STAATSKOERANT
VAN DIE REPUBLIEK VAN SUID-AFRIKA

REPUBLIC OF SOUTH AFRICA
GOVERNMENT GAZETTE

REGULASIEKOERANT No. 2117
As 'n Nuusblad by die Poskantoor Geregistreer

PRYS 20c PRICE
OORSEE 30c OVERSEAS
POSVRY — POST FREE

REGULATION GAZETTE No. 2117
Registered at the Post Office as a Newspaper

VOL. 116] PRETORIA, 21 FEBRUARIE / 21 FEBRUARY 1975 [No. 4594

PROKLAMASIE

van die Staatspresident van die Republiek van Suid-Afrika

No. R. 52, 1975

DATUM VAN INWERKINGTREDING VAN—

(1) DIE WET OP APTEKERS, 1974 (WET 53 VAN 1974);
(2) DIE WET OP GENEESHERE, TANDARTSE EN AANVULLENDE GESONDHEIDSDIENSBEROEPE, 1974 (WET 56 VAN 1974); EN
(3) DIE WYSIGINGSWET OP DIE BEHEER VAN MEDISYNE, 1974 (WET 65 VAN 1974)

Kragtens die bevoegdheid my verleen by—

(i) artikel 53 van die Wet op Aptekers, 1974 (Wet 53 van 1974);

(ii) artikel 66 van die Wet op Geneeshere, Tandartse en Aanvullende Gesondheidsdiensberoepe, 1974 (Wet 56 van 1974); en

(iii) artikel 39 van die Wysigingswet op die Beheer van Medisyne, 1974 (Wet 65 van 1974);

verklaar ek hierby dat die bepalings van genoemde Wette op die datum van publikasie hiervan in werking tree.

Gegee onder my Hand en die Seël van die Republiek van Suid-Afrika te Kaapstad, op hede die Elfde dag van Februarie Eenduisend Negehonderd Vyf-en-sewentig.

J. J. FOUCHÉ, Staatspresident.

Op las van die Staatspresident-in-rade:

S. W. VAN DER MERWE.

PROCLAMATION

by the State President of the Republic of South Africa

No. R. 52, 1975

DATE OF COMMENCEMENT OF—

(1) THE PHARMACY ACT, 1974 (ACT 53 OF 1974);
(2) THE MEDICAL, DENTAL AND SUPPLEMENTARY HEALTH SERVICE PROFESSIONS ACT, 1974 (ACT 56 OF 1974); AND
(3) THE DRUGS CONTROL AMENDMENT ACT, 1974 (ACT 65 OF 1974)

Under the powers vested in me by—

(i) section 53 of the Pharmacy Act, 1974 (Act 53 of 1974);

(ii) section 66 of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974); and

(iii) section 39 of the Drugs Control Amendment Act, 1974 (Act 65 of 1974);

I hereby declare that the provisions of the said Acts shall come into operation on the date of publication hereof.

Given under my Hand and the Seal of the Republic of South Africa at Cape Town this Eleventh day of February, One thousand Nine hundred and Seventy-five.

J. J. FOUCHÉ, State President.

By Order of the State President-in-Council:

S. W. VAN DER MERWE.

GOEWERMENTSKENNISGEWINGS

DEPARTEMENT VAN GESONDHEID

No. R. 347 21 Februarie 1975

SUID-AFRIKAANSE APTEKERSRAAD

REGULASIES BETREFFENDE DIE PRAKTIESE OPLEIDING VAN 'N KWEKELING-APTEKER IN 'N LAND BUITE DIE REPUBLIEK

Die Minister van Gesondheid het kragtens artikel 49 (1) (p), gelees met artikel 20 (1) (b) van die Wet op Aptekers, 1974 (Wet 53 van 1974), die volgende regulasies op aanbeveling van die Suid-Afrikaanse Aptekersraad uitgevaardig:

1. 'n Persoon wat aan die vereistes vir 'n graad of 'n diploma in farmasie in die Republiek voldoen het, kan die praktiese opleiding in artikel 20 van die Wet op Aptekers, 1974 (Wet 53 van 1974), bepaal, in 'n apteek in Rhodesië wat vir dié doel deur die Mediese Raad van Rhodesië goedgekeur is, ondergaan.

2. 'n Persoon wat 'n Suid-Afrikaanse graad of diploma in farmasie besit en wat aansoek doen om registrasie as 'n apteker op grond van praktiese opleiding in Rhodesië voltooi, moet saam met sy aansoek 'n sertifikaat van die Registrateur van die Mediese Raad van Rhodesië indien te dien effekte dat hy op bevredigende wyse praktiese opleiding ondergaan het oor 'n tydperk van minstens een jaar kragtens die Mediese Raad se regulasies, en hy moet in alle ander opsigte aan die Aptekersraad se vereistes vir registrasie voldoen.

No. R. 348 21 Februarie 1975

REGULASIES BETREFFENDE REGISTERS VAN AANDEELHOUERS EN DIREKTEURE VAN REGSPERSONE WAT AS KLEINHANDELSAPTEKERS SAKE DOEN

Die Minister van Gesondheid het kragtens artikel 49 (1) (p) van die Wet op Aptekers, 1974 (Wet 53 van 1974), die volgende regulasies op aanbeveling van die Suid-Afrikaanse Aptekersraad uitgevaardig:

1. Die registrateur moet 'n register hou van direkteure van regspersone wat as kleinhandelsaptekers sake doen en 'n register van persone wat aandele in sodanige regspersone besit, waarin die volgende ingeskryf moet word:

(a) Die name en adresse van alle direkteure, hulle roepings of beroepe en die datum van hul aanstelling as direkteure; en

(b) die name en adresse van alle aandeelhouers, hulle roepings of beroepe en die datums waarop hulle aanvanklik 'n aandeelhouding in die regspersone verkry het.

2. Die regspersoon wat kragtens die Wet geregistreer is om as kleinhandelsapteker sake te doen, moet die registrateur binne 30 dae verwittig van—

(a) die naam van 'n aandeelhouer wat sy aandeel in sodanige regspersoon vervreem het; of

(b) die naam en adres van 'n nuwe aandeelhouer, sy roeping of beroep, en die datum waarop sodanige aandeelhouer sy aandeelhouding in sodanige regspersoon verkry het.

GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 347 21 February 1975

SOUTH AFRICAN PHARMACY BOARD

REGULATIONS RELATING TO THE PRACTICAL TRAINING OF A TRAINEE PHARMACIST IN A COUNTRY OUTSIDE THE REPUBLIC

The Minister of Health has, in terms of section 49 (1) (p) read with section 20 (1) (b) of the Pharmacy Act, 1974 (Act 53 of 1974), made the following regulations on the recommendation of the South African Pharmacy Board:

1. A person who has fulfilled the requirements for a degree or a diploma in pharmacy in the Republic may undergo the practical training prescribed in section 20 of the Pharmacy Act, 1974 (Act 53 of 1974), in a pharmacy in Rhodesia which has been approved for this purpose by the Medical Council of Rhodesia.

2. A person who holds a South African degree or diploma in pharmacy and who applies for registration as a pharmacist on the ground of practical training completed in Rhodesia shall submit with his application a certificate from the Registrar of the Medical Council of Rhodesia to the effect that he has undergone satisfactorily practical training extending over not less than one year in accordance with the Medical Council's regulations and he shall comply in all other respects with the Pharmacy Board's requirements for registration.

No. R. 348 21 February 1975

REGULATIONS RELATING TO REGISTERS OF SHAREHOLDERS AND DIRECTORS OF BODIES CORPORATE CARRYING ON BUSINESS AS RETAIL PHARMACISTS

The Minister of Health has, in terms of section 49 (1) (p) of the Pharmacy Act, 1974 (Act 53 of 1974), made the following regulations on the recommendation of the South African Pharmacy Board:

1. The registrar shall maintain a register of directors of bodies corporate which carry on business as retail pharmacists and a register of persons who hold shares in such bodies corporate, in which shall be entered the following:

(a) The names and addresses of all directors, their occupations or professions and the date of their appointment as directors; and

(b) the names and addresses of all shareholders, their occupations or professions and the dates on which they initially acquired a shareholding in the bodies corporate.

2. The body corporate registered under the Act to carry on business as a retail pharmacist shall inform the registrar within 30 days of—

(a) the name of any shareholder who has alienated his share in such body corporate; or

(b) the name and address of any new shareholder, his occupation or profession and the date on which such shareholder acquired his shareholding in such body corporate.

No. R. 349 21 Februarie 1975

REGULASIES BETREFFENDE DIE GELDE WAT INGEVOLGE DIE WET OP APTEKERS, 1974, AAN EN DEUR DIE RAAD BETAALBAAR IS

Die Minister van Gesondheid het kragtens artikel 49 (1) (d) van die Wet op Aptekers, 1974 (Wet 53 van 1974), op aanbeveling van die Suid-Afrikaanse Aptekersraad, die volgende regulasies uitgevaardig:

1. Die volgende gelde is aan die Raad betaalbaar:

(1) Aptekerstudente—

(a) registrasie as aptekerstudent: R5;

(b) inskrywingsgelde vir die Diploma in Farmasie-eksamens—

Farmasie I: R30;

Farmasie II: R35;

Farmasie III: R35;

Farmasie IV: R40;

(c) gelde vir hereksamen, egrotateksamen of spesiale eksamen: R15 per vak;

(d) geld vir vrystelling van eksamen: R10;

(e) uitreik van sertifikaat van kursusse voltooi: R2.

(2) Kwekeling-aptekers—

(a) inspeksiegeld (moet deur toesighoudende apteker betaal word): R15;

(b) registrasiegeld (moet deur kwekeling-apteker betaal word): R20;

(c) geld vir oordrag van kontrak (moet deur kwekeling-apteker betaal word): R15.

(3) Ongekwalifiseerde assistente—

(a) registrasie as 'n ongekwalifiseerde assistent: R10;

(b) geld vir terugplasing op die register van ongekwalifiseerde assistente: R2.

(4) Aptekers—

(a) registrasie as 'n apteker: R40;

(b) registrasie van 'n addisionele kwalifikasie: R5;

(c) uitreik van duplikaat-registrasiesertifikaat: R5;

(d) uitreik van gesertifiseerde uittreksel uit die register: R3;

(e) terugplasing van naam op die register—

(i) ná skrapping kragtens artikel 23 van die Wet: R20;

(ii) ná skrapping kragtens artikel 45 van die Wet: R40;

(f) jaargeld: R25.

(5) Regspersone—

(a) registrasiegeld vir regspersoon: R25;

(b) registrasiegeld vir besturende direkteur van regspersoon: R25;

(c) uitreiking van nuwe registrasiesertifikate nadat 'n regspersoon sy naam verander het—

(i) vir die regspersoon: R5;

(ii) vir die besturende direkteur: R5.

2. Die volgende gelde en toelaes word deur die Raad betaal:

(1) Eksaminatore se gelde—

(a) sentrale eksaminatore—

opstel van teorievraestelle: R40;

opstel van praktiese vraestelle: R12;

nasien van eksamenskrifte—per eksamenskrif, met 'n minimum van R3 per eksamen: 65c;

nasien van chemie-praktiese eksamenskrifte—per eksamenskrif, met 'n minimum van R4,20 per eksamen: 80c;

No. R. 349 21 February 1975

REGULATIONS RELATING TO THE FEES PAYABLE BY AND TO THE BOARD UNDER THE PHARMACY ACT, 1974

The Minister of Health has, in terms of section 49 (1) (d) of the Pharmacy Act, 1974 (Act 53 of 1974), on the recommendation of the South African Pharmacy Board, made the following regulations:

1. The following fees shall be payable to the Board:

(1) Pharmacy students—

(a) registration as a pharmacy student: R5;

(b) Diploma in Pharmacy examination entrance fees—

Pharmacy I: R30;

Pharmacy II: R35;

Pharmacy III: R35;

Pharmacy IV: R40;

(c) re-examination, aegrotat or special examination fees: R15 per subject;

(d) fee for exemption from examination: R10;

(e) issue of certificate of courses completed: R2.

(2) Trainee pharmacists—

(a) inspection fee (payable by the supervising pharmacist): R15;

(b) registration fee (payable by the trainee pharmacist): R20;

(c) cession of contract fee (payable by the trainee pharmacist): R15.

(3) Unqualified assistants—

(a) registration as an unqualified assistant: R10;

(b) fee for restoration to the register of unqualified assistants: R2.

(4) Pharmacists—

(a) registration as a pharmacist: R40;

(b) registration of an additional qualification: R5;

(c) issue of duplicate registration certificate: R5;

(d) issue of certified extract from the register: R3;

(e) restoration of name to the register—

(i) after erasure in terms of section 23 of the Act: R20;

(ii) after erasure in terms of section 45: R40;

(f) annual fee: R25.

(5) Bodies corporate—

(a) registration fee for body corporate: R25;

(b) registration fee for managing director of a body corporate: R25;

(c) issue of new certificates of registration after a body corporate has changed its name—

(i) for the body corporate: R5;

(ii) for the managing director: R5.

2. The following fees and allowances shall be paid by the Board:

(1) Examiners' fees—

(a) central examiners—

setting theory question paper: R40;

setting practical question paper: R12;

marking examination scripts—per script, with a minimum of R3 per examination: 65c;

marking chemistry practical examination scripts—per script, with a minimum of R4,20 per examination: 80c;

(b) moderatore—

interne teorie-eksamens (halwe kursusse)—

modereer van vraestelle en eksamenskrifte: R50;

interne praktiese eksamens—modereer van vraestelle: R6;

bywoning van praktiese eksamens—per sessie: R10;

(c) interne eksaminatore—

opstel van teorievraestelle: R12;

nasien van eksamenskrifte—per eksamenskrif, met 'n minimum van R3 per eksamen: 65c;

(d) praktiese farmaseutika-eksamens—

opstel van vraestelle in algemene reseptuur: R12;

eksterne eksamen in algemene reseptuur—interne en eksterne eksaminatore, per eksamenskrif: R1,10;

eksterne eksaminatore, bywoning van algemenereseptuureksamens—per sessie: R15;

farmaseutika-projekte—eksterne eksaminatore, mondelinge eksamens—per dag: R20;

plus, per kandidaat: 65c;
interne eksaminatore, per kandidaat: 65c.

(2) Program vir praktiese opleiding—

(a) aan persone aangestel om opleidingsapteke te inspekteer: R15;

(b) aan persone in paragraaf a hierbo genoem word vervoerkoste teen 10c per kilometer betaal vir die heen-en-weerreis na die apteek wat geïnspekteer moet word.

(3) Gelde en toelaes van lede van die Raad:

(a) (i) Die President ontvang, bo en behalwe enige ander toelae wat kragtens hierdie regulasies aan hom betaal word, 'n honorarium van R500 per jaar betaalbaar halfjaarliks agterna.

(ii) Die Voorsitter van die Onderwyskomitee en die Penningmeester ontvang elkeen, bo en behalwe enige ander toelae wat kragtens hierdie regulasies aan hulle betaal word, 'n honorarium van R300 per jaar, halfjaarliks agterna betaalbaar.

(b) (i) Aan 'n lid wat 'n vergadering van die Raad of 'n komitee van die Raad bywoon of wat andersins met die werksaamhede van die Raad besig is, word die volgende betaal:

(aa) Ledegelde teen R25 per dag, insluitende reistyd;

(bb) indien die duur van die vergadering of ander werksaamhede van die Raad verhoed dat hy dieselfde dag na sy tuiste terugkeer of, indien die lid die nag voor die vergadering of ander werksaamhede weg van sy tuiste moet deurbring, 'n verblyftoelae van R20 per dag, insluitende reistyd;

(cc) indien hy dieselfde dag na sy tuiste terugkeer, sy redelike klein uitgawes ten opsigte van verblyfkoste;

(dd) sy werklike uitgawes aan reisgeld, per lug, trein, bus of huurmotor of, indien hy sy motor in die afwesigheid van gerieflike openbare vervoer gebruik, 'n vervoertoelae teen 10c per kilometer: Met dien verstande dat aan 'n lid wat verkies om per motor te reis waar voldoende en gerieflike lug- of treindienste bestaan, die toepaslike lug- of treingeld, na gelang van die geval, vergoed word.

(ii) Betaling van ledegelde en verblyftoelae word soos volg bereken:

(aa) Vir die eerste dag of gedeelte van 'n dag, 'n volle dag se gelde en verblyftoelaes, en daarna, vir elke 12 uur of gedeelte daarvan, 'n halwe dag se gelde en verblyftoelae;

(b) moderators—

internal theory examinations (half-courses)—moderation of question papers and examination scripts: R50;

internal practical examinations—moderation of question papers: R6;

attendance at practical examinations—per session: R10;

(c) internal examiners—

setting theory paper: R12;
marking examination scripts—per script, with a minimum of R3 per examination: 65c;

(d) practical pharmaceutics examinations—

setting question papers in general dispensing: R12;
general dispensing external examination—internal and external examiners, per script: R1,10;

external examiners, attendance at general dispensing examination—per session: R15;

pharmaceutics projects—external examiners, oral examinations—per day: R20;
plus, per candidate: 65c;
internal examiners, per candidate: 65c.

(2) Practical training programme—

(a) to persons appointed to inspect training pharmacies: R15;

(b) persons referred to in paragraph (a) above shall be paid transport expenses at the rate of 10c per kilometre for travelling to and from the pharmacy to be inspected.

(3) Fees and allowances of members of the Board:

(a) (i) The President shall, in addition to any other allowance payable to him in terms of these regulations, receive an honorarium of R500 per annum, payable half-yearly in arrears.

(ii) The Chairman of the Education Committee and the Treasurer shall each, in addition to any other allowance payable to them in terms of these regulations, receive an honorarium of R300 per annum, payable half-yearly in arrears.

(b) (i) A member who attends a meeting of the Board or a committee af the Board or who is otherwise engaged in the business of the Board shall be paid—

(aa) membership fees at the rate of R25 per day, including travelling time;

(bb) if the duration of the meeting or other business of the Board prevents him from returning to his place of residence on the same day, or if the member must spend the night prior to the meeting or other business away from home, a subsistence allowance of R20 per day, including travelling time;

(cc) if he returns to his place of residence on the same day, his reasonable out of pocket expenses in respect of subsistence;

(dd) his actual expenditure on air, rail, bus and taxi fares, or, if he uses his motor car, in the absence of convenient public transport, a transport allowance at the rate of 10c per kilometre: Provided that a member who elects to travel by motor car when adequate and convenient air or rail services exist shall be refunded the appropriate air or rail fare, as the case may be.

(ii) Payment of membership fees and the subsistence allowance shall be calculated as follows:

(aa) For the first day or part of a day, a full day's fees and subsistence allowance, and thereafter, for every 12 hours or parts thereof, a half of a day's fees and subsistence allowance;

(bb) 'n lid se gelde en verblyftoelae word betaal vanaf die laaste tyd waarop daar redelikerwyse verwag kan word dat hy sy tuiste moet verlaat om 'n vergadering by te woon tot die vroegste tyd waarop hy kan reël om na sy tuiste terug te keer: Met dien verstande dat—

(i) wanneer die duur van 'n vergadering onseker is, 'n lid 'n redelike tyd ná afloop van 'n vergadering toegelaat word, maar hoogstens 24 uur, om 'n lug- of treinbespreking vir sy terugrit huis toe te verkry;

(ii) ledegelde nie ten opsigte van 'n Sondag betaalbaar is nie.

No. R. 350 21 Februarie 1975

DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

Die Minister van Gesondheid, vaardig hierby op aanbeveling van die Suid-Afrikaanse Geneeskundige en Tandheelkundige Raad, die volgende regulasies uit kragtens artikel 61 (1) (q) van die Wet op Geneeshere, Tandartse en Aanvullende Gesondheidsdiensberoepe, 1974 (Wet 56 van 1974):

REGULASIES VIR DIE VERKIESING VAN LEDE VAN DIE RAAD

Aanstelling van kiesbeampte en versoek om nominasies

1. Die President moet hoogstens ses maande en minstens vier maande voor die datum waarop die ampstermyn van lede verstryk, skriftelik 'n kiesbeampte aanstel. Indien die aangestelde kiesbeampte om een of ander rede nie as kiesbeampte kan optree nie of nie kan voortgaan om aldus op te tree nie, moet die President 'n ander persoon skriftelik as kiesbeampte aanstel.

2. Die kiesbeampte moet hoogstens ses maande en minstens vier maande voor die datum waarop die ampstermyn van lede verstryk by kennisgewing in die *Staatskoerant* in die vorm uiteengesit in die Eerste Aanhangsel van hierdie regulasies, die indiening van nominasies (gedurende 'n tydperk van minstens een maand na die verskyning van die kennisgewing) versoek.

3. Indien 'n verkose lid sy amp ontruim voor die einde van die ampstermyn van lede moet die kiesbeampte die kennisgewing bedoel in regulasie 2 binne een maand nadat sodanige lid sy amp ontruim het in die *Staatskoerant* publiseer.

Vereistes vir geldige nominasies

4. (1) Niemand is as lid verkiesbaar nie, tensy—

(a) hy as geneesheer of tandarts (na gelang van die geval) geregistreer is;

(b) hy 'n Suid-Afrikaanse burger en in die Republiek woonagtig is;

(c) 'n nominasie so na as moontlik in die vorm uiteengesit in die Tweede Aanhangsel van hierdie regulasies die kiesbeampte voor of op die uur en dag vir die ontvangs van nominasies ingevolge regulasie 2 bepaal, bereik;

(d) die nominasievorm die volle voorname en van van die genomineerde aangee en sodanige ander besonderhede as wat in die Tweede Aanhangsel vermeld of vereis word;

(e) die nominasievorm geteken is deur twee geneeshere (in die geval van die verkiesing van 'n geneesheer) of twee tandartse (in die geval van die verkiesing van 'n tandarts) wat in die Republiek woonagtig is;

(f) elke nominasievorm net een persoon as kandidaat nomineer;

(bb) a member's fees and subsistence allowance shall be paid from the latest time that he can reasonably be expected to leave his place of residence in order to attend a meeting until the earliest time that he can arrange to return to his place of residence: Provided that—

(i) when the duration of a meeting is uncertain, a member shall be allowed a reasonable time after the conclusion of the meeting, but not exceeding 24 hours, for securing an air or train reservation for his return home;

(ii) membership fees shall not be paid in respect of a Sunday.

No. R. 350 21 February 1975

THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

The Minister of Health, on the recommendation of the South African Medical and Dental Council, hereby makes the following regulations in terms of section 61 (1) (q) of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974):

REGULATIONS FOR THE ELECTION OF MEMBERS OF THE COUNCIL

Appointment of returning officer and request for nominations

1. The President shall in writing appoint a returning officer not more than six months and not less than four months prior to the date of expiry of the term of office of members. If the appointed returning officer is for any reason unable to act as returning officer or is unable to continue to act as such, the President shall in writing appoint some other person returning officer.

