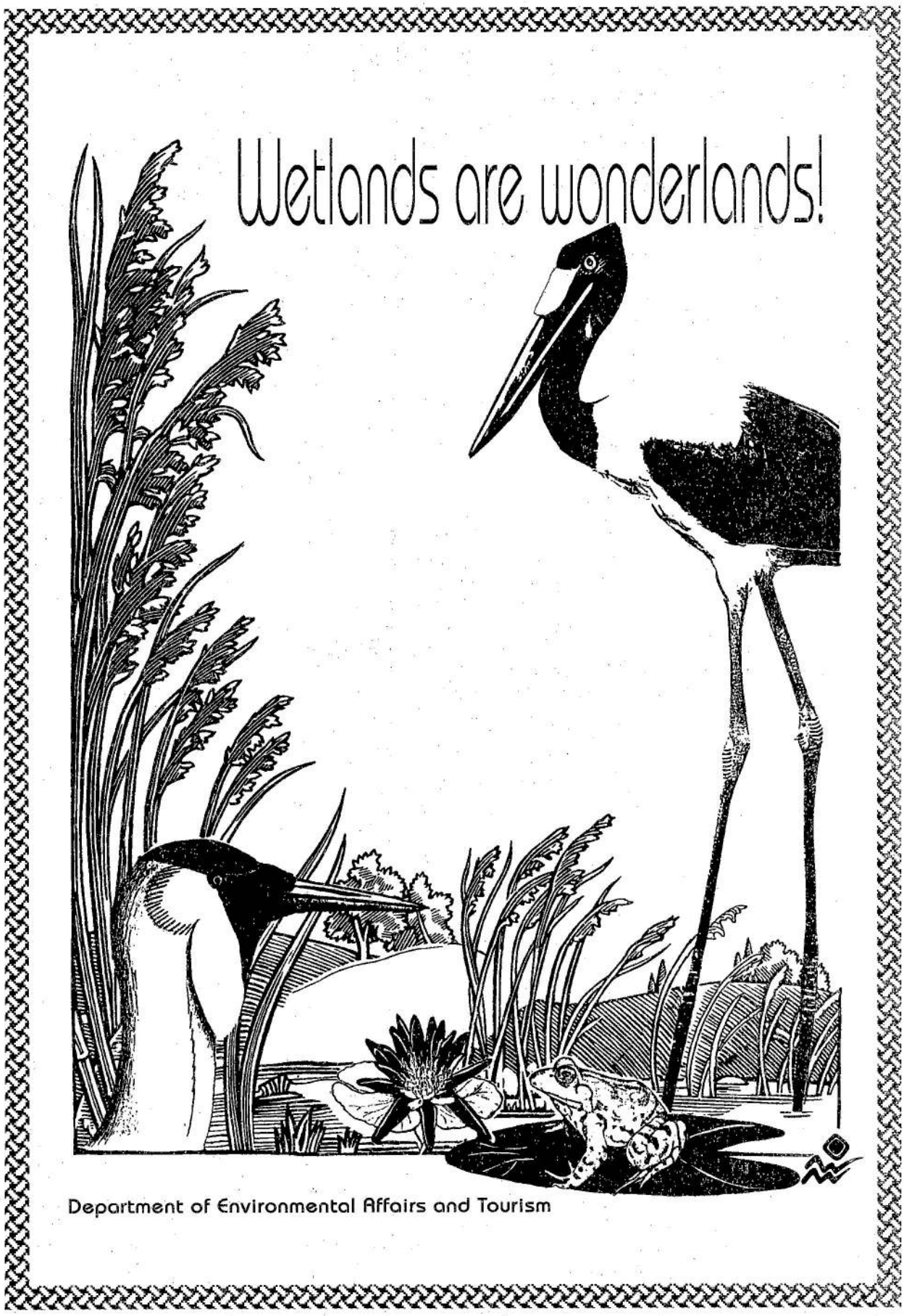
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