2. The returning officer shall not more than six months and not less than four months prior to the date of expiry of the term of office of members, by notice in the *Gazette* in the form set out in the First Annexure to these regulations, invite the submission of nominations (during a period of not less than one month after publication of the notice).

3. If an elected member vacates his office before the end of the term of office of members the returning officer shall publish the notice referred to in regulation 2 in the *Gazette* within one month after such member vacated his office.

Requirements for valid nominations

4. (1) No person shall be eligible for election as a member unless—

(a) he is registered as a medical practitioner or dentist (as the case may be);

(b) he is a South African citizen and is resident in the Republic;

(c) a nomination, as nearly as possible in the form set out in the Second Annexure to these regulations, reaches the returning officer not later than the hour and day appointed for the receiving of nominations in terms of regulation 2;

(d) the nomination form states the full first names and surname of the nominee and such other particulars as are mentioned in or required by the Second Annexure;

(e) the nomination form is signed by two medical practitioners (in the case of the election of a medical practitioner) or two dentists (in the case of the election of a dentist) who are resident in the Republic;

(f) each nomination form proposes only one person as a candidate;

(g) die genomineerde op die nominasievorm of per brief of telegram sy instemming tot die nominasie voor of op die datum in paragraaf (c) bedoel aan die kiesbeampte te kenne gegee het;

(h) 'n bedrag van R30 voor die datum in paragraaf (c) bedoel by die kiesbeampte gedeponeer word. Sodanige deposito word aan die kandidaat terugbetaal—

(i) as hy verkies word; of

(ii) indien 'n verkiesing deur stemming gehou is waarin hy 'n getal stemme gekry het wat gelyk is aan minstens een derde van die totale getal stemme wat enige suksesvolle kandidaat gekry het.

5. Iemand wat by 'n verkiesing stemgeregtig is, kan nominasievorms vir enige getal kandidate, wat die getal wat verkies moet word nie oorskry nie, onderteken, en sy handtekening is nietig en ongeldig op enige nominasievorms wat die kiesbeampte ontvang nadat die kiesbeampte nominasievorms wat so iemand onderteken het, ontvang het vir die volle getal kandidate wat verkies moet word: Met dien verstande dat indien die kiesbeampte 'n getal nominasievorms wat deur iemand onderteken is, ontvang, welke getal groter is as die getal kandidate wat verkies moet word en die kiesbeampte nie kan bepaal in watter chronologiese volgorde sodanige vorms ontvang is nie, so iemand se handtekening op alle nominasievorms wat hy onderteken het, nietig en ongeldig is.

6. By 'n verkiesing om 'n vakature te vul, word niemand geag geldig genomineer te wees nie as hy woonagtig is in 'n provinsie waarin die getal verkose lede wat gewoonlik daarin woonagtig is reeds gelykstaande is met die grootste getal wat die voorbehoudsbepaling van artikel 5 (1) (e) van die Wet vasstel.

7. 'n Genomineerde kan te eniger tyd voor die datum in regulasie 4 (1) (c) bedoel, die kiesbeampte skriftelik van die terugtrekking van sy kandidatuur verwittig. Na daardie datum word geen terugtrekking aanvaar nie.

Kennisgewing van verkiesing

8. (1) As die getal geldig genomineerde persone die getal persone wat verkies moet word nie oortref nie, word die aldus genomineerde persone geag behoorlik verkies te wees.

(2) As die getal geldig genomineerde persoon die getal persone oortref wat verkies moet word, moet die kiesbeampte so spoedig doenlik in die *Staatskoerant* 'n kennisgewing publiseer waarin—

(a) die name van die geldig genomineerde persone aangegee word; en

(b) 'n dag en uur vasgestel word (minstens een maand na verskyning van die kennisgewing) waarvoor elkeen wat geregtig is om by die verkiesing te stem die stembriefie in die Derde Aanhangsel van hierdie regulasies beskryf, kan teken en aan die kiesbeampte stuur of oorhandig.

Versending van stembriefies

9. (1) As 'n verkiesing deur stemming nodig word, moet die kiesbeampte minstens een maand voor die datum bedoel in regulasie 8 (2) (b), deur die pos na die geregistreerde adres van elkeen wat vir die verkiesing stemgeregtig is—

(a) 'n stembriefie stuur, so na as moontlik in die vorm aangedui in die Derde Aanhangsel van hierdie regulasies; vergesel van

(g) the nominee has signified to the returning officer his acceptance of the nomination on the nomination form or by letter or telegram not later than the date referred to in paragraph (c);

(h) an amount of R30 is deposited with the returning officer prior to the date referred to in paragraph (c). Such deposit shall be refunded to the candidate—

(i) if he is elected; or

(ii) if an election by vote was held and he received votes equal in number to at least one-third of the total number of votes received by any successful candidate.

5. A person eligible to vote in an election may sign nomination forms for any number of candidates not exceeding the number to be elected, and his signature shall be void and invalid on any nomination forms received by the returning officer after the returning officer has received nomination forms, signed by such person, for the full number of candidates to be elected: Provided that, if the returning officer receives a number of nomination forms signed by a person which number is greater than the number of candidates to be elected, and the returning officer cannot determine in which chronological sequence such forms were received, such person's signature shall be void and invalid on all nomination forms signed by him.

6. In an election to fill a vacancy no person shall be deemed to be validly nominated if he is resident in a province in which the number of elected members ordinarily resident therein is already equal to the largest number determined by the proviso to section 5 (1) (e) of the Act.

7. A nominee may at any time prior to the date referred to in regulation 4 (1) (c) notify the returning officer in writing of the withdrawal of his candidature. After such date no withdrawal shall be accepted.

Notice of election

8. (1) If the number of persons validly nominated does not exceed the number of persons to be elected, the persons so nominated shall be deemed to be duly elected.

(2) If the number of persons validly nominated exceeds the number of persons to be elected, the returning officer shall as soon as possible publish in the *Gazette* a notice—

(a) giving the names of the validly nominated persons; and

(b) appointing a day and hour (not less than one month after publication of the notice) before which every person entitled to vote in the election may sign and transmit or deliver to the returning officer the voting paper described in the Third Annexure to these regulations.

Transmission of voting papers

9. (1) If an election by vote becomes necessary, the returning officer shall, not less than one month prior to the date referred to in regulation 8 (2) (b), transmit by post to the registered address of every person eligible to vote in the election—

(a) a voting paper, as nearly as possible in the form set out in the Third Annexure to these regulations; accompanied by

(b) 'n identifikasiekoevert, so na as moontlik in die vorm aangedui in die Vierde Aanhangsel van hierdie regulasies;

en ingeval 'n aldus versende stembriefie of koevert verlore gaan of vernietig word of bederf word, moet hy, as hy van die verlies of vernietiging of bederwing oortuig is, en indien aldus versoek deur die persoon aan wie dit gestuur is, aan hom 'n nuwe stembriefie of koevert of albei stuur of oorhandig.

(2) Elke stembriefie en koevert ingevolge hierdie bepaling versend of oorhandig, moet op die betrokke verkiesing toepaslik wees, na gelang dit 'n verkiesing van 'n geneesheer of tandarts of beide is.

Wyse van stemming

10. (1) Elke kieser moet op die stembriefie wat hy ontvang het 'n kruis, aldus "X", maak teenoor die naam van elke kandidaat vir wie hy wil stem.

(2) 'n Kieser moet sy stembriefie in die identifikasiekoevert sit en die koevert verseël.

(3) 'n Kieser moet die verklaring beskryf in die Vierde Aanhangsel van hierdie regulasies, wat op die koevert verskyn, in teenwoordigheid van een getuie teken, wat ook op die koevert moet teken, die identifikasiekoevert in die omslagkoevert sit en dit deur die pos aan die kiesbeampte stuur of anders aan hom oorhandig.

(4) 'n Kieser word geag sy stembriefie te bederwe het en die stemme daarop word nie getel nie, as hy—

(a) vir meer kandidate stem as wat daar persone is wat gekies moet word;

(b) stem vir iemand wat nie geldig genomineer is nie;

(c) 'n merk of inskrywing op die stembrief maak waardeur hy geïdentifiseer kan word;

(d) meer as een maal vir dieselfde persoon stem of meer as een stembriefie terugstuur.

(5) Geen stem wat op 'n stembriefie uitgebring is, word getel nie, tensy die stembriefie, soos voormeld in die identifikasiekoevert ingesluit, op die bepaalde plek en voor die datum bedoel in regulasie 8 (2) (b) ontvang word.

Wyse van stemtelling

11. (1) Die kiesbeampte moet—

(a) die identifikasiekoeverte en die verklarings daarop ondersoek om te bepaal of die verklarings in ooreenstemming met die bepalings van hierdie regulasies voltooi is;

(b) so spoedig moontlik na die datum in regulasie 8 (2) (b) bedoel, en tesame met 'n stemopnemer deur die Minister benoemd, die identifikasiekoeverte wat na sy mening aan die bepalings van hierdie regulasies voldoen, oopmaak, en die stembriefies in 'n geslote stembus wat 'n opening vir die insit van die briefies het, plaas;

(c) die stembus oopmaak, die stembriefies ondersoek en die getal geldige stemme wat op elke kandidaat uitgebring is, vasstel.

(2) Die persone op wie die grootste aantal stemme uitgebring is, word [met inagneming van die bepalings van artikel 5 (1) (e) van die Wet] beskou as behoorlik verkose geneeskundige of tandheelkundige lede van die Raad (na gelang van die geval): Met dien verstande dat indien bevind word dat op twee of meer kandidate ewe veel stemme uitgebring is en dat die gelykheid van stemme die

(b) an identification envelope, as nearly as possible in the form set out in the Fourth Annexure to these regulations;

and in the event of any voting paper or envelope so transmitted being lost or destroyed or spoiled, he shall, if satisfied of the loss or destruction or spoiling, and if so requested by the person to whom it was transmitted, transmit or deliver to him a fresh voting paper or envelope, or both.

(2) Every voting paper or envelope transmitted or delivered under this provision shall apply to the particular election, according to whether the election is for a medical practitioner or dentist, or both.

Manner of voting

10. (1) Each voter shall mark upon the voting paper received by him a cross, thus "X", against the name of each candidate for whom he wishes to vote.

(2) A voter shall place the voting paper in the identification envelope and seal the envelope.

(3) A voter shall sign the declaration described in the Fourth Annexure to these regulations, which is on the envelope, in the presence of one witness, who shall also sign on the envelope, place the identification envelope in the covering envelope and transmit it by post to the returning officer or otherwise deliver it to him.

(4) A voter shall be deemed to have spoiled his voting paper, and the votes thereon shall not be counted, if he—

(a) votes for more candidates than there are persons to be elected;

(b) votes for a person who has not been validly nominated;

(c) makes a mark or inscription on the voting paper whereby he may be identified;

(d) votes more than once for the same person or returns more than one voting paper.

(5) No vote recorded on a voting paper shall be counted unless the voting paper, enclosed in the identification envelope as described above, is received at the appointed place and before the date referred to in regulation 8 (2) (b).

Manner of counting votes

11. (1) The returning officer shall—

(a) examine the identification envelopes and the declarations thereon to determine whether the declarations have been completed in accordance with the provisions of these regulations;

(b) as soon as possible after the date referred to in regulation 8 (2) (b), and in conjunction with a scrutineer appointed by the Minister, open the identification envelopes which in his opinion comply with the provisions of these regulations and place the voting papers into a closed ballot box which has an aperture for inserting the papers;

(c) open the ballot box, examine the voting papers and ascertain the number of valid votes recorded for each candidate.

(2) The persons for whom the greatest number of votes have been recorded [subject to the provisions of section 5 (1) (e) of the Act] shall be regarded as duly elected medical or dental members of the Council (as the case may be): Provided that, if the number of votes cast on two or more candidates is found to be equal

uitslag van die verkiesing beïnvloed, die kiesbeampte onmiddellik, in teenwoordigheid van die stemopnemer, deur die lot moet bepaal welke van die kandidate met 'n gelyke getal stemme verkose verklaar moet word.

(3) 'n Verkiesingskandidaat kan persoonlik of deur 'n verteenwoordiger skriftelik deur hom aangestel, aanwesig wees by die opening van die stembus en die daaropvolgende verrigtinge.

Bekendmaking van name van kandidate en aantal stemme op elkeen uitgebring en bewaring van stembriewe

12. So spoedig moontlik nadat die verkiesing beslis is, moet die kiesbeampte in die *Staatskoerant* die name van alle geldig genomineerde kandidate, die aantal stemme wat op elkeen uitgebring is en die name van die behoorlik verkose lede van die Raad bekendmaak.

13. Die kiesbeampte moet al die identifikasiekoeverte en stembriefies wat op 'n verkiesing betrekking het vir 'n tydperk van ses maande bewaar vanaf die datum waarop die stemme wat in daardie verkiesing uitgebring is, ingevolge regulasie 11 (1) (c) vasgestel is.

EERSTE AANHANGSEL

VERKIESINGSKENNISGEWING

VERKIESING VAN LID OF LEDE VAN DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

Hierby word ingevolge die bepalings van die regulasies vir die verkiesing van lede van die Raad kennis gegee dat 'n verkiesing gehou staan te word van*..... lid/lede van die Raad om te dien gedurende die tydperk wat op die .....dag van..... verstryk.

Nominasies van verkiesbare geneeshere/tandartse† word ingewag. Elke geregistreerde geneesheer/tandarts† (a) wat nie met sy skuldeisers 'n akkoord aangegaan het nie, of wie se boedel nie gesekwestreer is nie, (b) wat nie kragtens die Wet onbevoeg is om sy beroep te beoefen nie, (c) wat 'n Suid-Afrikaanse burger en in die Republiek (insluitende die gebied Suidwes-Afrika) woonagtig is‡, (d) wat nie 'n pasiënt is soos omskryf in artikel 1 van die Wet op Geestesgesondheid, 1973, nie, (e) wat nie aan 'n misdryf skuldig bevind is ten opsigte waarvan hy gevonnis is tot gevangenisstraf sonder die keuse van 'n boete nie, is nomineerbaar.

Elke kandidaat moet op 'n afsonderlike nominasievorm genomineer word maar elkeen wat by die verkiesing stemgeregtig is, kan die nominasievorms van enige aantal kandidate teken, dog nie meer as die getal wat verkies moet word nie.

Elke nominasievorm moet die voorname en die van van die genomineerde kandidaat aangee en moet geteken wees deur twee geregistreerde geneeshere/tandartse†. Die genomineerde persoon moet ook die vorm onderteken ter bekragtiging van sy instemming tot sy nominasie. Die geregistreerde adres van elkeen wat aldus teken, moet by sy handtekening gevoeg wees. As die genomineerde persoon nie in staat is om die nominasievorm te teken nie, kan hy die kiesbeampte per brief of telegram meedeel dat hy tot sy nominasie instem.

Elke nominasievorm moet die ondergetekende voor of op§ .....by onderstaande adres bereik, van wie nominasievorms op aanvraag verkry kan word.

'n Deposito van R30 moet die nominasie vergesel.

Elke nominasievorm ten opsigte waarvan een van hierdie bepalings nie nagekom is nie of wat nie teen voormelde datum by onderstaande adres ontvang is nie, is ongeldig.

.....
Kiesbeampte

Adres.....

Datum.....

* Vul hier in hoeveel lede verkies moet word en vermeld ook of hulle geneeskundige of tandheelkundige lede is.

† Die kennisgewing moet op die betrokke verkiesing toepaslik wees, na gelang dit 'n verkiesing van 'n geneesheer of tandarts of beide is.

‡ By 'n verkiesing om 'n vakature te vul en indien die voorbehoudsbepaling by artikel 5 (1) (e) geld, moet die kennisgewing aandui in welke provinsie 'n kandidaat woonagtig moet wees om geldig genomineer te wees.

§ Meld uur en dag.

and that this equality of votes affects the result of the election, the returning officer shall immediately determine by lot, in the presence of the scrutineer, which of the candidates with an equal number of votes shall be declared elected.

(3) A candidate for election may be present in person or by a representative appointed in writing by him at the opening of the ballot box and the subsequent proceedings.

Publication of names of candidates and number of votes recorded for each and keeping of voting papers

12. As soon as possible after the election has been determined, the returning officer shall publish in the *Gazette* the names of all the candidates validly nominated, the number of votes recorded for each candidate and the names of the duly elected members of the Council.

13. The returning officer shall keep all the identification envelopes and voting papers applicable to an election for a period of six months from the date on which the votes recorded in that election were ascertained in terms of regulation 11 (1) (c).

FIRST ANNEXURE

NOTICE OF ELECTION

ELECTION OF MEMBER OR MEMBERS OF THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

Notice is hereby given in terms of the provisions of the regulations for the election of members of the Council that an election of*..... member/members of the Council to serve during the period ending the..... day of ..... is about to be held.

Nominations of eligible medical practitioners/dentists† are awaited. Every registered medical practitioner/dentist† (a) who has not entered into a composition with the creditors of his estate, or whose estate has not been sequestrated, (b) who is not disqualified under the Act from practising his profession, (c) who is a South African citizen and is resident in the Republic (including the Territory of South-West Africa)‡, (d) who is not a patient as defined in section 1 of the Mental Health Act, 1973, (e) who has not been convicted of an offence in respect whereof he was sentenced to imprisonment without the option of a fine, is eligible for nomination.

Each candidate must be nominated on a separate nomination form, but any person entitled to vote in the election may sign the nomination forms of any number of candidates not exceeding the number to be elected.

Each nomination form must state the first names and the surname of the candidate nominated and must be signed by two registered medical practitioners/dentists†. The person nominated must also sign the form, confirming that he consents to his nomination. The registered address of each one so signing must be appended to his signature. If the person nominated is unable to sign the nomination form he may inform the returning officer by letter or telegram that he consents to his nomination. Every nomination form must reach the undersigned at the address given below not later than §..... ....., from whom nomination forms may be obtained on application.

A deposit of R30 must accompany the nomination.

Every nomination form in respect of which any of these provisions has not been complied with, or which is not received by the aforesaid date at the address given below, will be invalid.

.....
Returning officer

Address.....

Date.....

* Here insert how many members are to be elected and state also whether medical or dental members.

† The notice must apply to the particular election, according to whether it is an election of a medical practitioner or dentist or both.

‡ At an election to fill a vacancy and if the proviso to section 5 (1) (e) obtains, the notice must indicate in which province a candidate must be resident in order to be validly nominated.

§ State hour and day.

TWEEDE AANHANGSEL

NOMINASIEVORM

VERKIESING VAN 'N LID VAN DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

Ons, die ondergetekendes, geregistreerde*....., nomineer hierby†..... wat 'n Suid-Afrikaanse burger is en in die Republiek (insluitende die gebied Suidwes-Afrika) woonagtig is as 'n kandidaat vir verkiesing tot lid van die Raad by die aanstaande verkiesing.

(1) Handtekening.....
Voorname en van (in blokletters).....
Geregistreerde adres.....
Geteken in teenwoordigheid van‡.....
Handtekening.....
Handtekening.....
(2) Handtekening.....
Voorname en van (in blokletters).....
Geregistreerde adres.....
Geteken in teenwoordigheid van‡.....
Handtekening.....
Handtekening.....

Ek, die ondergetekende, stem hierby in tot my nominasie as 'n kandidaat vir verkiesing tot lid van die Suid-Afrikaanse Geneeskundige en Tandheelkundige Raad.

.....
Handtekening

* Vermeld hier geneesheer of tandarts.
† Voorname en van en geregistreerde adres.
‡ Daar moet twee getuies by elke handtekening wees.
L.W.—Die adresse in hierdie vorm vermeld, moet in elke geval ooreenstem met die adresse soos geregistreer by die Raad.

DERDE AANHANGSEL

STEMBRIEF

VERKIESING VAN *GENEESKUNDIGE/TANDHEELKUNDIGE LID OF LEDE VAN DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

Amptelike merk van kiesbeampte

Verkiesing van †..... lid/lede.

Kolom vir kieser se merk "X"	Name van kandidate‡	Geregistreerde adresse	Geregistreerde kwalifikasies	Provinsie waar kandidate woonagtig is
				Kaap die Goeie Hoop
				Natal
				Oranje-Vrystaat
				Transvaal

INSTRUKSIES AAN KIESERS

Die kieser is geregtig om te stem vir †..... kandidate en nie meer nie, en moet stem deur sy merk, aldus "X", te maak teenoor die naam van elke kandidaat op wie hy sy stem uitbring.

Nie meer as twee van die geneeshere wat verkies word, moet gewoonlik in dieselfde provinsie woonagtig wees nie.

Nie meer as een tandarts wat verkies word, moet gewoonlik in dieselfde provinsie woonagtig wees nie.

'n Stembrief is ongeldig as die kieser—

(a) vir meer as †..... kandidate stem; of

SECOND ANNEXURE

NOMINATION FORM

ELECTION OF A MEMBER OF THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

We, the undersigned, registered*..... hereby nominate†....., who is a South African citizen and resident in the Republic (including the Territory of South-West Africa), as a candidate for election as a member of the Council at the forthcoming election.

(1) Signature.....
First names and surname (in block letters).....
Registered address.....
Signed in the presence of‡
Signature.....
Signature.....
(2) Signature.....
First names and surname (in block letters).....
Registered address.....
Signed in the presence of‡
Signature.....
Signature.....

I, the undersigned, hereby consent to my nomination as a candidate for election as a member of the South African Medical and Dental Council.

.....
Signature

* Here state whether medical practitioner or dentist.
† First names and surname and registered address.
‡ There must be two witnesses to each signature.
N.B.—The addresses given in this form must in every case correspond with the addresses as registered with the Council.

THIRD ANNEXURE

VOTING PAPER

ELECTION OF MEDICAL/DENTAL MEMBER OR MEMBERS OF THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

Official mark of returning officer

Election of†..... member/members.

Column for voter's mark "X"	Names of candidates‡	Registered addresses	Registered qualifications	Province where candidate is resident
				Cape of Good Hope
				Natal
				Orange Free State
				Transvaal

INSTRUCTIONS TO VOTERS

The voter is entitled to vote for†..... candidates and no more, and must vote by placing his mark, thus "X", opposite the name of each candidate for whom he votes.

Not more than two medical practitioners elected shall be ordinarily resident in the same province.

Not more than one dentist elected shall be ordinarily resident in the same province.

A voting paper is invalid if the voter—

(a) votes for more than†..... candidates; or

(b) stem vir iemand wat nie geldig genomineer is nie; of
(c) op die stembriefie 'n merk of inskrywing maak waardeur hy geïdentifiseer kan word; of
(d) meer as een stem op dieselfde kandidaat uitbring; of
(e) meer as een stembriefie terugstuur; of
(f) sy stembriefie anders terugstuur as in die "Identifikasiekoevert", met die verklaring daarop behoorlik ingevul.

Hierdie briefie moet gevou en ingesluit word in bygaande "Identifikasiekoevert", wat verseël moet word en dan ingesluit moet word in 'n omslagkoevert, wat gestuur moet word aan §..... en wel so, dat dit hom voor of op die ‖.....dag van ..... bereik.

* Die stembrief moet op die betrokke verkiesing toepaslik wees, na gelang dit 'n verkiesing van 'n geneesheer of tandarts is.
† Die getal kandidate wat verkies moet word, moet hier vermeld word.
‡ Die name van alle geldig genomineerde kandidate moet in alfabetiese volgorde (volgens van) in hierdie kolom vermeld word.
§ Naam en adres van kiesbeampte.
‖ Die datum bepaal in die Eerste Aanhangsel.

VIERDE AANHANGSEL

VORM VAN VERKLARING OP IDENTIFIKASIEKOEVERT

DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

Ek *....., verklaar hierby dat—

(a) ek die persoon is aan wie die ingeslote stembrief geadresseer is,
(b) ek 'n geneesheer/tandarts† is wat by die Raad geregistreer is,
(c) ek in die Republiek of die gebied Suidwes-Afrika woonagtig is,
.....,
(d) my identiteitsno./persoonsno./bewysboekno. die volgende is:
.....,
(e) ek geen ander stembriefie in hierdie verkiesing teruggestuur het nie.

Handtekening.....
Geregistreerde adres.....
Geteken in teenwoordigheid van ‡.....
Handtekening.....

* Voorname, van en adres in blokletters.
† Skrap wat nie van toepassing is nie.
‡ Daar moet een getuie wees.

No. R. 351 21 Februarie 1975

DIE SUID-AFRIKAANSE GENEESKUNDIGE EN TANDHEELKUNDIGE RAAD

Die Minister van Gesondheid vaardig hierby op aanbeveling van die Suid-Afrikaanse Geneeskundige en Tandheelkundige Raad, die volgende regulasies uit kragtens artikel 61 (1) (e) van die Wet op Geneeshere, Tandartse en Aanvullende Gesondheidsdiensberoepe, 1974 (Wet 56 van 1974):

REGULASIES BETREFFENDE DIE GELDE WAT KRAGTENS DIE WET BETAALBAAR IS

Die volgende gelde is ingevolge die Wet betaalbaar:

Registrasie as geneesheer of tandarts—
kragtens artikel 24 of 25: R50;
kragtens artikel 26 of 30: R25.

Registrasie as intern: R10.

Registrasie as sielkundige: R10.

Registrasie van spesialiteit deur geneesheer of tandarts: R50.

Registrasie van addisionele kwalifikasie—
deur geneesheer of tandarts: R5;
deur sielkundige: R5;
deur lid van aanvullende gesondheidsdiensberoep: R5.

Vrystelling kragtens artikel 27 of 28 van beperkings—
geneesheer of tandarts: R25.

(b) votes for a person who has not been validly nominated; or
(c) places any mark or inscription on the voting paper by which he may be identified; or
(d) gives more than one vote for the same candidate; or
(e) returns more than one voting paper; or
(f) returns his voting paper otherwise than in the "Identification envelope", with the declaration thereon duly completed.

This paper must be folded and placed in the accompanying Identification envelope", which must be sealed and then placed in a covering envelope, which must be sent to §..... so as to reach him not later than the ‖.....day of.....

* The voting paper must apply to the particular election, according to whether it is an election of a medical practitioner or dentist.
† Number of candidates to be elected to be stated here.
‡ The names of all validly nominated candidates to be stated in alphabetical order (according to surname) in this column.
§ Name and address of returning officer.
‖ The date appointed in the First Annexure.

FOURTH ANNEXURE

FORM OF DECLARATION ON IDENTIFICATION ENVELOPE

THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

I,*....., hereby declare that—

(a) I am the person to whom the enclosed voting paper was addressed,

(b) I am a medical practitioner/dentist† who is registered with the Council,

(c) I am resident in the Republic or the Territory of South-West Africa,

(d) my identity No./reference book No. is the following,

(e) I have not returned any other voting paper in this election

Signature.....
Registered address.....
Signed in the presence of‡.....
Signature.....

* First names, surname and address in block letters.
† Delete the words not applicable.
‡ There must be one witness.

No. R. 351 21 February 1975

THE SOUTH AFRICAN MEDICAL AND DENTAL COUNCIL

The Minister of Health, on the recommendation of the South African Medical and Dental Council, hereby makes the following regulations in terms of section 61 (1) (e) of the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act 56 of 1974):

REGULATIONS REGARDING THE FEES PAYABLE UNDER THE ACT

The following fees are payable under the Act:

Registration as a medical practitioner or a dentist—
under section 24 or 25: R50;
under section 26 or 30: R25.

Registration as an intern: R10.

Registration as a psychologist: R10.

Registration of speciality by medical practitioner or dentist: R50.

Registration of additional qualifications—
by medical practitioner or dentist: R5;
by psychologist: R5;
by member of supplementary health service profession: R5.

Exemption under section 27 or 28 from restrictions—
medical practitioner or dentist: R25.

Terugplasing van 'n naam op 'n register kragtens artikel 19—

geneesheer of tandarts: R25;

sielkundige: R5;

lid van aanvullende gesondheidsdiensberoep: R5.

Terugplasing van 'n naam op 'n register kragtens artikel 42 of 51—

geneesheer of tandarts: R50;

sielkundige: R10;

lid van aanvullende gesondheidsdiensberoep: R10.

Terugplasing van 'n spesialiteit of 'n addisionele kwalifikasie kragtens artikel 35—

geneesheer of tandarts: R2.

Uitreiking van 'n sertifikaat van status of 'n gesertifiseerde uittreksel uit die register of 'n sertifikaat soos bepaal in artikel 22 of 'n duplikaatregistrasiesertifikaat—

geneesheer of tandarts: R5;

sielkundige: R2;

lid van aanvullende gesondheidsdiensberoep: R2.

No. R. 352 21 Februarie 1975

WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965

Die Minister van Gesondheid het kragtens artikel 35 (1) en (3) (b) van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965), die volgende regulasies uitgevaardig:

Woordomskrywing

1. Tensy uit die samehang anders blyk, beteken die uitdrukking "die Wet" die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965), en het elke uitdrukking waaraan in die Wet 'n betekenis geheg is, die betekenis aldus daaraan geheg, en beteken—

"applikant" die persoon deur of ten behoewe van wie aansoek om die registrasie van 'n medisyne gedoen word;

"vervaardig" maak, berei, verwerk en, uitgesonderd in regulasie 7 (g) en die aansoekvorm bedoel in regulasie 15 en die aanhangsels daarvan, ook verpak, en het "vervaardiger" en "vervaardigingsproses" ooreenstemmende betekenisse;

"lot", met betrekking tot 'n medisyne, 'n bepaalde hoeveelheid van die medisyne waarvan die eienskappe eenvormig is;

"lotnommer" 'n nommer of ander letterteken toegeken aan 'n medisyne deur die vervaardiger daarvan, met behulp waarvan die volledige vervaardigingsproses van die medisyne in enige bepaalde pakket van sodanige medisyne en die oorsprong van alle grondstowwe wat in die vervaardigingsproses gebruik is, nagegaan kan word;

"verstrykingsdatum", met betrekking tot enige lot van 'n medisyne, die datum tot wanneer die medisyne in daardie lot die sterkte en ander eienskappe aangedui op die etiket sal behou en wat deur die applikant op die etiket aangedui moet word met betrekking tot elke pakket bevattende medisyne van daardie lot waarvan die sterkte of enige ander eienskap met verloop van tyd kan verander, en die datum waarna die medisyne nie meer aan die publiek verkoop mag word nie;

"buite-etiket", met betrekking tot 'n medisyne, 'n etiket soos by die Wet voorgeskryf en aangeheg aan 'n karton, omslag of pakket waarin die onmiddellike houer van 'n medisyne verpak is;

"voubiljet" 'n pamflet waarop die besonderhede voorgeskryf in regulasie 10 gedruk is;

Restoration of a name to a register under section 19—

medical practitioner or dentist: R25;

psychologist: R5;

member of supplementary health service profession: R5.

Restoration of a name to a register under section 42 or 51—

medical practitioner or dentist: R50;

psychologist: R10;

member of supplementary health service profession: R10.

Restoration of a speciality or an additional qualification under section 35—

medical practitioner or dentist: R2.

Issue of a certificate of status or a certified extract from the register or a certificate as provided in section 22 or a duplicate registration certificate—

medical practitioner or dentist: R5;

psychologist: R2;

member of supplementary health service profession: R2.

No. R. 352 21 February 1975

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965

The Minister of Health has, in terms of section 35 (1) and (3) (b) of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), made the following regulations:

Definitions

1. Unless the context otherwise indicates the expression "the Act" shall mean the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), and any expression which is defined in the Act shall have the same meaning as in the Act, and further—

"applicant" means the person by or on whose behalf application for registration of a medicine is made;

"manufacture" means make, compound, process and, except in regulation 7 (g) and the application form provided for in regulation 15 and the annexures thereto, also pack, and "manufacturer" and "manufacturing process" have corresponding meanings;

"batch", in relation to any medicine, means a particular quantity of the medicine which has homogeneous properties;

"batch number" means the number or other cypher allocated to a medicine by the manufacturer thereof from which it is possible to determine the complete manufacturing process of the medicine and the origin of all the raw materials used in the manufacture of any specific package of such medicine;

"expiry date", in relation to any batch of a medicine, means the date up to which a medicine in that batch will retain the strength and other properties which are mentioned on the label and which must be stated on the label by the applicant in relation to every package containing medicines of that batch of which the strength or any other property can change after lapse of time and the date after which the medicine shall not be sold to the public;

"outer label", in relation to any medicine, means a label as prescribed by the Act which is affixed to a carton, wrapper or package in which the immediate container of a medicine is packed;

"package insert" means a pamphlet on which is printed the particulars as prescribed in regulation 10;

"sakeadres", met betrekking tot 'n besigheid wat in die Republiek of in die Gebied gedryf word, die volledige adres van die perseel waar daardie besigheid gedryf word; en

"land van herkoms", met betrekking tot 'n medisyne, die land waar die basiese navorsing in verband met die vervaardiging van dié medisyne onderneem is.

Aansoek om registrasie van 'n medisyne

2. Aansoek om registrasie van 'n medisyne kan gedoen word deur—

(a) 'n apteker; of

(b) 'n regspersoon wat as apteker sake doen kragtens artikel 22 van die Wet op Aptekers, 1974 (Wet 53 van 1974), of iemand wat deur sodanige regspersoon gemagtig is om namens hom aansoek te doen; of

(c) in die geval van 'n medisyne vervaardig deur 'n persoon wat beskik oor 'n permit uitgereik kragtens die bepalings van artikel 22A (13) van die Wet, daardie persoon.

3. Elke aansoek om registrasie van 'n medisyne wat onmiddellik voor 5 Julie 1968 in die Republiek of die Gebied vir verkoop beskikbaar was, moet in enkelvoud, en elke aansoek om registrasie van 'n medisyne wat nie onmiddellik voor 5 Julie 1968 in die Republiek of die Gebied vir verkoop beskikbaar was nie, in veertigvoud, op die vorm kragtens regulasie 15 voorgeskryf, saam met die voorgeskrewe registrasiegeld, by die Registrateur van Medisyne, Privaatsak X88, Pretoria, 0001, ingedien word.

Die klassifikasie van medisyne

4. Vir registrasiedoeleindes moet alle medisyne ingedeel word in die volgende twee basiese kategorieë:

(a) *Kategorie A.*—Medisyne wat sonder verdere verwerking gereed is vir toediening, met inbegrip van verpakte preparate waar slegs 'n basis by die effektiewe medisyne of medisynes gevoeg word.

(b) *Kategorie B.*—Medisyne wat nie normaalweg as sodanig sonder verdere verwerking gereed is vir toediening nie.

5. Beide Kategorieë A en B moet vir dieselfde doel verder op grond van hul vernaamste farmakologiese doel of terapeutiese effek in die volgende klasse onderverdeel word:

Farmakologiese klassifikasie

1. *Stimulante vir sentrale senuweestelsel.*

1.1 Sentrale analeptika.
1.2 Psigo-analeptika (wekmiddels).
1.3 Spesiale wekmiddelsamestellings.
1.4 Asemhalingstimulante.
1.5 Hallusinogene middels.

2. *Depressante van sentrale senuweestelsel.*

2.1 Narkosemiddels.
2.2 Kalmeermiddels, slaapmiddels.
2.3 Barbiturate.
2.4 Nie-barbiturate.
2.5 Stuipweermiddels met inbegrip van epilepsieweermiddels.
2.6 Bedaarmiddels (berustingsmiddels).
2.6.1 Fenotiasiene en derivate daarvan.
2.6.2 Rauwolfia: alkaloïede en samestellings daarvan.
2.6.3 Difenielmetaan en derivate daarvan.
2.6.4 Alkieldiole en derivate daarvan.
2.6.5 Diverse strukture.
2.7 Narkotiese analgetika.
2.8 Nie-narkotiese analgetika, antipirektika (koorsweermiddels).
2.9 Spesiale analgetiese samestellings.
2.10 Sentraalwerkende spierverslappers.

"business address", in relation to a business which is carried on in the Republic or in the Territory, means the full address of the premises where that business is carried on; and

"country of origin", in relation to a medicine, means the country where the basic research in connection with the manufacture of the particular drug was undertaken.

Application for registration of a medicine

2. Application for registration of a medicine may be made by—

(a) a pharmacist; or

(b) a body corporate which carries on business as a pharmacist in terms of section 22 of the Pharmacy Act, 1974 (Act 53 of 1974), or a person authorised by such body corporate to apply on its behalf; or

(c) in the case of a medicine which is manufactured by a person who is the holder of a permit issued under the provisions of section 22A (13) of the Act, that person.

3. Every application for the registration of a medicine which was available for sale in the Republic or the Territory immediately prior to 5 July 1968 shall be submitted in single copy and 40 copies of every application for the registration of a medicine which was not available for sale in the Republic or the Territory immediately prior to 5 July 1968 shall be submitted on the form prescribed by regulation 15, together with the prescribed registration fee, to the Registrar of Medicines, Private Bag X88, Pretoria, 0001.

The classification of medicines

4. For the purpose of registration all medicines shall be divided into the following two basic categories:

(a) *Category A.* — Medicines which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine or medicines.

(b) *Category B.*—Medicines which cannot normally be administered without further manipulation.

5. Both Categories A and B shall for the same purpose be further subdivided into the following classification based on their principal pharmacological purpose or therapeutic effect:

Pharmacological classification

1. *Central nervous system stimulants.*

1.1 Central analeptics.
1.2 Psychoanaleptics (antidepressants).
1.3 Special antidepressant combinations.
1.4 Respiratory stimulants.
1.5 Hallucinogenic medicines.

2. *Central nervous system depressants.*

2.1 Anaesthetics.
2.2 Sedatives, hypnotics.
2.3 Barbiturates.
2.4 Non-barbiturates.
2.5 Anticonvulsants, including anti-epileptics.
2.6 Tranquillisers.
2.6.1 Phenothiazines and derivatives.
2.6.2 Rauwolfia: Alkaloids and combinations.
2.6.3 Diphenylmethane and its derivatives.
2.6.4 Alkyldiols and their derivatives.
2.6.5 Miscellaneous structures.
2.7 Narcotic analgesics.
2.8 Non-narcotic analgesics, antipyretics.
2.9 Special analgesic combinations.
2.10 Centrally active muscle relaxants.

3. *Bindweefselmiddels.*

3.1 Rumatiekmiddels (anti-inflammatoriese middels).
3.2 Hormoonvrye preparate.
3.3 Jigpreparate.
3.4 Samestellings bevattende kortikosteroïede (skorshormone).

4. *Plaaslike anestetika.*

5. *Middels met uitwerking op outonome funksies.*

5.1 Adrenomimetika (simpatomimetika).
5.2 Adrenolitika (simpatolitika).
5.3 Cholinominetika (cholinergiese middels).
5.4 Cholinolitika (anticholinergiese middels).
5.4.1 Preparate teen Parkinsonisme.
5.4.2 Algemeen.
5.5 Ganglionblokkeermiddels.
5.6 Histamine.
5.7 Antihistaminika, anti-emetika en antivertigomiddels.
5.7.1 Antihistaminika.
5.7.2 Anti-emetika en antivertigopreparate.
5.8 Verkouemiddels, insluitende neusontstoppingsmiddels en antihistaminika.
5.9 5-hidroksitriptamien (serotonien).
5.10 Serotonien-antagoniste.

6. *Hartmiddels.*

6.1 Hartstimulante.
6.2 Hartdepressante.
6.3 Hartglikosiede.

7. *Vaskulêre middels.*

7.1 Vasodilators (vaatverwyders), hipotensiewe middels.
7.1.1 Rauwolfia en samestellings daarvan.
7.1.2 Rauwolfia: diuretiese samestellings daarvan.
7.1.3 Ander hipotensiewe middels.
7.1.4 Koronêre vasodilators (kroonvaatverwyders) en ander middels vir gebruik teen angina pectoris.
7.1.5 Perifere vasodilators.
7.2 Vasokonstriktors (vaatvernouers), pressormiddels.
7.3 Migraine-preparate.
7.4 Lipotropiese middels.
7.5 Anti-serumcholesterolmiddels.

8. *Middels met uitwerking op bloed en hemopoietiese stelsel.*

8.1 Bloedstolmiddels, bloedstelpmiddels (hemostatika).
8.2 Antistolmiddels.
8.3 Eritropoïetika.
8.4 Plasma-aanvullers.

9. *Anti-alkoholismemiddels.*

10. *Middels met uitwerking op asemhalingstelsel.*

10.1 Hoesonderdrukkers en slymmiddels.
10.2 Brongodilators.
10.2.1 Inasemmiddels.
10.2.2 Ander.

11. *Middels met uitwerking op maagdermkanaal.*

11.1 Spysverteringsmiddels.
11.2 Maagdermkanaal: spasmolitiese en cholinolitiese middels (anticholinergiese middels).
11.3 Eetlusdempers.
11.3.1 Ander.
11.4 Teensure.
11.4.1 Suurneutraliseerders.
11.4.2 Suurneutraliseerders met spasmolitika.
11.4.3 Ander.
11.5 Lakseermiddels.
11.6 Smeermiddels en ontlastingversagters
11.7 Galdrywers.
11.8 Setpille en anale salwe.
11.9 Diarreemiddels.

3. *Connective tissue medicines.*

3.1 Antirheumatics (anti-inflammatory agents).
3.2 Non-hormonal preparations.
3.3 Antigout preparations.
3.4 Combinations with corticosteroids.

4. *Local anaesthetics.*

5. *Medicines affecting autonomic functions.*

5.1 Adrenomimetics (sympathicomimetics).
5.2 Adrenolytics (sympathicolytics).
5.3 Cholinomimetics (cholinergics).
5.4 Cholinolytics (anticholinergics).
5.4.1 Anti-Parkinsonism preparations.
5.4.2 General.
5.5 Ganglion blockers.
5.6 Histamine.
5.7 Antihistaminics, anti-emetics and antivertigo preparations.
5.7.1 Antihistaminics.
5.7.2 Anti-emetics and antivertigo preparations.
5.8 Preparations for the common cold including nasal decongestants and antihistaminics.
5.9 5-hydroxytryptamine (serotonin).
5.10 Serotonin antagonists.

6. *Cardiac medicines.*

6.1 Cardiac stimulants.
6.2 Cardiac depressants.
6.3 Cardiac glycosides.

7. *Vascular medicines.*

7.1 Vasodilators, hypotensive medicines.
7.1.1 Rauwolfia and combinations.
7.1.2 Rauwolfia: Diuretic combinations.
7.1.3 Other hypotensives.
7.1.4 Vasodilators — coronary and other medicines used in angina pectoris.
7.1.5 Vasodilators—peripheral.
7.2 Vasoconstrictors, pressor medicines.
7.3 Migraine preparations.
7.4 Lipotropic agents.
7.5 Serum-cholesterol reducers.

8. *Medicines acting on blood and haemopoietic system.*

8.1 Caogulants, haemostatics.
8.2 Anticoagulants.
8.3 Erythropoietics (haematinics).
8.4 Plasma expanders.

9. *Medicines against alcoholism.*

10. *Medicines acting on respiratory system.*

10.1 Antitussives and expectorants.
10.2 Bronchodilators.
10.2.1 Inhalants.
10.2.2 Other.

11. *Medicines acting on gastro-intestinal tract.*

11.1 Digestants.
11.2 Gastro-intestinal antispasmodics and cholinolytics (anti-cholinergics).
11.3 Anorexigenics.
11.3.1 Other.
11.4 Antacids.
11.4.1 Acid neutralisers.
11.4.2 Acid neutralisers with antispasmodics.
11.4.3 Other.
11.5 Laxatives.
11.6 Lubricants and faecal softeners.
11.7 Cholagogues.
11.8 Suppositories and anal ointments.
11.9 Antidiarrhoeals.

11.9.1 Diarreemiddels in samestelling met anti-infeksiemiddels.
11.9.2 Ander.
11.10 Besondere samestellings.

12. *Wurm-, Bilharzia- en Filaramiddels, ens.*

13. *Velpreparate.*

13.1 Antiseptika, ontsmettings- en skoonmaakmiddels.
13.2 Middels teen jeuksiekte.
13.3 Oppervlakverdowingsmiddels.
13.4 Jeukmiddels (antipruritiese middels).
13.4.1 Kortikosteroïede met of sonder anti-infeksiemiddels.
13.4.2 Ander.
13.5 Versagtende en beskermende middels.
13.6 Hiperemie-veroorsakende middels.
13.7 Teenprikkelmiddels.
13.8 Keratolitika.
13.9 Besondere samestellings.
13.9.1 Preparate teen psoriase.
13.9.2 Swamdoders.
13.10 Beskermingsmiddels teen straling.
13.11 Melanieninhibitors en -stimulante.
13.12 Akneepreparate.

14. *Wondbehandelingsmiddels.*

14.1 Wondontsmettingsmiddels.
14.2 Wonddekkings.

15. *Oogpreparate (oftalmiese preparate).*

15.1 Oogpreparate met antibiotika en/of sulfoonamiede.
15.2 Oogpreparate met kortikosteroïede (skorshormone).
15.3 Samestellings van antibiotika en/of sulfoonamiede en kortikosteroïede.
15.4 Ander.

16. *Oor-, neus- en keelpreparate.*

16.1 Neusontstoppingsmiddels.
16.2 Oorpreparate, oordruppels.
16.3 Oppervlakverdowingsmiddels.
16.4 Neus-, mond-en-keelantiseptika.

17. *Middels met uitwerking op spierstelsel.*

17.1 Spierverslappers met perifere werking.
17.2 Spieraktiveerders.

18. *Middels met uitwerking op urogenitale stelsel.*

18.1 Diuretika.
18.2 Antidiuretika.
18.3 Ioonuitruilingspreparate.
18.4 Urolitolitika.
18.5 Urienweg-antiseptika.
18.6 Vaginale preparate.
18.7 Middels vir voorkoming van bevrugting.
18.8 Ovulasiebeheermiddels.
18.9 Uterusspasmolitika.

19. *Oksitosika.*

20. *Antimikrobiese (chemoterapeutiese) middels.*

20.1 Antibiotika en antibiotiese samestellings.
20.1.1 Breë-en mediumspektrumantibiotika.
20.1.2 Penisilliene.
20.1.3 Penisillien-streptomisiensamestellings.
20.1.4 Antibiotikum-sulfoonamiedsamestellings.
20.1.5 Streptomisien en streptomisiensamestellings.
20.1.6 Plaaslik aanwendbare antibiotika.
20.1.7 Swambestrydende antibiotika.
20.2 Nie-antibiotiese middels.
20.2.1 Sulfoonamiede.
20.2.2 Swamdoders.
20.2.3 Tuberkulostatika.
20.2.4 Leprostatika.
20.2.5 Kiemdoders.

11.9.1 Antidiarrhoeals in combination with anti-infective agents.
11.9.2 Other.
11.10 Special combinations.

12. *Anthelmintics, Bilharzia medicines, Filaricides, etc.*

13. *Dermatological preparations.*

13.1 Antiseptics, disinfectants, cleansing agents.
13.2 Antiscabies medicines.
13.3 Surface anaesthetics.
13.4 Antipruritics.
13.4.1 Corticosteroids with or without anti-infective agents.
13.4.2 Other.
13.5 Emollients and protectives.
13.6 Rubefacients.
13.7 Counterirritants.
13.8 Keratolytics.
13.9 Special combinations.
13.9.1 Preparations for psoriasis.
13.9.2 Fungicides.
13.10 Radiation protectants.
13.11 Melanin inhibitors and stimulants.
13.12 Acne preparations.

14. *Treatment of wounds.*

14.1 Wound disinfectants.
14.2 Wound dressings.

15. *Ophthalmic preparations.*

15.1 Ophthalmic preparations with antibiotics and/or sulphonamides.
15.2 Ophthalmic preparations with corticosteroids.
15.3 Combination antibiotics and/or sulphonamides and corticosteroids.
15.4 Other.

16. *Ear, nose and throat preparations.*

16.1 Nasal decongestants.
16.2 Aural preparations, ear drops.
16.3 Surface anaesthetics.
16.4 Naso-, bucco-pharyngeal antiseptics.

17. *Medicines acting on muscular system.*

17.1 Peripherally acting muscle relaxants.
17.2 Muscle activators.

18. *Medicines acting on genito-urinary system.*

18.1 Diuretics.
18.2 Antidiuretics.
18.3 Ion-exchange preparations.
18.4 Urolitholytics.
18.5 Urinary tract antiseptics.
18.6 Vaginal preparations.
18.7 Contraceptive preparations.
18.8 Ovulation controlling agents.
18.9 Uterine antispasmodics.

19. *Oxytocics.*

20. *Antimicrobial (chemotherapeutic) agents.*

20.1 Antibiotics and antibiotic combinations.
20.1.1 Broad and medium spectrum antibiotics.
20.1.2 Penicillins.
20.1.3 Penicillin-streptomycin combinations.
20.1.4 Antibiotic-sulphonamide combinations.
20.1.5 Streptomycin and combinations.
20.1.6 Topical antibiotics.
20.1.7 Antifungal antibiotics.
20.2 Other than antibiotics.
20.2.1 Sulphonamides.
20.2.2 Fungicides.
20.2.3 Tuberculostatics.
20.2.4 Leprostatics.
20.2.5 Germicides.

20.2.6 Middels teen protosoë.
20.2.7 Spirocheetdoders.
20.2.8 Antivirusmiddels.

21. *Hormone en antihormone, en hipoglukemieslukmiddels.*

21.1 Insulienpreparate.
21.2 Hipoglukemieslukmiddels.
21.3 Tireoïedpreparate.
21.4 Paratireoïedpreparate.
21.5 Kortikosteroïede (skorshormone).
21.5.1 Kortikosteroïede (skorshormone) en analoga.
21.5.2 Analgetiese samestellings.
21.5.3 Anti-infeksiesamestellings.
21.5.4 Ander samestellings.
21.6 Anaboliese steroïede.
21.7 Manlike geslagshormone.
21.8 Vroulike geslagshormone.
21.8.1 Estrogene.
21.8.2 Progesterone met of sonder estrogene.
21.9 Androgeen-estrogeensamestellings.
21.10 Tropiese hormone.
21.11 Hiperglukemiehormone.
21.12 Hormooninhibitors.

22. *Vitamiene.*

22.1 Multivitamiene en multivitamiene met minerale.
22.1.1 Vitamiene vir pediatriese gebruik.
22.1.2 Vitamiene vir voorgeboortegebruik.
22.1.3 Vitamiene vir geriatriese gebruik.
22.1.4 Ander.
22.1.5 B-kompleks met vitamien C.

23. *Aminosure.*

24. *Aanvullende mineraalpreparate, elektroliete.*

25. *Spesieale voedsel.*

25.1 Babavoedsel en ander samestellings, voedingsmiddels wat slegs gebruik word as 'n vervangmiddel vir moedersmelk uitgesluit.
25.2 Ander voedingsmiddels.

26. *Sitostatika.*

27. *Chelaatvormende middels teen swaarmetaalvergiftiging.*

28. *Kontrasmedia.*
29. *Diagnostiese hulpmiddels.*
30. *Biologiese middels.*
31. *Ensiempreparate.*
32. *Ensieminhibitors.*
33. *Tonika.*
34. *Ander.*

Monsters saam met aansoek om registrasie

6. 'n Aansoek om registrasie moet, indien die Raad daarom versoek, vergesel wees van—

(a) 'n monster van die finale produk in die kleinste van elk van die verpakkingsvorms waarin dit vir verkoop aan die publiek beskikbaar is of indien sodanige produk nog nie aldus beskikbaar is nie, 'n monster in 'n houer waarin die applikant van voorneme is om die produk te bemark;

(b) monsters van alle advertensiemateriaal en voubiljette, of konsepte daarvan, bevattende die basiese inligting wat die applikant van voorneme is om te gebruik, en monsters van die grondstowwe wat in die vervaardiging van die produk gebruik word.

Gegewens wat in die medisyneregister moet verskyn

7. Wanneer 'n medisyne geregistreer word, moet die volgende gegewens ingeskryf word in die medisyneregister wat kragtens artikel 13 van die Wet gehou moet word:

(a) Die naam van die medisyne kragtens artikel 15 (5) deur die Raad goedgekeur;

20.2.6 Medicines against protozoa.
20.2.7 Spirochaeticides.
20.2.8 Antiviral agents.

21. *Hormones and antihormones and oral hypoglycaemics.*

21.1 Insulin preparations.
21.2 Oral hypoglycaemics.
21.3 Thyroid preparations.
21.4 Parathyroid preparations.
21.5 Corticosteroids.
21.5.1 Corticosteroids and analogues.
21.5.2 Analgesic combinations.
21.5.3 Anti-infective combinations.
21.5.4 Other combinations.
21.6 Anabolic steroids.
21.7 Male sex hormones.
21.8 Female sex hormones.
21.8.1 Oestrogens.
21.8.2 Progesterones with or without oestrogens.
21.9 Androgen-oestrogen combinations.
21.10 Tropic hormones.
21.11 Hyperglycaemic hormones.
21.12 Hormone inhibitors.

22. *Vitamins.*

22.1 Multivitamins and multivitamins with minerals.
22.1.1 Vitamins for pediatric use.
22.1.2 Vitamins for prenatal use.
22.1.3 Vitamins for geriatric use.
22.1.4 Other.
22.1.5 B-complex with vitamin C.

23. *Amino-acids.*

24. *Mineral substitutes, electrolytes.*

25. *Special foods.*

25.1 Infant foods and other formulae excluding foods used solely as a substitute for human milk.
25.2 Other nutrients.

26. *Cytostatic agents.*

27. *Chelating agents (versenates) as heavy metal antidotes.*

28. *Contrast media.*
29. *Diagnostic agents.*
30. *Biologicals.*
31. *Enzymatic preparations.*
32. *Enzyme inhibitors.*
33. *Tonics.*
34. *Other.*

Samples with application for registration

6. An application for registration of a medicine shall, if so requested by the Council, be accompanied by—

(a) a sample of the final product in the smallest of each of the package forms available for sale to the public or if such product be not yet so available, a sample in a container in which the applicant intends to make it available on the market;

(b) samples of all advertising material and package inserts which may be in draft form listing the basic information which the applicant intends to use and samples of the raw materials used in the manufacture of the product.

Information which shall appear in the medicines register

7. When a medicine is registered the following information shall be written in the medicines register which shall be kept in terms of section 13 of the Act:

(a) The name of the medicine approved by the Council in terms of section 15 (5);

(b) die handelsnaam van die medisyne, as daar een is;

(c) die registrasienommer van die medisyne;

(d) die naam en hoeveelheid van elke aktiewe bestanddeel van die medisyne, per eenheid;

(e) die bereidingsvorm van die medisyne;

(f) die voorwaardes waaraan die registrasie onderworpe is, as daar is;

(g) die naam en sakeadres van die vervaardiger;

(h) die naam en sakeadres van die applikant;

(i) die datum van registrasie van die medisyne.

Vorm van registrasiesertifikaat

8. Onderstaande registrasiesertifikaat moet uitgereik word nadat 'n medisyne geregistreer is kragtens artikel 15 (4) van die Wet:

MBR 13

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

REGISTRASIESERTIFIKAAT VAN 'N MEDISYNE

Hierby word gesertifiseer dat die medisyne soos hieronder beskryf kragtens artikel 15 (4) geregistreer is, onderworpe aan die voorwaardes aangedui:

1. Goedgekeurde naam.....
2. Handelsnaam waaronder dit bemark word.....
3. Registrasienommer.....
4. Aktiewe bestanddele en hoeveelhede per eenheid.....
.....
5. Bereidingsvorm.....
6. Voorwaardes waaronder hierdie medisyne geregistreer is.....
.....
7. Naam en sakeadres van vervaardiger.....
.....
8. Geregistreer op naam van.....
Sakeadres.....
9. Datum van registrasie.....

.....
Registrateur van Medisyne

Pretoria,

.....19.....

Die etikettering van medisyne en gelyste stowwe

9. (1) Die pakket waarin 'n medisyne of gelyste stof verkoop word, moet 'n etiket aanhê waarop in duidelike en onuitwisbare letters in beide amptelike tale die volgende besonderhede vermeld word:

(a) Die naam en sakeadres van die applikant op wie se naam die medisyne geregistreer is of in wie se naam aansoek om registrasie gedoen is;

(b) die vereistes, as daar is, betreffende die metode van opberging of ander voorsorgmaatreëls wat nodig is vir die preservering van die medisyne of gelyste stof;

(c) die besonderhede kragtens artikel 15 (7) van die Wet deur die Raad bepaal;

(d) die naam en persentasie van enige bakteriostatiese of bakteriedodende middel wat as preserveermiddel by die medisyne of gelyste stof gevoeg is;

(e) die lotnommer van die medisyne of gelyste stof;

(f) die verstrykingsdatum van die medisyne of gelyste stof, waar van toepassing;

(g) waar prakties moontlik, die dosis van die medisyne of gelyste stof;

(h) in die geval van 'n gelyste stof, die letter "S" gevolg deur die nommer van die bylae waarin sodanige stof gelys is, in 'n prominente lettergrootte en van 'n rand voorsien;

(i) in die geval van 'n medisyne wat fenasetien, aspirien of parasetamol bevat, die waarskuwing: Moenie langer as 10 dae aaneenlopend gebruik sonder om u geneesheer te raadpleeg nie;

(b) the trade name of the medicine, if any;

(c) the registration number of the medicine;

(d) the name and quantity of each active ingredient of the medicine, per unit;

(e) the form of preparation of the medicine;

(f) the conditions of registration, if any;

(g) the name and business address of the manufacturer;

(h) the name and business address of the applicant; and

(i) the date of registration of the medicine.

Form of certificate of registration

8. The following certificate of registration shall be issued after a medicine has been registered in terms of section 15 (4) of the Act:

MBR 13

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (Act 101 of 1965)

MEDICINE REGISTRATION CERTIFICATE

It is hereby certified that the medicine as described hereunder has been registered in terms of section 15 (4), subject to the conditions indicated:

1. Approved name.....
2. Trade name under which marketed.....
3. Registration number.....
4. Active ingredients and quantities per unit.....
.....
5. Form of preparation.....
6. Conditions under which medicine in registered.....
.....
7. Name and business address of manufacturer.....
.....
8. Registered in the name of.....
.....
Business address.....
.....
9. Date of registration.....

.....
Registrar of Medicines

Pretoria,

.....19.....

The labelling of medicines and scheduled substances

9. (1) The package in which a medicine or scheduled substance is sold shall bear a label on which is stated in clear and indelible letters and in both official languages the following information:

(a) The name and business address of the applicant in whose name the medicine is registered or in whose name the application for registration was made;

(b) the requirements, if any, for the method of storage or other necessary precautions for the preservation of the medicine or scheduled substance;

(c) the particulars determined by the Council in terms of section 15 (7) of the Act;

(d) the name and percentage of any bacteriostatic or bactericidal agent which is added to the medicine or scheduled substance as a preservative;

(e) the batch number of the medicine or scheduled substance;

(f) the expiry date of the medicine or scheduled substance, where applicable;

(g) where practicable, the dosage of the medicine or scheduled substance;

(h) in the case of scheduled substances, the letter "S" followed by the number of the schedule in which the substance is listed, in a prominent type size and surrounded by a border;

(i) in the case of a medicine which contains phenacetin, aspirin or paracetamol, the warning: Do not use continuously for more than 10 days without consulting your doctor;

(j) in die geval van 'n preparaat vir mondelike gebruik wat antihistamienstof bevat, die waarskuwing: Die gebruik van hierdie medisyne lei tot lomerigheid wat vererger word deur die gelyktydige inname van alkohol.

(2) In die geval van 'n verpakking van medisyne of 'n gelyste stof van 10 ml of minder is dit voldoende om die gegewens vereis by subregulasie (1) (a), (b), (c), (d), (g), (h), (i) en (j) op die buite-etiket aan te bring.

(3) In die geval van die verkoop van 'n medisyne ingevolge die bepalings van artikel 18 (3) (a) en (b) van die Wet moet die pakket waarin sodanige medisyne verkoop word, 'n etiket aanhê waarop die volgende besonderhede vermeld word:

(a) Die naam en adres van die apteker of geneesheer deur wie die medisyne verkoop word: Met dien verstande dat indien sodanige verkoop deur 'n apteker of geneesheer in diens van 'n hospitaal geskied, die naam en adres van sodanige hospitaal op die etiket moet verskyn;

(b) aanwysings (as daar is) oor die wyse waarop sodanige medisyne gebruik behoort te word;

(c) die naam van die persoon vir wie se behandeling sodanige medisyne verkoop word; en

(d) die verwysingsnommer bedoel in regulasie 28 (1) (e).

(4) Die bepalings van subregulasie (1) is nie van toepassing in die geval van die verkoop op voorskrif van 'n medisyne deur 'n geneesheer, tandarts, veearts of apteker vir die behandeling van 'n bepaalde persoon of dier nie: Met dien verstande dat sodanige medisyne, behoudens die bepalings van artikel 18 (1) van die Wet, voorsien moet wees van 'n etiket waarop die volgende verskyn:

(a) Die naam en adres van die verkoper;

(b) die aanwysings (as daar is) oor die wyse waarop sodanige medisyne gebruik behoort te word; en

(c) die naam van die persoon vir wie se behandeling die medisyne verkoop word, of in die geval van 'n voorskrif deur 'n veearts uitgereik, die naam van die persoon aan wie die medisyne verkoop moet word.

(5) Die Raad kan op versoek van 'n applikant en na oorweging van die redes wat deur die applikant verstrek is, enige afwyking van die regulasies met betrekking tot etikettering goedkeur.

Voubiljette

10. (1) Elke medisynepakket moet 'n voubiljet inhê waarop die volgende in prominente letters in beide amptelike tale gedruk is:

(a) Alle gegewens wat ingevolge artikel 18 (1) van die Wet en regulasie 9 (1) op etikette moet verskyn;

(b) gebruiksaanwysings;

(c) enige nodige waarskuwings in verband met die onveilige gebruik van die medisyne deur kinders, oumense en swanger vrouens, en moontlike gevare verbonde aan die langduringe gebruik van die medisyne of die toediening van die medisyne;

(d) 'n samevatting van verbandhebbende gegewens betreffende die doel van gebruik, die heilsame uitwerking en enige skadelike of nadelige of ander uitwerking van die medisyne; en

(e) alle verbandhebbende besonderhede, insluitende besonderhede van 'n spesifieke medisyne as teenmiddel (indien bekend), van die behandeling van 'n pasiënt in gevalle waar 'n oormaat van die medisyne toegedien is.

(2) Die gegewens moet onder die opskrifte en in die volgorde soos hieronder aangedui op die voubiljet gedruk wees:

(a) Registrasienommer (vir toekenning deur die Raad).

(b) Farmakologiese klassifikasie.

(c) Skeduleringskategorie (vir toekenning deur die Raad).

(j) in the case of a preparation intended for oral use containing an antihistaminic substance, the warning: The use of this medicine leads to drowsiness which is aggravated by the simultaneous intake of alcohol.

(2) In the case of a package of a medicine or scheduled substance of 10 ml or less, it will be adequate to record the information required by subregulation (1) (a), (b), (c), (d), (g), (h), (i) and (j) on the outer label.

(3) In the case of the sale of a medicine in terms of the provisions of section 18 (3) (a) and (b) of the Act, the package in which such medicine is sold shall bear a label on which the following details appear:

(a) The name and address of the pharmacist or medical practitioner by whom the medicine is sold: Provided that if such sale is effected by a pharmacist or medical practitioner in the service of a hospital, the name and address of such hospital shall appear on the label;

(b) directions (if any) regarding the manner in which such medicine should be used;

(c) the name of the person for the treatment of whom the medicine is sold; and

(d) the reference number referred to in regulation 28 (1) (e).

(4) The provisions of subregulation (1) shall not apply in the case of the sale on prescription of a medicine by a medical practitioner, dentist, veterinarian or pharmacist for the treatment of a specified person or animal: Provided that subject to the provisions of section 18 (1) of the Act, such medicine shall bear a label stating—

(a) the name and address of the seller;

(b) the directions (if any) regarding the manner in which the medicine should be used; and

(c) the name of the person for the treatment of whom the medicine is sold, or in the case of a prescription issued by a veterinarian, the name of the person to whom the medicine should be sold.

(5) The Council may authorise, at the request of and after consideration of the reasons submitted by the applicant, any deviation from the regulations with regard to labelling.

Package inserts

10. (1) Each package of a medicine shall contain a package insert on which is printed in prominent type in both official languages:

(a) All the information which shall in terms of section 18 (1) of the Act and regulation 9 (1) appear on labels;

(b) directions for use;

(c) any necessary warning concerning the unsafe use of the medicine by children, old people and pregnant women and the possible dangers that may arise from the prolonged use of the medicine or in connection with the administration of the medicine;

(d) a summary of relevant information concerning the purpose and the beneficial, detrimental, injurious or other effects of the medicine; and

(e) all relevant information, including particulars in regard to a specific medicine as an antidote (if known), concerning the treatment of a patient in cases where an overdose of the medicine has been administered.

(2) The information shall be printed on the package insert under the headings and in the order indicated hereunder:

(a) Registration number (to be allocated by the Council).

(b) Pharmacological classification.

(c) Scheduling category (to be allocated by the Council).

(d) Goedgekeurde naam (waar van toepassing).
(e) Handelsnaam.
(f) Samestelling (insluitende preserveermiddels, as daar is).
(g) Identifikasie (fiesiese voorkoms).
(h) Farmakologiese werking.
(i) Indikasies.
(j) Kontra-indikasies.
(k) Dosis en gebruiksaanwysings.
(l) Newe-effekte en spesiale voorsorgmaatreëls.
(m) Bekende simptome van oordosering en besonderhede van behandeling daarvan (indien prakties moontlik om in te sluit).
(n) Voorwaardes waaronder die medisyne geregistreer is (as daar is) soos deur die Raad gestel.
(o) Aanbieding.
(p) Bergingsvoorskrifte.
(q) Naam van applikant.

(3) Die bepalings van subregulasie (1) is nie van toepassing in die gevalle bedoel in artikel 18 (3) (a), (b) en (c) van die Wet en regulasie 9 (3) en (4) nie.

(4) Die Raad kan op versoek van 'n applikant en na oorweging van die redes wat deur die applikant verstrek is, enige afwyking van die regulasies met betrekking tot voubiljette goedkeur.

Advertensies

11. Wanneer 'n medisyne vir die eerste keer mondeling deur of namens die applikant by 'n lid van die mediese of tandheelkundige beroep of die farmaseutiese beroep geadverteer word, moet skriftelike gegewens, wat minstens gegewens insluit soos bepaal in regulasie 10, terselfdertyd aan die persoon aan wie sodanige mondelinge advertensie gerig is, oorhandig word, en sodanige gegewens moet by daaropvolgende geleenthede wanneer mondelinge advertensie plaasvind, op versoek beskikbaar wees.

Standaarde ten opsigte van samestelling, terapeutiese geskiktheid en uitwerking, suiwerheid, ens., waaraan 'n medisyne moet voldoen

12. (a) Alle medisyne moet voldoen aan die standaarde, as daar is, bepaal in die jongste uitgawe van die British Pharmacopoeia of the British Pharmaceutical Codex of die European Pharmacopoeia of die Pharmacopeia of the United States na gelang van die geval, of aan standaarde wat die Raad bevredig.

(b) Elke applikant moet die Raad sonder versuim verwittig van enige afwyking van die besonderhede deur hom verstrek saam met die aansoek om die registrasie van 'n medisyne, ongeag of sodanige verandering bewerkstellig is voor of nadat sodanige medisyne geregistreer is.

Besonderhede wat in die Staatskoerant *gepubliseer moet word kragtens artikel* 15 (11) *van die Wet*

13. Die volgende besonderhede moet kragtens artikel 15 (11) van die Wet in die *Staatskoerant* gepubliseer word:

(a) Die handelsnaam van die medisyne (as daar een is);
(b) die naam en hoeveelheid van elke aktiewe bestanddeel van die medisyne;
(c) die naam en sakeadres van die applikant; en
(d) die bereidingsvorm van die medisyne.

Reglement betreffende die verrigting van die sake van die Medisynebeheerraad

14. Behoudens die Wet se bepalings betreffende die verrigting van die sake van die Raad, geld die volgende bykomende bepalings:

(1) Kennisgewings van gewone en buitengewone vergaderings van die Raad moet deur die Registrateur onderteken wees en moet die sake vermeld wat op die vergadering behandel moet word. In die geval van gewone

(d) Approved name (where applicable).
(e) Trade name.
(f) Composition (including preservatives, if present).
(g) Identification (physical appearance).
(h) Pharmacological action.
(i) Indications.
(j) Contra-indications.
(k) Dosage and directions for use.
(l) Side effects and special precautions.
(m) Known symptoms of overdosage and particulars of its treatment (where practicable to include).
(n) Conditions of registration of the medicine (if any) imposed by the Council.
(o) Presentation.
(p) Storage directions.
(q) Name of application.

(3) The provisions of subregulation (1) shall not be applicable in those cases to which section 18 (3) (a), (b) and (c) of the Act and regulation 9 (3) and (4) apply.

(4) The Council may, on the request of an applicant, and after consideration of the reasons submitted by the applicant, approve any deviation from the regulations relative to package inserts.

Advertisements

11. When a medicine is advertised orally for the first time by or on behalf of the applicant to any member of the medical or dental profession or the pharmaceutical profession, written information, which shall include at least the information called for in terms of regulation 10, shall simultaneously be given to the person to whom the oral advertisement is directed and when the medicine is advertised orally on subsequent occasions such information shall be available on request.

Standards for composition, therapeutic suitability and effect, purity, etc., with which a medicine shall comply

12. (a) All medicines shall comply with the standard, if any, laid down in the most recent edition of the British Pharmacopoeia or the British Pharmaceutical Codex or the European Pharmacopoeia or the Pharmacopeia of the United States, as the case may be, or with standards which satisfy the Council.

(b) Every applicant shall, without delay, inform the Council of any departure from the particulars furnished by him with any application for the registration of a medicine, irrespective of whether such alteration is made before or after such medicine was registered.

Particulars which shall be published in the Government Gazette *in terms of section* 15 (11) *of the Act*

13. The following particulars shall be published in the *Government Gazette* in terms of section 15 (11) of the Act:

(a) The trade name of the medicine, if any;
(b) the name and quantity of each active ingredient of the medicine;
(c) the name and business address of the applicant; and
(d) the form of preparation of the medicine.

Rules relating to the conduct of business of the Medicines Control Council

14. In addition to the provisions concerning the conducting of the business of the council as prescribed in the Act, the following additional rules shall apply:

(1) Notices convening ordinary and special meetings of the Council shall be signed by the Registrar, and shall specify the business to be transacted at the meeting. They shall be sent by post or by hand to each member

vergaderings moet hulle minstens tien (10) dae voor die bepaalde datum van die vergadering aan elke lid per pos gestuur of oorhandig word. Vir buitengewone vergaderings moet sodanige kennisgewing geskied as wat deur die Voorsitter voldoende geag word, en indien nodig, kan kennisgewing per telegram of telefoon geskied. Indien alle lede toestem, kan 'n spesifieke vergadering op korter of sonder skriftelike kennisgewing belê word.

(2) Geen ander sake as dié in die betrokke kennisgewing genoem, mag op 'n vergadering behandel word nie, uitgesonderd sake wat die Raad, om dringende redes, besluit om te behandel.

(3) Die Raad kan 'n vergadering tot enige dag of uur verdaag, maar op 'n voortsettingsvergadering mag geen ander sake behandel word nie as dié uiteengesit in die kennisgewing van die vergadering waarvan dit 'n voortsetting is, uitgesonderd sake wat die Raad om dringende redes, besluit om te behandel.

(4) Die Registrateur moet 'n presensielys hou van al die lede wat 'n vergadering bywoon.

(5) 'n Lid wat 'n saak aan die Raad wil voorlê, moet minstens 30 dae voor die datum waarvoor 'n vergadering belê moet word, 'n skriftelike kennisgewing van sy mosie aan die Registrateur stuur, en die kennisgewing van sy mosie moet vermeld staan in die kennisgewing van die vergadering en moet saam met die ander sake wat aan die Raad voorgelê moet word, in die aangeduide volgorde oorweeg word.

(6) Geen saak mag behandel word sonder behoorlike kennisgewing ooreenkomstig die voorgaande reël nie, tensy verlof van die vergadering verkry is om die saak as 'n mosie in te dien. As daar geen sekondant vir die mosie is nie, word dit nie verder behandel nie.

(7) Die meerderheid van die lede van 'n komitee wat kragtens artikel 9 (1) (b) van die Wet saamgestel word en van die Uitvoerende Komitee, maak 'n kworum van sodanige komitee uit.

(8) As die Raad nie sit nie, moet die Registrateur, sover moontlik, alle sake binne die opdrag van 'n komitee na sodanige komitee verwys en sodanige komitee moet, indien moontlik, daaroor verslag doen aan die volgende vergadering van die Raad. Hierdie reël is nie van toepassing op gewone roetine-aangeleenthede of op sake waarvan die beginsel reeds by regulasie of besluit van die Raad bepaal is nie.

(9) Die reglement van orde soos hierin bepaal vir die hou van gewone en buitengewone vergaderings van die Raad is *mutatis mutandis* van toepassing op komiteevergaderings.

(10) Afskrifte van komiteeverslae moet, waar moontlik, aan elke lid van die Raad gestuur word saam met die kennisgewing van die vergadering waarop die verslae oorweeg moet word.

(11) Die verrigtings van vergaderings van die Raad moet vasgelê word in die vorm van getikte notule wat op die volgende vergadering, na goedkeuring, deur die Voorsitter met sy handtekening bekragtig moet word.

(12) (a) Die notule van elke vergadering van die Raad en van die Uitvoerende Komitee moet 'n opsomming bevat van die sake wat behandel is en van die mosies en amendemente wat voorgestel en aanvaar of verwerp is, met vermelding van die name van die voorsteller en sekondant, maar kommentaar of opmerkings van lede moet nie vermeld word nie.

(b) Die notule van alle vergaderings van komitees van die Raad saamgestel kragtens artikel 9 (1) (b) van die Wet moet 'n opsomming bevat van die sake wat behandel en besluite wat geneem is, maar kommentaar of opmerkings van lede moet nie vermeld word nie.

and issued, in the case of ordinary meetings, at least ten (10) days before the date for which the meeting is convened. In the case of special meetings such notice shall be given as the Chairman may deem sufficient, and, if necessary, may be given by telegram or telephone. If all members agree, a specific meeting can be convened at shorter notice, or without written notice.

(2) No business shall be transacted at a meeting other than that specified in the notice relating thereto, except matters which the Council shall resolve to deal with as urgent.

(3) The Council may adjourn a meeting to any day or hour, but no business shall be transacted at an adjourned meeting except such as was set out in the notice convening the meeting of which it is an adjournment, other than matters which are brought forward in accordance with the preceding rule.

(4) An attendance register of all members attending a meeting shall be kept by the Registrar.

(5) Any member desirous of bringing any matter before the Council shall forward in writing to the Registrar at least 30 days before the date for which a meeting is to be convened, a written notice of his motion, and the notice of his motion shall appear in the notice convening the meeting and shall be considered with the other business to be brought before the Council in the order indicated.

(6) No matter shall be considered unless due notice has been given in accordance with the preceding rule, unless permission is obtained from the meeting to bring it forward as a motion. Should the motion find no seconder, it shall not be further considered.

(7) The quorum of any committee established under section 9 (1) (b) of the Act and of the Executive Committee shall consist of the majority of the members of the relevant committee.

(8) The Registrar shall, when the Council is not sitting, refer, as far as possible, all matters within the terms of reference of a committee to such committee, and such committee shall, if possible, report thereon to the next meeting of the Council. This rule shall not apply to matters of ordinary routine or such matters, the principle of which has already been laid down by regulation or resolution of the Council.

(9) The rules of procedure laid down herein for the conduct of ordinary and special meetings of the Council shall apply, *mutatis mutandis*, to meetings of committees.

(10) Copies of reports of committees shall, whenever practicable, be forwarded to each member of the Council with the notice convening the meeting at which such reports are to be considered.

(11) The proceedings of meetings of the Council shall be preserved in the form of typewritten minutes authenticated, after confirmation, at the next meeting by the signature of the Chairman.

(12) (a) The minutes of each meeting of the Council and the Executive Committee shall contain a résumé of the subject matter dealt with, and such motions and amendments as have been proposed and adopted or rejected, with the names of the proposer and seconder, but without any comment or observation of the members.

(b) The minutes of all meetings of committees of the Council established under section 9 (1) (b) of the Act shall contain a résumé of the subject matter dealt with and resolutions adopted, but without any comment or observation of the members.

(13) Die Registrateur moet so spoedig as redelik moontlik na afloop van 'n vergadering van die Raad of van 'n komitee 'n afskrif van die notule aan al die lede van die Raad stuur.

(14) Die notule kan as gelees beskou word: Met dien verstande dat enige lid kan voorstel dat 'n sekere notule gelees word sodat sodanige verbetering of toevoeging aangebring kan word as wat nodig mag blyk.

(15) By die opening van elke afsonderlike sessie van die Raad moet geleentheid aan lede van die Raad gegee word om vrae te stel ten opsigte van die werksaamhede van die Raad, en dié vrae moet dan, indien moontlik, onmiddellik of so nie op 'n volgende vergadering beantwoord word deur die Voorsitter of deur sodanige ampsdraer of beampte as wat die Voorsitter mag gelas. Geen bespreking word daaroor toegelaat nie.

(16) Die agenda vir elke vergadering van die Raad of 'n komitee van die Raad moet deur die Registrateur in oorleg met die Voorsitter opgestel word en moet vir elke vergadering die volgende items insluit:

(a) Goedkeuring van die notule van die vorige vergadering;
(b) sake voortspruitende uit die notule van die vorige vergadering;
(c) verslae van vaste komitees;
(d) mosies;
(e) korrespondensie;
(f) algemeen.

'n Lid van die Raad is egter bevoeg om op 'n bepaalde vergadering voor te stel dat 'n item op die agenda van daardie bepaalde vergadering van die Raad voor ander items op die agenda behandel word.

(17) Alle mosies en amendemente moet, tensy anders deur die Voorsitter toegelaat, skriftelik en deur die voorsteller onderteken wees, en voordat ander lede daaroor praat, moet hulle deur die Voorsitter of deur die Registrateur met die toestemming van die Voorsitter voorgelees word, en dan gesenkondeer word. Alle formele amendemente moet so geformuleer word dat hulle as selfstandige mosies voorgelees kan word.

'n Amendement moet betrekking hê op die mosie wat dit bestem is om te wysig en moet die oorspronklike mosie nie op so 'n manier wysig dat dit in werklikheid 'n nuwe mosie word nie. Die amendement moet so geformuleer word dat—

(a) sekere woorde toe- of ingevoeg word; of
(b) sekere woorde weggelaat word; of
(c) sekere woorde weggelaat en ander woorde toe- of ingevoeg word.

(18) Tensy die Raad toestem, mag geen mosie of amendement teruggetrek word nadat dit deur of met die toestemming van die Voorsitter voorgelees is nie.

(19) Die sekondant van 'n mosie of amendement kan sy toespraak voorbehou tot enige stadium van die bespreking.

(20) As 'n amendement voorgestel word, kan ander amendemente daarop volg en kom die laaste amendement die eerste onder bespreking.

(21) As elke amendement verwerp word, moet die oorspronklike mosie in stemming gebring word.

(22) As 'n amendement aangeneem word, word dit as 'n selfstandige mosie beskou en met betrekking tot verdere amendemente in alle ander opsigte as 'n oorspronklike mosie behandel.

(23) Wanneer 'n mosie onder bespreking is, word geen ander voorstel toegelaat nie, uitgesonderd een van die volgende:

(a) 'n Amendement nl. "dat die mosie soos volg gewysig word: . . .";

(b) die uitstel van die saak, nl. "dat die vergadering oorgaan tot die volgende item op die agenda";

(13) The Registrar shall forward a copy of the minutes of each meeting of the Council and of any committee to all members of the Council as soon as reasonably possible after the meeting has been held.

(14) The minutes may be taken as read: Provided that any member may move that a particular minute should be read with a view to such correction therein or addition thereto as may be found necessary.

(15) At the opening of each separate session of the Council, opportunity shall be given to members to put questions with regard to the work of the Council, which questions shall be answered forthwith, if possible, or if not, at a later session by the Chairman or by such office-bearer or official as the Chairman may direct. No discussion thereon shall be permitted.

(16) The agenda for every meeting of the Council or of a committee of the Council shall be compiled by the Registrar in consultation with the Chairman and shall include the following:

(a) Confirmation of the minutes of the previous meeting;
(b) matters arising from the minutes of the previous meeting;
(c) reports of standing committees;
(d) motions;
(e) correspondence;
(f) general.

It shall, however, be competent for a member of the Council to move at a particular meeting that any item appearing on the agenda for that particular meeting of the Council be advanced in the agenda.

(17) All motions and amendments shall, unless otherwise permitted by the Chairman, be committed to writing and signed by the mover, and, before they are spoken to by other members, shall be read by the Chairman or by the Registrar under the authority of the Chairman, and seconded. All formal amendments shall be so framed that they may be read as independent motions.

An amendment shall be relevant to the motion it is intended to amend, and shall not alter the original motion in such a way as to make it virtually a new motion. It shall be so framed as—

(a) to add or insert certain words; or
(b) to omit certain words; or
(c) to omit certain words and add or insert others.

(18) No motion or amendment shall be withdrawn after having been read by the Chairman or by the authority of the Chairman unless by permission of the Council.

(19) The seconder of a motion or of an amendment may reserve his speech until any period of the debate.

(20) If an amendment be proposed, it may be followed by other amendments, and the last amendment shall be considered first.

(21) Should every amendment be rejected, the original motion shall then be put to the vote.

(22) If an amendment be carried, it shall then be regarded as a substantive motion and, as to further amendments, in all other respects be treated as an original motion.

(23) When a motion is under debate, no further proposal shall be received except one of the following:

(a) An amendment, namely, "that the motion be amended as follows: . . .";

(b) the postponement of the question, namely, "that the meeting do proceed to the next business";

(c) die beëindiging van die bespreking, nl. "dat die saak nou in stemming gebring word";
(d) die verdaging van die bespreking, nl. "dat die bespreking van die mosie verdaag word"; of
(e) die verdaging van die Raad, nl. "dat die Raad nou verdaag word".

(24) Wanneer 'n amendement onder bespreking is, word geen ander voorstel toegelaat nie, uitgesonderd een van die volgende:

(a) 'n Amendement, nl: "dat die mosie soos volg gewysig word: . . .";
(b) die beëindiging van die bespreking, nl. "dat die saak nou in stemming gebring word";
(c) die verdaging van die bespreking, nl. "dat die bespreking van die mosie nou verdaag word"; of
(d) die verdaging van die Raad, nl. "dat die Raad nou verdaag word".

(25) Die voorstel om die saak uit te stel (waarin 'n datum vir die verdere oorweging van die saak vermeld kan word) moet ingedien en gesekondeer word sonder bespreking, en kan te eniger tyd ingedien word selfs gedurende die bespreking van 'n amendement. As die voorstel aangeneem word, moet die saak oorstaan. As die voorstel nie aangeneem word nie, duur die bespreking voort.

(26) Die voorstel om die bespreking te beëindig moet sonder bespreking ingedien en gesekondeer word en moet onmiddellik in stemming gebring word. As die voorstel aangeneem word, moet die Raad dadelik oor die mosie of amendement onder bespreking stem.

(27) As die voorstel vir die verdaging van die bespreking aangeneem word, moet die Raad tot die volgende item op die agenda oorgaan en moet die bespreking hervat word op die volgende gewone vergadering van die Raad. Die voorsteller van die verdaging het by hervatting van die bespreking die reg om eerste te praat.

(28) As die voorstel vir die verdaging van die Raad gedoen en gesekondeer is, kan die Voorsitter, voordat hy die saak in stemming bring, die Raad vra of die Raad voor die sluiting van die vergadering tot die behandeling van onbestrede sake wil oorgaan.

(29) 'n Mosie tot herroeping van 'n besluit geneem op 'n vorige vergadering word alleen oorweeg indien kennis daarvan gegee is ingevolge reël (6). Dit word aangeneem indien 'n meerderheid van stemme ten gunste daarvan is.

'n Mosie tot herroeping van 'n besluit geneem tydens 'n sessie van die Raad kan egter ondanks bostaande bepaling tydens dieselfde sessie van die Raad oorweeg word, mits skriftelik kennis gegee word dat die aangeleentheid op die daaropvolgende dag van daardie sessie oorweeg sal word. Dit word alleen aangeneem indien twee derdes van die stemme ten gunste daarvan is.

(30) Die Registrateur moet in die notule enige beslissing van die Voorsitter betreffende die vertolking van hierdie reglement opneem as 'n lid, wanneer die beslissing gegee word, daarom vra.

(31) Kennis kan gegee word van 'n mosie om 'n beslissing van die Voorsitter oor die vertolking van hierdie reglement te hersien, indien ten tyde van die beslissing deur 'n lid daarom gevra word.

(32) Kennis kan gegee word van 'n mosie om 'n beslissing van die Voorsitter in hersiening te neem, en met die gee daarvan word dit geag 'n opdrag aan die Uitvoerende Komitee te wees om sodanige beslissing te oorweeg en daaroor aan die Raad verslag te doen, en sodanige kennisgewing moet op die agenda geplaas word.

(33) Die beslissing van die voorsitter van enige komitee oor 'n punt van orde kan op versoek van enige twee lede van die komitee wat aanwesig was op die vergadering waarop die beslissing gegee is, in hersiening geneem word deur die Uitvoerende Komitee, wat, as hy dit goedvind, kan gelas dat sodanige beslissing herroep of gewysig word,

(c) the closure, namely, "that the question be now put";
(d) the adjournment of the debate, namely, "that the debate on the motion be adjourned"; or
(e) the adjournment of the Council, namely, "that the Council do now adjourn".

(24) When an amendment is under debate, no further proposal shall be received except one of the following:

(a) An amendment, namely, "that the motion be amended as follows: . . .";
(b) the closure, namely, "that the question be now put";
(c) the adjournment of the debate, namely, "that the debate on the motion be adjourned"; or
(d) the adjournment of the Council, namely, "that the Council do now adjourn".

(25) The proposal for the postponement of the question (which may specify a date for the further consideration of the question) shall be made and seconded without debate, and may be moved at any time, even during debate on an amendment. If the proposal is carried, the question shall be dropped from the programme of business. If it is lost, the debate shall proceed.

(26) The proposal for the closure shall be made and seconded without debate and shall be put forthwith. Should the proposal be carried, the motion or amendment under debate shall at once be voted on by the Council.

(27) If the proposal for the adjournment of the debate is carried, the Council shall pass to the next item on the programme of business and the debate shall be resumed at the next ordinary meeting of the Council. The proposer of the adjournment shall, on the resumption of the debate, be entitled to speak first.

(28) If the proposal for the adjournment of the Council is proposed and seconded, it shall be competent for the Chairman, before putting the question, to take the opinion of the Council as to whether it shall, before rising, proceed to the transaction of unopposed business.

(29) A motion to rescind a resolution which has been passed at a previous meeting shall be considered only if notice thereof has been given in terms of rule (6). It shall be passed if a majority of the votes recorded is in its favour. A motion to rescind a resolution which has been passed during a session of the Council may, however, notwithstanding what is prescribed above, be considered at the same session of the Council, provided that written notice thereof is given that the matter be considered on a subsequent day of that session. It shall be passed only if two thirds of the votes recorded are in its favour.

(30) The Registrar shall embody in the minutes any rulings of the Chairman as to the interpretation of these rules, if so requested by a member at the time of the ruling.

(31) Notice may be given of a motion to review any ruling of the Chairman as to the interpretation of these rules, if so requested by a member at the time of the ruling.

(32) Notice may be given of a motion to review any ruling of the Chairman, and when given shall constitute an instruction to the Executive Committee to consider and report to the Council on such ruling, and shall be placed on the agenda.

(33) The ruling of the chairman of any committee on a point of order may, on the request of any two members of the committee present at the meeting at which such ruling was given, be reviewed by the Executive Committee, which may, if it thinks fit, direct that such ruling shall be cancelled or amended, and the decision of the

en die beslissing van die Uitvoerende Komitee moet nagekom word deur die voorsitter van die komitee wie se beslissing in twyfel getrek is, tensy en totdat dit deur die Raad herroep word.

As enige beslissing van die Voorsitter van die Uitvoerende Komitee in twyfel getrek word, moet die Voorsitter die voorsitterstoel verlaat onderwyl die saak bespreek word: Met dien verstande dat geen beslissing bespreek of hersien mag word op 'n vergadering van die komitee waarop dit gegee is nie.

(34) As 'n lid nie met die meerderheid saamstem nie en hy sy meningsverskil genotuleer wil hê, moet hy dit dadelik vermeld; sodanige meningsverskil moet dan in die notule opgeneem word.

15. Onderstaande vorm moet gebruik word by die aansoek om registrasie van 'n medisyne:

MBR 1

VERTROULIK

AANSOEK OM REGISTRASIE VAN 'N MEDISYNE

Artikel 15 van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965)]

L.W.—Bestudeer die aanwysings op die keersy hiervan asseblief sorgvuldig voordat u die vorm invul.

BESONDERHEDE VAN APPLIKANT

Naam (1*).....
Sakeadres.....
Posadres.....
Telefoonnommer.....

BESONDERHEDE VAN MEDISYNE

Voorgestelde goedgekeurde naam (2*).....
Handelsmerk (handelsnaam, as daar een is) (3*).....
Bereidingsvorm (4*).....
Land van herkoms (land waar die basiese navorsing gedoen is).....
.....
Naam en sakeadres van vervaardiger van die preparaat.....
.....
.....
Klassifikasie (5*).....

Die medisyne was voor 5 Julie 1968 in hierdie formulering beskikbaar.

☐

Die medisyne was nie voor 5 Julie 1968 in hierdie formulering beskikbaar nie.

☐

(Maak 'n kruisie in die betrokke blokkie)

Die ondergetekende verklaar hierby dat al die inligting hierin en in die Aanhangsels hiervan waar en juis is (6*).

.....
Handtekening van applikant

Datum van aansoek.....

.....
Hoedanigheid

* (1*), (2*), ens. verwys na die aanwysings op die keersy.

ALGEMENE INLIGTING

1. Aansoek om die registrasie van 'n medisyne kan gedoen word deur—

(a) 'n apteker; of

(b) 'n regspersoon wat as apteker sake doen kragtens artikel 22 van die Wet op Aptekers, 1974 (Wet 53 van 1974), of iemand wat deur so 'n regspersoon gemagtig is om namens hom aansoek te doen; of

(c) in die geval van 'n medisyne vervaardig deur 'n persoon wat beskik oor 'n permit uitgereik kragtens die bepalings van artikel 22A (13) van die Wet, daardie persoon.

2. Indien geen goedgekeurde naam deur 'n aanvaarbare internasionale liggaam aan die medisyne toegeken is nie, moet die naam wat vir goedkeuring voorgestel is of gaan word, hier genoem word.

3. Die aandag word gevestig op artikel 1 (2) van die Wet. Verder moet daarop gelet word dat medisyne wat nie van presies dieselfde samestelling of sterkte is nie, nie

Executive Committee shall be acted on by the chairman of the committee whose ruling is called in question unless and until reversed by the Council.

If any ruling of the Chairman of the Executive Committee is called in question, the Chairman shall vacate the chair while the matter is under discussion: Provided, however, that no ruling may be discussed or reviewed during the meeting of the committee at which it has been given.

(34) If any member dissents from the opinion of the majority and wishes to have his dissent recorded, he shall state so forthwith; such dissent shall then be entered in the minutes.

15. The following form shall be used for application for the registration of a medicine:

MBR 1

CONFIDENTIAL

APPLICATION FOR REGISTRATION OF A MEDICINE

[Section 15 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965)]

N.B.—Please study the directions on the reverse side carefully before completing the form.

PARTICULARS OF APPLICANT

Name (1*).....
Business address.....
.....
Postal address.....
.....
Telephone No.....

PARTICULARS OF MEDICINE

Proposed approved name (2*).....
Trade mark (trade name, if any) (3*).....
.....
Form of preparation (4*).....
.....
Country of origin (country in which the basic research was conducted).....
Name and business address of manufacturer of the preparation
.....
.....
Classification (5*).....

The medicine was available in this formulation before 5 July 1968.

☐

The medicine was not available in this formulation before 5 July 1968.

☐

(I dicate with an X)

The undersigned he eby declares that all the information contained herein and in the Annexures hereto is correct and true (6*).

.....
Date of application..... Signature of applicant

.....
Designation

* (1*), (2*), etc. refer to directions on reverse side.

GENERAL INFORMATION

1. Application for the registration of a medicine may be made by—

(a) a pharmacist; or

(b) a body corporate which carries on business as a pharmacist in terms of section 22 of the Pharmacy Act, 1974 (Act 53 of 1974), or a person authorised by such body corporate to apply on its behalf; or

(c) in the case of a medicine which is manufactured by a person who is the holder of a permit issued under the provisions of section 22A (13) of the Act, that person.

2. If no approved name has been given to the medicine by an acceptable international body, the name which was, or will be, submitted for approval should be mentioned here.

3. Attention is drawn to section 1 (2) of the Act. Furthermore, it should be noted that medicines which are not identical in composition or strength are not

as dieselfde medisyne beskou word nie. Aansoeke om die registrasie van medisyne waarvan slegs die sterkte verskil, kan op dieselfde vorm gedoen word. Registrasiegelde is egter betaalbaar vir elke afsonderlike sterkte.

4. Die bereidingsvorm, byvoorbeeld oplossings, suspensies, oogdruppels, oordruppels, emulsies, salwe, setpille, tablette, kapsules en inspuitings, moet hier vermeld word.

5. Die klassifikasie van die medisyne soos beskryf in regulasies 4 en 5 moet hier vermeld word.

6. Enige persoon wat in verband met 'n medisyne 'n valse of misleidende verklaring doen—

(i) in 'n aansoek om die registrasie daarvan; of
(ii) by die verkoop daarvan;

begaan 'n misdryf (artikel 29).

7. Die registrasieprosedure kan 'n aanvang neem slegs indien Vorm MBR 1 en sy Aanhangsels behoorlik ingevul is. Slegs die inligting wat op die Aanhangsels gevra word, moet verskaf word.

8. Verwysings na literatuur moet in die toepaslike Aanhangsel verstrek word.

9. Alle dokumente moet in een van die amptelike tale voorgelê word.

10. 'n Monster van die kleinste beskikbare verpakking van die medisyne moet ingedien word indien die Raad daarom versoek.

MBR 1

AANHANGSEL 1

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die teks van die voubiljet moet voorgelê word en wel in die volgende volgorde:

1. Registrasienommer (vir toekenning deur die Raad).
2. Farmakologiese klassifikasie.
3. Skeduleringskategorie (vir toekenning deur die Raad).
4. Goedgekeurde naam (waar van toepassing).
5. Handelsnaam.
6. Samestelling (insluitende preserveermiddels, as daar is).
7. Identifikasie (fisiese voorkoms).
8. Farmakologiese werking.
9. Indikasies.
10. Kontra-indikasies.
11. Dosis en gebruiksaanwysings.
12. Newe-effekte en spesiale voorsorgmaatreëls.
13. Bekende simptome en spesifieke behandeling van oordosering (indien prakties moontlik om in te sluit).
14. Voorwaardes waaronder die medisyne geregistreer is (as daar is) soos deur die Raad gestel.
15. Aanbieding.
16. Bergingsvoorskrifte.
17. Naam van applikant.

MBR 1

AANHANGSEL 2

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....
Doseringseenheid.....

Die volgende is 'n lys van die name en hoeveelhede van elke aktiewe en nie-aktiewe bestanddeel wat die medisyne per doseringseenheid of ander geskikte massa- of volume-eenheid bevat en wat met betrekking tot die aktiewe bestanddele ooreen moet stem met die betrokke besonderhede in die voubiljet en op die etiket.

Besonderhede met betrekking tot oormaattoevoegings in die formulering moet afsonderlik aangedui word.

Bestanddeel		Hoeveelheid	Aktief of nie-aktief
Chemiese naam	Goedgekeurde naam (as daar een is)		

regarded as the same medicine. Applications for the registration of medicines of which only the strength varies may be made on the same form. However, registration fees in respect of each strength are payable.

4. The form of preparation, e.g. solutions, suspensions, eye drops, ear drops, emulsions, ointments, suppositories, tablets, capsules, injections, should be mentioned here.

5. The classification of the medicine as described in regulations 4 and 5 should be mentioned here.

6. Any person who makes any false or misleading statement in connection with any medicine—

(i) in an application for the registration thereof; or
(ii) in the course of the sale thereof;

is guilty of an offence (section 29).

7. The registration procedure can be commenced only if Form MBR 1 and its Annexures have been properly completed. Only the information required in the Annexures should be furnished.

8. References to literature should be furnished in the appropriate Annexure.

9. All documents shall be submitted in either of the official languages.

10. A sample of the smallest available pack of the medicine must be submitted if requested by the Council.

MBR 1

ANNEXURE 1

Name of applicant.....
Name of medicine.....
Form of preparation.....

The text of the package insert shall be submitted, and must be in the following order:

1. Registration number (to be allocated by the Council).
2. Pharmacological classification.
3. Scheduling category (to be allocated by the Council).
4. Approved name (where applicable).
5. Trade name.
6. Composition (including preservatives, if present).
7. Identification (physical appearance).
8. Pharmacological action.
9. Indications.
10. Contra-indication.
11. Dosage and directions for use.
12. Side effects and special precautions.
13. Known symptoms of overdosage and particulars of its specific treatment (where practicable to include).
14. Conditions of registration of the medicine (if any) imposed by the Council.
15. Presentation.
16. Storage directions.
17. Name of applicant.

MBR 1

ANNEXURE 2

Name of applicant.....
Name of medicine.....
Form of preparation.....
Dosage unit.....

The following is a schedule of the names and quantities of each active and non-active ingredient contained in a dosage unit or other suitable mass or volume unit of the medicine and must conform with the relevant particulars in the package insert and on the label with regard to the active ingredients.

Particulars with regard to averages in the formulation should be given separately.

Constituent		Quantity	Active or non-active
Chemical name	Approved name (if any)		

1. Goedgekeurde en chemiese name moet sover moontlik volgens die gepubliseerde lys van 'n aanvaarbare internasionale liggaam, bv. I.N.N., wees.
2. Waar die aangegewe hoeveelheid van die aktiewe bestanddeel verskil van dié op die etiket van die medisyne, moet hierdie verskil verduidelik word.

MBR 1

AANHANGSEL 3

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die name en struktuurformules van die aktiewe bestanddele is soos volg:

Goedgekeurde of chemiese naam	Struktuurformule
.....	.....
.....	.....
.....	.....

1. Goedgekeurde en chemiese name moet sover moontlik volgens die gepubliseerde lys van 'n aanvaarbare internasionale liggaam, bv. I.N.N., wees.
2. Verwysing na die volgende publikasies sal, waar van toepassing, aanneemlik wees:

British Pharmacopoeia, British Pharmaceutical Codex, Pharmacopeia of the United States, European Pharmacopoeia Pharmacopoeia Internationalis, Merck Index, Remington's Pharmaceutical Sciences of ander naslaanbronne wat vir die Raad aanvaarbaar is.

MBR 1

AANHANGSEL 4

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Spesifikasies vir al die aktiewe en nie-aktiewe grondstowwe wat in die vervaardigingsproses van die medisyne gebruik word, is soos volg:

.....
.....
.....

Verwysing na die publikasies vermeld in voetnoot 2 van Aanhangsel 3 sal, waar van toepassing, aanneemlik wees. Waar verwys word na ander bronne, moet die gegewens die aansoek vergesel.

MBR 1

AANHANGSEL 5

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die analitiese kontroleprosedures wat met alle aktiewe en nie-aktiewe grondstowwe voor gebruik in die vervaardigingsproses gevolg word, is soos volg:

.....
.....
.....

Vermeld *in elke geval* in watter laboratorium genoemde analitiese kontroleprosedures uitgevoer word.
Indien in ooreenstemming met Aanhangsel 4, sal 'n verwysing voldoende wees.

MBR 1

AAHNANGSEL 6

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die analitiese kontroleprosedures gedurende die vervaardigingsproses gevolg, en die gereeldheid waarmee uitgevoer, is soos volg:

.....
.....
.....

Sien voetnoot van Aanhangsel 5.

MBR 1

AANHANGSEL 7

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Volledige spesifikasies van die finale vervaardigde produk is soos volg:

.....
.....
.....

1. Approved and chemical names should, where possible, be given in terms of the published list of an acceptable international body, e.g. I.N.N.
2. Where the stated amount of active ingredient differs from that on the label of the medicine, this difference should be explained.

MBR 1

ANNEXURE 3

Name of applicant.....
Name of medicine.....
Form of preparation.....

The names and structural formulae of the active ingredients are as follows:

Approved or chemical name	Structural formula
.....	.....
.....	.....
.....	.....

1. Approved and chemical names should, where possible, be given in terms of a published list of an acceptable international body, e.g. I.N.N.
2. Reference to the following publications will, where applicable, be acceptable:

British Pharmacopoeia, British Pharmaceutical Codex, Pharmacopeia of the United States, European Pharmacopoeia, Pharmacopeia Internationalis, Merck Index, Remington's Pharmaceutical Sciences, or such other works of reference as will be acceptable to the Council.

MBR 1

ANNEXURE 4

Name of applicant.....
Name of medicine.....
Form of preparation.....

Specifications for all the active and non-active raw materials used in the manufacturing process of the medicines are as follows:

.....
.....
.....

Reference to publications mentioned in footnote 2 of Annexure 3 will, where applicable, be acceptable. Where reference is made to other sources, the information must accompany the application.

MBR 1

ANNEXURE 5

Name of applicant.....
Name of medicine.....
Form of preparation.....

The analytical control procedures which are performed on all active and non-active raw materials before they are used in the manufacturing process are as follows:

.....
.....
.....

Specify *in each case* in which laboratory the said analytical control procedures are carried out.
If the above corresponds to Annexure 4, reference thereto will suffice.

MBR 1

ANNEXURE 6

Name of applicant.....
Name of medicine.....
Form of preparation.....

The analytical control procedures and the frequency with which they are performed during the manufacturing process are as follows:

.....
.....
.....

See footnote to Annexure 5.

MBR 1

ANNEXURE 7

Name of applicant.....
Name of medicine.....
Form of preparation.....

Full specifications of the final manufactured product are as follows:

.....
.....
.....

MBR 1

AANHANGSEL 8

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die aard van en, waar van toepassing, die spesifikasies van die verpakkingsmateriaal in direkte kontak met die doseringsvorm is soos volg:

.....
.....
.....

MBR 1

AANHANGSEL 9

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die analitiese kontroleprosedures wat op die finale vervaardigde produk toegepas word, is soos volg:

.....
.....
.....

1. Verwysing na die publikasies genoem in voetnoot 2 van Aanhangsel 3 sal, waar van toepassing, aanneemlik wees.
2. Vermeld die laboratorium waar bovermelde analitiese kontroleprosedures uitgevoer word.

MBR 1

AANHANGSEL 10

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Hieronder volg—

(a) die eksperimentele besonderhede en resultate van stabiliteitstoetse op die finale vervaardigde produk uitgevoer;
(b) die interpretasie van bovermelde resultate; en
(c) die afgeleide rakleeftyd.

.....
.....

MBR 1

AANHANGSEL 11

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Opsommings van die metodes van vervaardiging en verpakking is soos volg:

.....
.....

Indien enige van die vervaardigings- of verpakkingsprosedures by 'n ander adres as dié van die vervaardiger uitgevoer word, moet volle besonderhede daarvan verstrek word.

MBR 1

AANHANGSEL 12

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

Die volgende verslae ten opsigte van registrasie is uitgereik deur die statutêre lisensie- of registrasieowerheid in die land van herkoms of enige ander land. (Indien geen sodanige verslag beskikbaar is nie, moet alle tersaaklike besonderhede verstrek word met betrekking tot die vordering wat reeds in verband met die registrasie van die medisyne gemaak is.)

MBR 1

AANHANGSEL 13

Naam van applikant.....
Naam van medisyne.....
Bereidingsvorm.....

L.W.—In die volgende gevalle moet ondergemelde inligting slegs verstrek word indien die Raad daarom vra:

(i) Medisyne wat in die Republiek of die Gebied vir verkoop aangebied was voor die afkondiging van die regulasies.

(ii) Indien besonderhede en resultate soos beskryf in item B van Aanhangsel 15 verstrek word.

MBR 1

ANNEXURE 8

Name of applicant.....
Name of medicine.....
Form of preparation.....

The nature, and the specifications, where applicable, of the packaging materials in immediate contact with the dosage form, are as follows:

.....
.....
.....

MBR 1

ANNEXURE 9

Name of applicant.....
Name of medicine.....
Form of preparation.....

The analytical control procedures which are performed on the final manufactured product are as follows:

.....
.....
.....

1. Reference to the publications mentioned in footnote 2 to Annexure 3 will, where applicable, be acceptable.

2. Mention should be made of the laboratory where the above analytical control procedures are carried out.

MBR 1

ANNEXURE 10

Name of applicant.....
Name of medicine.....
Form of preparation.....

The following is a description of—

(a) the experimental details and results of stability tests performed on the final manufactured product;
(b) the interpretation of the above results; and
(c) the inferred shelf life.

.....
.....

MBR 1

ANNEXURE 11

Name of applicant.....
Name of medicine.....
Form of preparation.....

Summaries of the methods of manufacture and packaging are as follows:

.....
.....

Should any of the manufacturing or packaging procedures be carried out at an address other than that of the manufacturer, full particulars of such procedures must be furnished.

MBR 1

ANNEXURE 12

Name of applicant.....
Name of medicine.....
Form of preparation.....

The following reports with regard to registration were issued by the statutory licensing or registering authority in the country of origin or any other country. (If no such report is available, all relevant particulars with regard to the progress already made concerning the registration of the medicine must be furnished.)

MBR 1

ANNEXURE 13

Name of applicant.....
Name of medicine.....
Form of preparation.....

N.B.—In the following instances the particulars below should be furnished only if called for by the Council:

(i) Medicines which were available for sale in the Republic or the Territory prior to the promulgation of the regulations.

(ii) Where details and results as described in item B of Annexure 15 are submitted.

Eksperimentele besonderhede en resultate van die toetse uitgevoer op die medisyne om die fisiologiese beskikbaarheid daarvan te bevestig:

.....
.....
.....

MBR 1

AANHANGSEL 14

Naam van applikant.....

Naam van medisyne.....

Bereidingsvorm.....

L.W.—Met betrekking tot medisyne wat in die Republiek of die Gebied vir verkoop beskikbaar was voor die afkondiging van die regulasies, moet ondergemelde besonderhede slegs verskaf word indien die Raad daarom vra.

A. Opsommings* van, en gevolgtrekkings uit, proewe wat op diere uitgevoer is om alle aspekte van toksisiteit van die medisyne aan te toon, en om die veiligheid van die gebruik van die medisyne te staaf, met spesiale verwysing na:

(i) LD 50-bepalings;
(ii) Teratogenisiteitstudies;
(iii) Karsinogenisiteitstudies;
(iv) Ander proewe om die veiligheid van die medisyne te staaf:

.....
.....

In bepaalde gevalle waar goed bekende aktiewe bestanddele betrokke is, kan die Raad vrystelling van die voorlegging van bovermelde inligting verleen.

B. Opsommings* van die metodes, eksperimentele resultate en gevolgtrekkings van proewe wat op diere uitgevoer is met betrekking tot die doeltreffendheid van die gebruik van die medisyne, veral met betrekking tot die verband tussen die aard van die proewe en die doel waarvoor die medisyne gepropageer word of sal word, en verder met betrekking tot die dosis en wyse van toediening van die medisyne, met spesiale verwysing na farmakokinetiese toetse op proefdiere:

.....
.....

* Volle besonderhede sal, indien nodig, deur die Raad aangevra word.

MBR 1

AANHANGSEL 15

Naam van applikant.....

Naam van medisyne.....

Bereidingsvorm.....

L.W.—Met betrekking tot medisyne wat in die Republiek of die Gebied vir verkoop beskikbaar was voor die afkondiging van die regulasies, moet ondergemelde besonderhede slegs verskaf word indien die Raad daarom vra:

.....
.....
.....

A. Opsomming* van die proewe wat op mense uitgevoer is met betrekking tot die veiligheid van die gebruik van die medisyne, met spesiale verwysing na die bepaalde dosis, toedieningsroetes gebruik en newe-effekte waargeneem:

.....
.....

B. Besonderhede van kliniese proewe uitgevoer met betrekking tot die doeltreffendheid van die gebruik van die medisyne, met 'n opsomming* van die aard van die proewe, deur wie uitgevoer en waar, resultate, ens. met spesiale verwysing na vergelykende of gekontroleerde kliniese proewe, dubbelblinde proewe, ens.:

.....
.....
.....

C. Eksperimentele besonderhede en resultate van die toetse uitgevoer om die bloed- of ander geskikte fisiologiese peile wat gepaard gaan met die werking van die medisyne waarop aanspraak gemaak word, te bepaal:

.....
.....

* Volle besonderhede sal, indien nodig, deur die Raad aangevra word.

Experimental details and results of the tests performed on the medicine to confirm its physiological availability:

.....
.....
.....

MBR 1

ANNEXURE 14

Name of applicant.....

Name of medicine.....

Form of preparation.....

N.B.—With regard to medicines which were available for sale in the Republic or the Territory prior to the promulgation of the regulations, the particulars below should be furnished only if called for by the Council.

A. Summaries* of, and conclusions derived from, tests performed on animals to demonstrate all aspects of the toxicity of the medicine, and to substantiate the safety of its use, with special reference to:

(i) LD 50 determinations;
(ii) teratogenicity studies;
(iii) carcinogenicity studies;
(iv) other tests to substantiate the safety of the medicine:

.....
.....

In certain cases where well-known active constituents are concerned the Council may grant exemption from the submission of the above information.

B. Summaries* of methods of, experimental results of, and conclusions drawn from, tests performed on animals with reference to the efficacy of the medicine, with special emphasis on the relationship between the tests performed and the purpose for which the medicine is, or will be, propagated, and further with regard to the dosage and method of administration of the medicine, with special reference to pharmacokinetic tests on experimental animals:

.....
.....

* Full particulars will be requested by the Council, if required.

MBR 1

ANNEXURE 15

Name of applicant.....

Name of medicine.....

Form of preparation.....

N.B.—With regard to medicines which are available for sale in the Republic or the Territory prior to the promulgation of the regulations, the particulars below should be furnished only if called for by the Council:

.....
.....

A. Summaries* of the tests performed on human beings in regard to the safety of the use of the medicine, with special reference to the particular dosage, routes of administration used and the side effects observed:

.....
.....
.....

B. Particulars of clinical tests conducted with reference to the efficacy of the use of the medicine, with a summary* of the nature of the tests, by whom conducted and where, results, etc., with special reference to comparative or controlled clinical tests, double blind tests, etc:

.....
.....
.....

C. Experimental details and results of the tests performed to establish the blood or other suitable physiological levels associated with the action claimed for the medicine:

.....
.....
.....

* If required, full particulars will be requested by the Council.

AANHANGSEL 16 MBR 1

BESONDERHEDE VAN AANSOEK VIR PUBLIKASIE IN *STAATSKOERANT*

(Moet in duplo in albei amptelike tale ingevul word)

Naam en sakeadres van applikant
Name and business address of applicant.....

Naam en sakeadres van vervaardiger (volledige adres)
Name and business address of manufacturer (full address).....

Voorgestelde goedgekeurde naam van medisyne
Proposed approved name of medicine.....

Bereidingsvorm
Form of preparation.....

Aktiewe bestanddele (hoeveelheid per doseringseenheid)
Active ingredients (quantity per dosage unit).....

16. Onderstaande vorm moet uitgereik word deur inspekteurs ten opsigte van monsters kragtens die Wet geneem:

29 (a)

MEDISYNEBEHEERRAAD

SERTIFIKAAT DEUR INSPEKTEUR

'N AFSKRIF VAN DIE SERTIFIKAAT MOET AAN DIE EIENAAR OF VERKOPE VAN DIE MEDISYNE OF GELYSTE STOF OF SY AGENT OORHANDIG OF PER GEREGISTREERDE POS AAN HOM GESTUUR WORD

Hierby sertifiseer ek dat bygaande ('n) monster(s) is wat op.....te *.....
van 'n medisyne of gelyste stof verkry uit voorrade onder toesig van †.....
geneem is in die teenwoordigheid van ‡.....

Die volgende is besonderhede in verband met die monster(s) van die medisyne of gelyste stof:

1. Goedgekeurde naam.....
2. Handelsnaam (as daar een is).....
3. Registrasienommer.....
4. Geraamde hoeveelheid.....
5. Naam en sakeadres:
   (a) Vervaardiger.....
   .....
   (b) Verkoper.....
6. Lotnommer op etiket.....
7. Verstrykingsdatum op etiket.....
8. Ander besonderhede op etiket.....
9. Besonderhede wat in die voubiljet voorkom.....
10. Enige ander verbandhebbende besonderhede.....
    .....

Getuie..... Inspekteur.....
Datum.....

* Volledige adres.
† Naam en volledige adres.
‡ Naam en volledige adres van getuie.

17. Onderstaande vorm moet uitgereik word in verband met die toets, ondersoek of ontleding van monsters kragtens die Wet geneem:

MEDISYNEBEHEERRAAD

SERTIFIKAAT DEUR ONTLEDER, FARMAKOLOOG OF PATOLOOG OOR DIE RESULTAAT VAN DIE ONTLEDING OF TOETS OF ONDERSOEK VAN 'N MONSTER VAN 'N MEDISYNE OF GELYSTE STOF

Ek (volle naam).....,
'n behoorlik aangestelde: (i) ontleder; (ii) farmakoloog of (iii) patoloog kragtens artikel 27 van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965), verklaar hierby dat ek op (datum)..... 'n monster van*.....
van †.....
vir: (i) ontleding; (ii) toets; (iii) ondersoek ontvang het; dat die monster soos volg gemerk was ‡.....; dat ek die monster ontleed en/of getoets het en dat my bevindings is soos hieronder aangedui.

Opmerkings in verband met resultate.....
.....

.....
Ontleder, Farmakoloog, Patoloog

* Naam van inhoud soos dit op die etiket voorkom.
† Naam van persoon van wie monster ontvang is.
‡ Naam van vervaardiger, lotnommer en enige ander besonderhede wat op die etiket voorkom.
(i), (ii), (iii) Skrap wat nie van toepassing is nie.

ANNEXURE 16 MBR 1

PARTICULARS OF THE APPLICATION FOR PUBLICATION IN THE *GOVERNMENT GAZETTE*

(Must be completed in duplicate in both official languages)

Naam en sakeadres van applikant
Name and business address of applicant.....

Naam en sakeadres van vervaardiger (volledige adres)
Name and business address of manufacturer (full address).....

Voorgestelde goedgekeurde naam van medisyne
Proposed approved name of medicine.....

Bereidingsvorm
Form of preparation.....

Aktiewe bestanddele (hoeveelheid per doseringseenheid)
Active ingredients (quantity per dosage unit).....

16. The following form shall be issued by inspectors in respect of samples taken in terms of the Act:

29 (a)

MEDICINES CONTROL COUNCIL

CERTIFICATE BY INSPECTOR

A COPY OF THIS CERTIFICATE SHALL BE HANDED OR FORWARDED BY REGISTERED POST TO THE OWNER OR SELLER OF THE MEDICINE OR SCHEDULED SUBSTANCE OR TO HIS AGENT

I hereby certify that the accompanying is (are) a sample/samples of a medicine or scheduled substance taken on.....
at *.....
from stock in charge of †.....
in the presence of ‡.....

The following are particulars in connection with the sample(s) of the medicine)or scheduled substance:

1. Approved name.....
2. Trade name (if any).....
3. Registration number.....
4. Estimated quantity.....
5. Name and business address:
   (a) Manufacturer.....
   .....
   (b) Seller.....
6. Batch number on label.....
7. Expiry date on label.....
8. Other particulars on label.....
9. Particulars on package insert.....
10. Any other appropriate particulars.....
    .....

Witness..... Inspector.....
Date.....

* Full address.
† Name and full address.
‡ Name and full address of witness.

17. The following form shall be issued with regard to the testing, examination or analysis of samples taken under the Act:

MEDICINES CONTROL COUNCIL

CERTIFICATE BY ANALYST, PHARMACOLOGIST OR PATHOLOGIST OF RESULTS OF ANALYSIS OR TESTING OR EXAMINATION OF SAMPLE OF A MEDICINE OR SCHEDULED SUBSTANCE

I, (full name).....
a duly appointed: (i) analyst; (ii) pharmacologist; of (iii) pathologist in terms of section 27 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), hereby declare that on (date).....
I received a sample of *.....from †.....
for: (i) analysis; (ii) testing: (iii) examination; that the sample was marked as follows ‡.....
.....;
that I have analysed and/or tested the sample and found the results which are subjoined.....
Remarks with regard to results.....
.....

.....
Analyst, Pharmacologist, Pathologist

* Name of contents as described on the label.
† Name of person from whom sample was received.
‡ Name of manufacturer, batch number and any other particulars on the label.
(i), (ii), (iii) Delete whichever is not applicable.

Verkoop van medisyne en stowwe nie in Bylaes vervat nie, deur ander persone as aptekers, geneeshere, tandartse en veeartse

18. (1) 'n Lisensie vir die verkoop van 'n medisyne of 'n stof wat nie in die Bylaes van die Wet vervat is nie kan, onderworpe aan die bepalings van die betrokke provinsiale ordonnansie of van die betrokke ordonnansie van die gebied, aan 'n persoon uitgereik word op voorwaarde dat—

(a) sodanige persoon by die owerheid vermeld in die ordonnansie om sodanige lisensie aansoek doen;

(b) die medisyne slegs van die perseel in die lisensie genoem, verkoop word; en

(c) die lisensie te alle tye vir insae op die perseel daarin genoem, gehou word.

(2) Die vorm wat vir aansoek om 'n lisensie gebruik moet word, moet voldoen aan die vereistes van die lisensiërende owerheid.

(3) Die lisensiërende owerheid moet, by die uitreiking van die lisensie, 'n afskrif aan die Raad verskaf.

Voorskrif vir 'n medisyne of 'n gelyste stof

19. Elke voorskrif moet uitgeskryf en onderteken wees deur 'n geneesheer, tandarts of veearts en moet die volgende vermeld:

(a) Die datum waarop die voorskrif uitgereik is;

(b) die naam en hoeveelheid van die medisyne of gelyste stof wat daarvolgens gelewer kan word: Met dien verstande dat in die geval van Bylae 6- en Bylae 7-stowwe die hoeveelheid wat verkoop kan word in syfers sowel as in woorde aangedui moet word: Met dien verstande voorts dat waar die persoon wat die voorskrif uitreik in gebreke gebly het om die hoeveelheid in syfers sowel as woorde aan te dui, die geneesheer, tandarts, veearts of apteker, na die verkryging van bevestiging van die persoon wat die voorskrif uitgereik het, die syfers of woorde wat uitgelaat is, kan invoeg;

(c) die naam en adres van die pasiënt of, in die geval van 'n voorskrif deur 'n veearts uitgereik, die naam en adres van die persoon aan wie die medisyne of gelyste stof verkoop moet word: Met dien verstande dat indien die geneesheer, tandarts of veearts wat die voorskrif uitgereik het, nagelaat het om die adres van die pasiënt of die persoon soos hierbo vermeld, daarop aan te bring, bedoelde adres aangebring kan word deur die persoon wat die voorskrif toeberei; en

(d) die naam, kwalifikasies en adres van die geneesheer, tandarts of veearts deur wie sodanige voorskrif uitgereik is: Met dien verstande dat genoemde gegewens op die voorskrif gedruk kan word.

Bestellings vir Bylae 6- en Bylae 7-stowwe deur aptekers, geneeshere, tandartse en veeartse

20. Elke bestelling vir 'n Bylae 6- of Bylae 7-stof, uitgereik deur 'n apteker, geneesheer, tandarts, of veearts, moet die volgende vermeld:

(a) Die naam en hoeveelheid van die stof wat daarvolgens gelewer kan word: Met dien verstande dat die hoeveelheid wat gelewer kan word in syfers sowel as in woorde aangedui moet word;

(b) die naam, sakeadres en kwalifikasies van die betrokke apteker, geneesheer, tandarts of veearts, wat die Bylae 6- of Bylae 7-stof bestel; en

(c) die datum van die bestelling.

Sale of medicines and substances not contained in the Schedules by persons other than pharmacists, medical practitioners, dentists and veterinarians

18. (1) A licence for the sale of a medicine or substance not contained in the Schedules to the Act may, subject to the provisions of the appropriate provincial ordinance or of the ordinance of the territory, be issued to a person on condition that—

(a) such person applies for such licence to the authority specified in the ordinance;

(b) the medicine is sold only from the premises stated in the licence;

(c) the licence is at all times available for inspection on the premises mentioned therein.

(2) The form to be used for application for a licence shall conform to the requirements of the licensing authority.

(3) The licensing authority shall, when a licence is issued, furnish the Council with a copy thereof.

Prescription for a medicine or scheduled substance

19. Every prescription shall be written and signed by a medical practitioner, dentist or veterinarian and shall state—

(a) the date of issue of the prescription;

(b) the name and quantity of the medicine or scheduled substance to be supplied thereunder: Provided that in the case of Schedule 6 and Schedule 7 substances the quantity to be supplied shall be expressed in figures as well as in words: Provided further that where the prescriber has failed to express the quantity in figures as well as in words, the medical practitioner, dentist, veterinarian or pharmacist dispensing the prescription may, after obtaining confirmation from the prescriber, insert the words or figures that have been omitted;

(c) the name and address of the patient or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance shall be sold: Provided that where the medical practitioner, dentist or veterinarian who issued the prescription has omitted to insert thereon the address of the patient or person as aforesaid, such address may be inserted by the person by whom the prescription is dispensed; and

(d) the name, qualifications and address of the medical practitioner, dentist or veterinarian by whom the prescription was issued: Provided that such particulars may be printed on the prescription.

Orders for Schedule 6 and Schedule 7 substances by pharmacists, medical practitioners, dentists and veterinarians

20. Every order for a Schedule 6 or Schedule 7 substance, issued by a pharmacist, medical practitioner, dentist or veterinarian, shall state—

(a) the name and quantity of the substance to be supplied thereon: Provided that the quantity to be supplied shall be expressed in figures as well as in words;

(b) the name, business address and qualifications of the particular pharmacist, medical practitioner, dentist or veterinarian ordering the Schedule 6 or Schedule 7 substance; and

(c) the date of the order.

Aanhou en verkoop van Bylae 1-, Bylae 2-, Bylae 3- en Bylae 4-stowwe deur persone in diens van 'n vervaardiger van of groothandelaar in farmaseutiese produkte

21. 'n Persoon wat by 'n vervaardiger van, of groothandelaar in farmaseutiese produkte in diens is en deur sodanige vervaardiger of groothandelaar daartoe gemagtig is, kan Bylae 1-, Bylae 2-, Bylae 3- en Bylae 4-stowwe aanhou en verkoop: Met dien verstande dat—

(a) sodanige persoon in besit is van 'n magtigingsdokument waarin sy naam, adres en handtekening, en die naam, sakeadres en handtekening van die betrokke vervaardiger of groothandelaar, asook die naam en hoeveelheid van elke gelyste stof wat hy op 'n gegewe tydstip kan aanhou en die periode waarvoor aldus hy gemagtig is, voorkom; en voorts met dien verstande dat sodanige magtigingsdokument op versoek van 'n persoon aan wie sodanige stowwe verkoop word, getoon moet word;

(b) sodanige persoon 'n register aanhou waarin die hoeveelheid van alle ontvangste en verkope van die betrokke gelyste stowwe aangeteken word, en die balans daarvan moet opmaak sodat duidelik blyk hoeveel van elke gelyste stof in voorraad oorbly op die laaste dag van Maart, Junie, September en Desember van elke jaar, welke balans opgemaak moet word binne 14 dae na elkeen van voornoemde datums, en deur die betrokke vervaardiger of groothandelaar geïnspekteer en as korrek gesertifiseer moet word; en

(c) die verkoop van sodanige gelyste stowwe slegs kan plaasvind volgens 'n bestelling uitgereik en onderteken deur 'n apteker, geneesheer, tandarts of veearts, waarin die naam en hoeveelheid van die stowwe wat verkoop kan word, die naam, sakeadres en kwalifikasies van die apteker, geneesheer, tandarts of veearts aan wie die stowwe verkoop is en die datum waarop sodanige bestelling uitgevoer is, vermeld word: Met dien verstande voorts dat geen herhaling van die verkoop kragtens sodanige bestelling mag geskied nie en dat die bestelling vir 'n tydperk van een jaar behou moet word.

Rekord van Bylae 5-stowwe, vir gebruik deur vervaardiger, groothandelaar, invoerder of uitvoerder

22. (1) 'n Rekord van Bylae 5-stowwe moet gehou word en moet die volgende inligting bevat:

(a) Die naam en sakeadres van die persoon van wie elke sodanige stof ontvang is of aan wie sodanige stof verkoop is;

(b) die datum waarop sodanige stof ontvang of verkoop is; en

(c) die hoeveelheid van sodanige stof wat ontvang of verkoop is.

(2) 'n Rekord van Bylae 5-stowwe moet vir 'n tydperk van minstens drie jaar behou word.

Register van Bylae 6-stowwe, vir gebruik deur vervaardiger, groothandelaar, invoerder of uitvoerder

23. (1) Die register van Bylae 6-stowwe moet in die vorm wees soos hieronder aangedui, en die volgende besonderhede moet daarin aangeteken word:

(a) Die naam en sakeadres van die persoon van wie elke sodanige stof ontvang is of aan wie dit verkoop is;

(b) die datum waarop sodanige stof ontvang of verkoop is;

(c) die hoeveelheid van sodanige stof wat ontvang of verkoop is; en

(d) die hoeveelheid wat in voorraad oorbly op die laaste dag van Maart, Junie, September en Desember van elke jaar.

Keeping and sale of Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substances by persons in the service of a manufacturer of or a wholesale dealer in pharmaceutical products

21. A person who is in the service of a manufacturer of or wholesale dealer in pharmaceutical products and who has been authorised thereto by such manufacturer or wholesale dealer may keep and sell Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substances: Provided that—

(a) such person shall be in possession of a document of authorisation on which appear his name and address and signature and the name, business address and signature of the manufacturer or wholesale dealer concerned, as well as the name and quantity of each scheduled substance which he may keep at any given time and the period for which he is so authorised: Provided further that such document of authorisation shall be produced, on request, to any person to whom such substances are sold;

(b) such person shall keep a register in which the quantities of all receipts and sales of the scheduled substances concerned have been entered, and shall balance such register so as to show clearly the quantity of every scheduled substance remaining in stock as on the last day of March, June, September and December of each year, the balancing to be completed within 14 days of the aforementioned dates, and the balances so shown shall be inspected and certified as correct by the manufacturer or wholesale dealer concerned; and

(c) the sale of such scheduled substances shall take place only on an order issued and signed by a pharmacist, medical practitioner, dentist or veterinarian, on which shall appear the name and quantity of the substances which may be sold thereon, the name and business address and qualifications of the pharmacist, medical practitioner, dentist or veterinarian to whom the substances were sold and the date on which such order was executed: Provided further that not more than one issue of such substances shall be made on such order and that such order shall be retained for one year.

Schedule 5 substances record for use by manufacturer, wholesaledealer, importer or exporter

22. (1) A Schedule 5 substances record shall be kept and shall contain the following information:

(a) The name and business address of the person from whom each such substance has been received or to whom such substance has been sold;

(b) the date on which such substance was received or sold;

(c) the quantity of such substance received or sold;

(2) A Schedule 5 substances record shall be retained for a period of not less than three years.

Schedule 6 substances register for use by manufacturer, wholesaledealer, importer or exporter

23. (1) The Schedule 6 substances register should be in the form indicated hereunder and the undermentioned details must be entered therein:

(a) the name and business address of the person from whom each such substance was received or to whom it was sold;

(b) the date on which such substance was received or sold;

(c) the quantity of such substance received or sold; and

(d) the quantity in stock on the last day of March, June, September and December of each year.

(2) Die register van Bylae 6-stowwe dien ook as die bestelboek vereis by artikel 22A (8) (b) (iii) van die Wet, en die besonderhede vervat in subregulasie (1) moet daarin aangeteken word.

(3) Die register van Bylae 6-stowwe moet vir 'n tydperk van minstens drie jaar nadat die laaste aantekening daarin gedoen is, by die sakeadres van die verkoper behou word.

REGISTER VAN BYLAE 6-STOWWE

Naam van Bylae 6-stof.....

Ontvangste			Uitreikings		
Datum	Naam en adres van leweransier	Hoeveelheid	Datum	Naam en adres van koper	Hoeveelheid

Rekord van ontvangs van Bylae 5- en Bylae 6-stowwe gehou deur aptekers wat by kleinhandel verkoop, en deur geneeshere, tandartse en veeartse

24. (1) Elke apteker wat by kleinhandel verkoop, en elke geneesheer, tandarts of veearts moet 'n rekord hou van alle ontvangste van Bylae 5- en Bylae 6-stowwe en moet sodanige rekord vir 'n tydperk van minstens drie jaar behou.

(2) Die rekord in subregulasie (1) bedoel, moet bestaan uit die fakture van aankoop of 'n afsonderlike register van sodanige stowwe.

Register van Bylae 7-stowwe

25. (1) Die register van Bylae 7-stowwe moet in die vorm wees soos hieronder aangedui, en die volgende besonderhede moet daarin aangeteken word:

(a) Die naam en sakeadres van die persoon van wie elke sodanige stof ontvang is of aan wie dit verkoop is;

(b) die datum waarop sodanige stof ontvang of verkoop is;

(c) die hoeveelheid van sodanige stof wat ontvang of verkoop is;

(d) die hoeveelheid wat in voorraad oorbly op die laaste dag van Maart, Junie, September en Desember van elke jaar; en

(e) in die geval van 'n voorskrif deur 'n geneesheer, tandarts of veearts uitgereik, ook die naam en sakeadres van sodanige persoon.

(2) Die register van Bylae 7-stowwe moet vir 'n tydperk van minstens drie jaar nadat die laaste aantekening daarin gedoen is, by die sakeadres van die verkoper behou word.

(2) The Schedule 6 substances register also serves as an order book as required in terms of section 22A (8) (b) (iii) of the Act and the details contained in subregulation (1) shall be entered therein.

(3) The Schedule 6 substances register shall be retained at the business address of the seller for a period of not less than three years after the date of the last entry therein.

SCHEDULE 6 SUBSTANCES REGISTER

Name of Schedule 6 substance.....

Receipts			Issues		
Date	Name and address of supplier	Quantity	Date	Name and address of purchaser	Quantity

Record of receipt of Schedule 5 and Schedule 6 substances to be kept by pharmacists who sell by retail, and medical practitioners, dentists and veterinarians

24. (1) Every pharmacist who sells by retail, and every medical practitioner, dentist or veterinarian shall keep a record of all receipts of Schedule 5 and Schedule 6 substances, and shall retain such record for a period of not less than three years.

(2) The record referred to in subregulation (1) shall consist of the invoices of purchase or a separate register of such substances.

Schedule 7 substances register

25. (1) The Schedule 7 substances register should be in the form indicated hereunder and the undermentioned details must be entered therein:

(a) The name and business address of the person from whom each such substance or to whom it was sold was received;

(b) the date on which such substance was received or sold;

(c) the quantity of such substance received or sold;

(d) the quantity in stock on the last day of March, June, September and December of each year; and

(e) in the case of a prescription issued by a medical practitioner, dentist or veterinarian, also the name and business address of such person.

(2) The Schedule 7 substances register shall be retained at the business address of the seller for a period of not less than three years after the date of the last entry therein.

REGISTER VAN BYLAE 7-STOWWE

Naam van Bylae-stof.....

Ontvangste				Uitreikings			
Datum	Naam en adres van leweransier	Hoeveelheid	Datum	Naam en adres van koper of pasiënt	Naam en adres van voorskrywer	Hoeveelheid	Voorskrifnommer

SCHEDULE 7 SUBSTANCES REGISTER

Name of Schedule 7 substance.....

Receipts			Issues				
Date	Name and address of supplier	Quantity	Date	Name and address of purchaser or patient	Name and address or prescriber	Quantity	Prescription No.

Invoer, uitvoer en vervaardiging van Bylae 6- en Bylae 7-stowwe

26. (1) 'n Permit vir die invoer of uitvoer deur 'n goedgekeurde poskantoor of inklarings- of uitklaringshawe of die vervaardiging van 'n Bylae 6- of Bylae 7-stof kan uitgereik word onderworpe daaraan dat 'n aansoek om sodanige permit onderteken deur 'n geneesheer, tandarts, veearts of apteker en met vermelding van die volgende gegewens by die Registrateur van Medisyne, Privaatsak X88, Pretoria, 0001, ingedien word:

(a) Die naam en hoeveelheid van die betrokke Bylae 6- of Bylae 7-stof;

(b) die bereidingsvorm waarin die stof voorkom;

(c) die naam en sakeadres van die persoon aan wie die stof uitgevoer of van wie die stof ingevoer gaan word, sowel as die land van herkoms of bestemming van die stof;

(d) die doel waarvoor sodanige stof nodig is;

(e) in die geval van 'n aansoek om 'n uitvoerpermit, 'n sertifikaat van 'n behoorlik gemagtigde beampte van die regering of administrasie van die land waarheen uitgevoer word, ten effekte dat daardie regering of administrasie oortuig is dat die medisyne uitsluitlik vir geneeskundige, wetenskaplike of opvoedkundige doeleindes gebruik gaan word en dat dit die invoer daarvan goedkeur; en

(f) enige verdere besonderhede deur die Sekretaris of die Raad verlang.

(2) 'n Permit vir die invoer of uitvoer van 'n Bylae 6- of Bylae 7-stof, ingevolge subregulasie (1) uitgereik, moet die volgende inligting bevat:

(a) Die naam en sakeadres van die aansoeker;

(b) die naam en sakeadres van die persoon aan wie die stof uitgevoer word of van wie die stof ingevoer word, sowel as die land van herkoms of bestemming van die stof;

(c) die naam en hoeveelheid van elke stof wat kragtens die permit ingevoer of uitgevoer kan word;

(d) die geldigheidsduur van die permit;

(e) in die geval van 'n invoerpermit, die plek waar die stof geberg of verwerk gaan word;

(f) die voorwaardes waarkragtens sodanige permit uitgereik word;

(g) voorskrifte ten opsigte van die verslae en opgawes wat deur die aansoeker ingedien moet word; en

(h) enige ander gegewens deur die Sekretaris bepaal.

(3) 'n Permit ingevolge subregulasie (1) uitgereik, is onderworpe aan die voorwaardes daarin vermeld en kan gewysig of ingetrek word.

Kweek of insamel van plante waaruit Bylae 6- en Bylae 7-stowwe afgetrek, verkry, voortgebring of vervaardig kan word

27. (1) 'n Permit vir die kweek of insamel van plante of gedeeltes daarvan waaruit Bylae 6- of Bylae 7-stowwe afgetrek, verkry, voortgebring of vervaardig kan word,

Importation, exportation and manufacture of Schedule 6 and Schedule 7 substances

26. (1) A permit for the importation or exportation through an approved post office or port of entry or exit or the manufacture of a Schedule 6 or Schedule 7 substance may be issued after the submission to the Registrar of Drugs, Private Bag X88, Pretoria, 0001, of an application for such permit, signed by a medical practitioner, dentist, veterinarian or a pharmacist and containing the following particulars:

(a) The name and quantity of the Schedule 6 or Schedule 7 substance concerned;

(b) the form of preparation of the substance;

(c) the name and business address of the person to whom the substance is to be exported or from whom the substance is to be imported, as well as the country of origin or destination of the substance;

(d) the purpose for which the substance is required;

(e) in the case of an application for an export permit, a certificate issued by a duly authorised officer of the government or administration of the importing country to the effect that such government or administration is satisfied that the medicine will be used exclusively for medicinal, scientific or educational purposes, and that it approves its importation; and

(f) any further particulars required by the Secretary or the Council.

(2) A permit for the importation or exportation of a Schedule 6 or Schedule 7 substance issued in terms of subregulation (1) shall contain the following information:

(a) The name and business address of the applicant;

(b) the name and business address of the person to whom the substance is to be exported or from whom the substance is to be imported, as well as the country of origin or destination of the substance;

(c) the name and quantity of each substance which may be imported or exported under the permit;

(d) the period of validity of the permit;

(e) in the case of an import permit, the place where the substance is to be stored or processed;

(f) the conditions under which the permit is issued;

(g) instructions regarding the reports and returns to be submitted by the applicant; and

(h) any other particulars determined by the Secretary.

(3) A permit issued in terms of subregulation (1) shall be subject to the conditions set out therein and may be amended or withdrawn.

Cultivation or collection of plants from which Schedule 6 and Schedule 7 substances can be extracted, derived, produced or manufactured

27. (1) A permit for the cultivation or collection of plants or portions thereof from which Schedule 6 or Schedule 7 substances can be extracted, derived, produced

kan uitgereik word onderworpe daaraan dat 'n aansoek met vermelding van sodanige gegewens soos deur die Sekretaris of die Raad verlang, skriftelik by die Registrateur van Medisyne, Privaatsak X88, Pretoria, 0001, ingedien word.

(2) 'n Permit ingevolge subregulasie (1) uitgereik, moet die volgende gegewens bevat:

(a) Die naam en sakeadres van die persoon aan wie die permit uitgereik is;
(b) die name van die plante of gedeeltes daarvan wat gekweek of ingesamel gaan word;
(c) die name van die Bylae 6- of Bylae 7-stowwe wat uit die plante of gedeeltes daarvan afgetrek, verkry, voortgebring of vervaardig gaan word en die doel waarvoor hulle gebruik gaan word;
(d) die geldigheidsduur van die permit;
(e) die plek waar die kweek of insameling gaan plaasvind;
(f) die voorwaardes waaronder die permit uitgereik is; en
(g) enige ander gegewens deur die Sekretaris bepaal.

(3) 'n Permit ingevolge subregulasie (1) uitgereik, kan ingetrek of gewysig word indien die voorwaardes daarin vermeld nie nagekom word nie, of na goeddunke van die Sekretaris op aanbeveling van die Raad.

Voorskrifboeke

28. (1) 'n Voorskrifboek of ander permanente rekord, moet op elke perseel waar voorskrifte toeberei word, gehou word en moet die vorm aanneem van 'n rekord waarin die volgende besonderhede betreffende elke verkoop van 'n medisyne of gelyste stof aangeteken en gerieflik nageslaan kan word:

(a) Die datum waarop die voorskrif toeberei is;
(b) die bereidingsvorm en hoeveelheid van die medisyne of gelyste stof wat verkoop is;
(c) die naam en adres van die pasiënt of, in die geval van 'n voorskrif deur 'n veearts uitgereik, die naam en adres van die persoon aan wie die medisyne of gelyste stof verkoop is;
(d) waar van toepassing die naam van die geneesheer, tandarts of veearts deur wie sodanige voorskrif uitgereik is, of in die geval van 'n Bylae 2-stof wat sonder 'n voorskrif verkoop is kragtens artikel 22A (4) van die Wet, die naam van die apteker of kwekelingapteker of ongekwalifiseerde assistent deur wie die Bylae 2-stof verkoop is; en
(e) in die geval van die verkoop van 'n medisyne of gelyste stof ingevolge die bepalings van artikel 18 (3) (a) en (b) van die Wet, die verwysingsnommer deur die verkoper aan die verkoop toegeken.

(2) 'n Voorskrifboek of sodanige ander rekord moet vir 'n tydperk van minstens drie jaar nadat die laaste aantekening daarin gedoen is, by die sakeadres van die verkoper behou word.

Inklaringshawens vir Bylae 6- en Bylae 7-stowwe

29. Geen persoon mag enige Bylae 6- of Bylae 7-stof in die Republiek of die Gebied invoer nie behalwe deur een van die volgende "inklaringshawens", naamlik Kaapstad, Mosselbaai, Port Elizabeth, Oos-Londen, Durban, Johannesburg, Kempton Park, Bloemfontein, Kimberley, Pietermaritzburg, Pretoria, Germiston, Windhoek, Walvisbaai, Lüderitz en ook Queenstown, Grahamstad en King William's Town vir invoer slegs per pakketpos.

Versending van Bylae 6- en Bylae 7-stowwe per pos

30. Geen Bylae 6- of Bylae 7-stof mag die Republiek of die Gebied per briefpos binnekom nie, en geen persoon mag sodanige medisyne per briefpos in die Republiek of die Gebied versend nie. Waar enige sodanige medisyne

or manufactured may be issued after the submission to the Registrar of Drugs, Private Bag X88, Pretoria, 0001, of a written application for such permit, containing such particulars as may be required by the Secretary or the Council.

(2) A permit issued in terms of subregulation (1) shall contain the following particulars:

(a) The name and business address of the person to whom the permit has been issued;
(b) the names of the plants or portions thereof to be cultivated or collected;
(c) the names of the Schedule 6 or Schedule 7 substances to be extracted, derived, produced or manufactured and the purpose for which they will be used;
(d) the period of validity of the permit;
(e) the place where the cultivation or collection will take place;
(f) the conditions under which the permit has been issued; and
(g) any other particulars determined by the Secretary.

(3) A permit issued in terms of subregulation (1) may be amended or withdrawn if the conditions contained therein are not complied with or at the discretion of the Secretary on the recommendation of the Council.

Prescription books

28. (1) A prescription book or other permanent record shall be kept on every premises where prescriptions are dispensed and shall be in the form of a record in which the following details relating to every sale of a medicine or scheduled substance are entered for easy reference:

(a) The date on which the prescription was dispensed;
(b) the form of preparation and quantity of the medicine or scheduled substance sold;
(c) the name and address of the patient, or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance was sold;
(d) where applicable the name of the medical practitioner, dentist or veterinarian by whom the prescription was issued, or in the case of a Schedule 2 substance sold without a prescription in terms of section 22A (4) of the Act, the name of the pharmacist or trainee pharmacist or unqualified assistant by whom the Schedule 2 substance was sold; and
(e) in the case of the sale of a medicine or scheduled substance in terms of the provisions of sections 18 (3) (a) and (b) of the Act, the reference number allocated to the sale by the seller.

(2) A prescription book or such other record shall be retained at the business address of the seller for a period of at least three years after the date of the last entry made therein.

Ports of entry for Schedule 6 and Schedule 7 substances

29. No person shall import any Schedule 6 or Schedule 7 substance into the Republic or the Territory except through one of the following "ports of entry": Cape Town, Mossel Bay, Port Elizabeth, East London, Durban, Johannesburg, Kempton Park, Bloemfontein, Kimberley, Pietermaritzburg, Pretoria, Germiston, Walvis Bay, Windhoek, Lüderitz, and in addition Queenstown, Grahamstown and King William's Town for imports by parcel post only.

Transmission of Schedule 6 and Schedule 7 substances by post

30. No Schedule 6 or Schedule 7 substance shall be conveyed into the Republic or the Territory by letter post, and no person shall despatch or transmit any such medicine in the Republic or the Territory by Letter post.

die Republiek of die Gebied deur die pos binnekom, of binne die Republiek of die Gebied deur die pos versend word, moet dit per gesertifiseerde pakketpos geskied.

Die aankoop, verkryging, aanhou of gebruik van gelyste stowwe deur die gesagvoerder van 'n skip of deur die bevelvoerende offisier van 'n vliegtuig

31. Ondanks die bepalings van artikel 22A van die Wet en die bepalings van die regulasies, kan die Streeksdirekteur, Staatsgesondheidsdienste, van 'n betrokke streek, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste of 'n mediese beampte deur hom aangewys, op skriftelike versoek van die gesagvoerder van 'n skip of die bevelvoerende offisier van 'n vliegtuig die aankoop, verkryging, aanhou of gebruik van 'n Bylae 3-, Bylae 4-, Bylae 5-, Bylae 6- of Bylae 7-stof magtig: Met dien verstande dat die hoeveelheid binne redelike perke moet wees en onder die voorwaarde dat sodanige stof vir medisinale gebruik bedoel is.

Verkryging van petidien of preparate of mengsels daarvan deur geregistreerde vroedvroue

32. (1) Elkeen wat as 'n vroedvrou ingevolge die Wet of Verpleging, 1957 (Wet 69 van 1957), geregistreer is en wat verlang om 'n voorraad van 'n samestelling van petidienhidrochloried 50 mg/ml met levallorfantartaat 0,625 mg/ml te verkry (hieronder "die medisyne" genoem) vir toediening aan 'n verloskundige geval in 'n noodgeval, moet skriftelik om 'n permit daarvoor aansoek doen by die Streeksdirekteur, Staatsgesondheidsdienste, van die betrokke streek, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste en die volgende meld:

(a) Die presiese aard en hoeveelheid van die medisyne; en

(b) die naam en adres van die apteker van wie dit die voorneme is om die medisyne te verkry.

(2) Die Streeksdirekteur, Staatsgesondheidsdienste, van die betrokke streek, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste, kan by ontvangs van sodanige aansoek en nadat hy sodanige navrae gedoen het as wat hy nodig ag, na goeddunke 'n permit uitreik wat die applikant (vroedvrou) magtig om tydens die geldigheidsduur van die permit, so dikwels as wat nodig is, hoogstens 600 mg op 'n keer by daardie apteek van die medisyne aan te koop of te verkry, uitgesonderd in spesiale gevalle waar die Streeksdirekteur, Staatsgesondheidsdienste, van die betrokke streek, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste, die verskaffing van 'n groter hoeveelheid kan magtig tot 'n maksimum van 1 200 mg.

(3) Alle permitte in paragraaf (2) hierbo beskryf, word op die volgende voorwaardes uitgereik:

(a) Die permit moet in die vorm wees soos hieronder uiteengesit.

(b) By voorlegging van die permit moet die apteker wat die medisyne verskaf, benewens die aanteken van besonderhede in sy register van Bylae 7-stowwe, ook die datum van verskaffing, die aard, sterkte en die hoeveelheid medisyne verskaf en sy handtekening in die betrokke ruimte op die permit verstrek.

(c) Die permit bly van krag vir 'n tydperk van ses maande na die datum van uitreiking daarvan tensy dit gekanselleer of ingetrek word soos bepaal in paragraaf (d) hiervan.

(d) Die Streeksdirekteur, Staatsgesondheidsdienste, van die betrokke streek, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste, kan enige permit te eniger tyd kanselleer of intrek, en sodra die houer van sodanige permit van sodanige kansellering of intrekking in kennis gestel is, moet sy sodanige permit onverwyld tesame met enige hoeveelheid van die medisyne wat sy

Where any such medicine is conveyed into or within the Republic or the Territory by post it shall be sent or conveyed by certified parcel post.

The purchase, acquisition, keeping or use of scheduled substances by the master of a ship or by the officer in charge of any aircraft

31. The Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, or a medical practitioner designated by him may, notwithstanding the provisions of section 22A of the Act and the provisions of the regulations, on the written request of the master of a ship or the officer in charge of an aircraft, authorise the purchase, acquisition, keeping or use of a Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 substance: Provided that the quantity shall be within reasonable limits and subject to the condition that such substance is intended for medicinal use.

Obtaining of pethidine or preparations or admixtures thereof by registered midwives

32. (1) Every person registered as a midwife in terms of the Nursing Act, 1957 (Act 69 of 1957), who wishes to obtain a supply of a combination of pethidine hydrochloride 50 mg/ml with levallorphan tartrate 0,625 mg/ml (hereinafter referred to as "the medicine") for administration to a midwifery case in an emergency, shall apply, in writing, to the Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, for a permit therefor, stating—

(a) the exact nature and quantity of the medicine; and

(b) the name and address of the pharmacist from whom it is proposed to obtain the medicine.

(2) The Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, may, upon receipt of such application and after making such enquiries as he may deem necessary, issue at his discretion a permit authorising the (midwife) applicant to purchase or obtain as frequently as may be necessary during the period of validity of the permit not more than 600 mg of the medicine at any one time, at that pharmacy except in special cases when the Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, may authorise the supply of a larger quantity not exceeding 1 200 mg.

(3) All permits described in paragraph (2) above shall be issued subject to the following conditions:

(a) The permit shall be in the form as set out hereunder.

(b) The pharmacist supplying the medicines shall, upon production of a permit, in addition to entering the particulars in his Schedule 7 substances register, enter in the space provided on the permit the date of supply, the nature, strength and quantity of medicines supplied and his signature.

(c) The permit shall be of force and effect for a period of six months from the date of issue thereof unless cancelled or withdrawn as provided in paragraph (d) hereof.

(d) The Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, may cancel or withdraw any permit at any time and on being notified of such cancellation or withdrawal, the holder thereof shall forthwith return such permit, together with any quantity of the

nog in haar besit het aan die Streeksdirekteur, Staatsgesondheidsdienste, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste, terugbesorg vir beskikking soos deur hom beveel.

(e) Die houer van 'n permit moet dit op versoek van enige persoon skriftelik daartoe gemagtig deur die Sekretaris van Gesondheid, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste, vir inspeksie toon, tesame met enige hoeveelheid van die medisyne wat sy in haar besit het.

(4) Die medisyne wat kragtens 'n permit aangekoop of verkry is, moet deur die vroedvrou agter slot gehou word en sy mag nooit meer as 'n totale hoeveelheid van 1 200 mg van die medisyne gespesifiseer in die permit in haar besit hê nie.

(5) (a) Die houer van 'n permit kan die medisyne slegs in noodgevalle aan 'n verloskundige geval toedien wanneer 'n geneesheer nie beskikbaar is nie of terwyl daar op die aankoms van 'n geneesheer gewag word.

(b) Die houer van 'n permit mag nie meer as 100 mg van die medisyne aan 'n verloskundige geval toedien nie.

(c) Die toediening van die medisyne kan slegs een keer herhaal word en dan slegs na verloop van minstens vier uur en slegs as 'n geneesheer nog steeds nie beskikbaar is nie.

(6) Die houer van 'n permit moet na die toediening van die medisyne die besonderhede van sodanige toediening in die betrokke ruimte op die keersy van die permit aanteken.

(7) As die medisyne aan 'n verloskundige geval toegedien is op gesag van 'n geneesheer, moet sy handtekening in die betrokke ruimte op die keersy van die permit verskyn.

(8) 'n Aansoek om die hernuwing van 'n permit moet die Streeksdirekteur, Staatsgesondheidsdienste, van die betrokke streek, of, in die geval van Suidwes-Afrika, die Direkteur van Gesondheidsdienste, minstens 14 dae voor die verstryking van sodanige permit bereik en moet vergesel gaan van sodanige permit waarop die hoeveelheid medisyne in besit van die houer ten tyde van die aansoek om hernuwing aangeteken is.

PERMIT VIR BYLAE 7-STOWWE VIR GEBRUIK DEUR VROEDVROUE

Permit vir Bylae 7-stof No.....

Uitgereik kragtens Goewermentskennisgewing R..... Datum.....,

Hierby word toestemming verleen aan.....

van.....,

'n vroedvrou geregistreer ingevolge die bepalings van die Wet op Verpleging, 1957 (Wet 69 van 1957), om ondergenoemde Bylae 7-stof te koop of te verkry, so dikwels as wat nodig is, van.....,

te....., om in verloskundige noodgevalle toe te dien.

Hierdie permit verval op.....

.....

Streeksdirekteur: Staatsgesondheidsdienste/
Direkteur van Gesondheidsdienste

Amptelike datumstempel.

Hoeveelheid Bylae 7-stowwe in besit van vroedvrou op datum van aansoek om hierdie permit.

Moet deur die beampte wat die permit uitreik, ingevul word:

Datum	Medisyne	Sterkte	Hoeveelheid

Opmerking.—Die vroedvrou mag nooit meer as 1 200 mg van die medisyne in bogenoemde Goewermentskennisgewing genoem, in haar besit hê nie.

medicine still in her possession, to the Regional Director, State Health Services, or, in the case of South-West Africa, the Director of Health Services, for disposal as directed by him.

(e) On the request of any person authorised thereto, in writing, by the Secretary for Health, or, in the case of South-West Africa, the Director of Health Services, the holder of a permit shall produce the same for inspection, together with any quantity of the medicine in her possession.

(4) The medicines purchased or obtained by virtue of a permit shall be kept under lock and key by the midwife, who shall at no time have in her possession more than a total quantity of 1 200 mg of the medicine specified in such permit.

(5) (a) The holder of a permit may administer the medicine to a midwifery case, in emergencies only, when a medical practitioner is not available or pending the arrival of a medical practitioner.

(b) The holder of a permit shall not administer to a midwifery case more than 100 mg of the medicine.

(c) The administration of the medicine may be repeated once only and then only after the lapse of at least four hours and only if a medical practitioner is still not available.

(6) The holder of a permit shall, after the administration of the medicine, enter the particulars of such administration in the space provided on the reverse side of the permit.

(7) If the medicine is administered to a midwifery case on the authority of a medical practitioner, his signature shall appear in the space provided therefor on the reverse side of the permit.

(8) An application for the renewal of a permit shall reach the Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, at least 14 days before the expiration of such permit and shall be accompanied by such permit on which shall be entered the quantity of medicines in the possession of the holder at the time of the application for renewal.

PERMIT FOR SCHEDULE 7 SUBSTANCE FOR USE BY MIDWIVES

Schedule 7 substance Permit No.....

Issued in terms of Government Notice R.....

Date.....

Permission is hereby granted to.....

of.....,

a midwife registered in terms of the provisions of the Nursing Act, 1957 (Act 69 of 1957), to purchase or obtain, as often as may be necessary, from..... at.....

the undermentioned Schedule 7 substance for the purpose of administration in emergency midwifery cases.

This permit will expire on.....

.....

Regional Director: State Health Services/
Director of Health Services

Official date stamp.

Quantity of Schedule 7 substances in possession of midwife on date of application for this permit.

To be completed by the officer issuing the permit:

Date	Medicine	Strength	Quantity

Note.—A midwife shall at no time have in her possession more than 1 200 mg of the medicine referred to in the above-mentioned Government Notice.

Besonderhede wat deur die apteker wat die Bylae 7-stowwe verskaf, verstrek moet word:

Datum	Beskrywing van Bylae 7-stowwe	Sterkte	Hoeveelheid	Handtekening

Verslag van toediening van Bylae 7-stowwe:

Datum	Tydstip	Aan wie toegedien (naam en adres)	Medisyne	Rede waarom vroedvrou die medisyne toegedien het, of geneesheer se handtekening [subregulasie (7)]
			Naam, sterkte en hoeveelheid	

Besonderhede wat deur die vroedvrou by aansoek om hernuwing van hierdie permit verstrek moet word: Naam, sterkte en hoeveelheid van medisyne voorhande op datum van aansoek om hernuwing

.....

.....

.....

Datum..... Handtekening van applikant

Besit van sekere gelyste stowwe deur persone wat die Republiek of die Gebied binnekom of verlaat

33. Ondanks enige ander bepalings in die Wet of die regulasies, kan 'n persoon wat die Republiek of die Gebied binnekom of verlaat in besit wees, vir persoonlike medisinale gebruik, van 'n hoeveelheid Bylae 5-, Bylae 6-, Bylae 7- of Bylae 9-stof wat nie 'n redelike hoeveelheid wat nodig is vir gebruik vir 'n tydperk van hoogstens een maand, oorskry nie: Met dien verstande dat sodanige persoon in besit is van—

(a) 'n voorskrif vir sodanige stof; of

(b) 'n sertifikaat deur 'n apteker ten effekte dat die betrokke stof deur 'n geneesheer vir sodanige persoon voorgeskryf is.

Invoer van medisyne

34. Geen persoon uitgesonderd 'n apteker, geneesheer, tandarts, veearts of ander persoon deur die Sekretaris gemagtig, mag enige medisyne of gelyste stof in die Republiek of die Gebied invoer nie.

Registrasiegelde

35. Die volgende gelde is aan die Registrateur betaalbaar:

(a) Ten opsigte van die registrasie van 'n medisyne: R60.

(b) Jaarliks ten opsigte van die behoud van die registrasie van 'n medisyne waarvoor 'n registrasiesertifikaat ingevolge artikel 15 (4) van die Wet uitgereik is: R20.

Die eerste betaling van die gelde bedoel in paragraaf (b), moet geskied nadat 'n medisyne vir 'n tydperk van een jaar geregistreer is, en daarna gereeld jaarliks binne 30 dae na daardie datum.

Particulars to be furnished by pharmacist supplying the Schedule 7 substances:

Date	Description of Schedule 7 substances	Strength	Quantity	Signature

Record of administration of Schedule 7 substances:

Date	Hour	To whom administered (Name and address)	Medicine	Reason why midwife administered medicine, or medical practitioner's signature [Subregulation (7)]
			Name, strength and quantity	

Particulars to be furnished by the midwife on application for renewal of this permit: Name, strength and quantity of medicines on hand on date of application for renewal.....

.....

.....

Date..... Applicant's signature

Possession of certain scheduled substances by persons entering or departing from the Republic or the Territory

33. Any person entering or departing from the Republic or the Territory may, notwithstanding anything to the contrary in the Act or the regulations, be in possession for personal medicinal use of a quantity of a Schedule 5, Schedule 6, Schedule 7 or Schedule 9 substance, which shall not exceed a reasonable quantity required for use for a period of not more than one month: Provided that such person is in possession of—

(a) a prescription for such substance; or

(b) a certificate by a pharmacist to the effect that the substance concerned was prescribed by a medical practitioner for such person.

Importation of medicines

34. No person except a pharmacist, medical practitioner, dentist, veterinarian or other person authorised by the Secretary may import any medicine or scheduled substance into the Republic or the Territory.

Registration fees

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

(a) In respect of the registration of a medicine: R60.

(b) Annually, in respect of the retention of the registration of a medicine for which a registration certificate has been issued in terms of section 15 (4) of the Act: R20.

The first payment of the prescribed fee referred to in paragraph (b) shall be made after a medicine has been registered for a period of one year, and annually thereafter within 30 days of such date.

INHOUD

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Gedruk deur en verkrygbaar by Die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001

Printed by and obtainable from The Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001