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GOEWERMENTSKENNISGEWINGS.

DEPARTEMENT VAN GESONDHEID.

No. R. 457.] [31 Maart 1967.

WET OP DIE BEHEER VAN MEDISYNE, 1965.

KONSEPREGULASIES.

Hierby word vir algemene inligting bekendgemaak dat die Medisyne-beheerraad, ingestel by artikel 2 van die Wet op die Beheer van Medisyne, 1965 (Wet No. 101 van 1965), ingevolge artikel 35 (2) van genoemde Wet, by die uitoefening van die bevoegdheid hom verleen by artikel 35 (1) van genoemde Wet en na oorlegpleging met die Minister van Gesondheid, voornemens is om die volgende regulasies te maak.

Belanghebbende persone en organisasies word uitgenooi om binne drie maande na die datum hiervan opmerkings oor of vertoë in verband met die konsepregulasies by die Registrateur van Medisyne, Privaatsak 88, Pretoria, in te dien.

A. Definisies.

1. Tensy uit die samehang anders blyk, beteken in hierdie regulasies—

„ applikant " die persoon of regspersoon wat aansoek doen om medisyne te registreer ingevolge die voorskrifte van die Wet;

„ vervaardig " om te maak, te berei, te verwerk of te verpak;

„ bereidingsvoorskrif ", met betrekking tot 'n medisyne, die besonderhede in verband met sodanige medisyne verskaf in Bylae I van vorm M.B.R. I.;

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

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

GOVERNMENT NOTICES.

DEPARTMENT OF HEALTH.

No. R. 457.] [31 March 1967.

DRUGS CONTROL ACT, 1965.

DRAFT REGULATIONS.

It is hereby notified for general information in terms of section 35 (2) of the Drugs Control Act, 1965 (Act No. 101 of 1965), that the Drugs Control Council established in terms of Section 2 of the said Act, in the exercise of the powers conferred upon it by Section 35 (1) of the said Act and after consultation with the Minister of Health, intends to make the following regulations.

Interested persons and organisations are invited to submit comments or representations on the draft regulations within three months from the date hereof to the Registrar of Drugs, Private Bag 88, Pretoria.

Definitions.

1. In these regulations unless the context otherwise indicates—

" applicant " means the person or body corporate who applies for registration of a drug as prescribed by the Act;

" manufacture " means to make, compound, process, prepare or to pack;

" working formula " in relation to a drug means the particulars in respect of such drug furnished in Appendix I of form M.B.R. I.;

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

" expiry date " means the date up to which a drug will retain the strength and other properties which are mentioned on the label and which must be determined by the applicant in respect of every batch of every drug of which the strength or any other property can change after elapse of time and the date after which the drug shall not be sold to the public;

„buite-etiket" 'n etiket soos in die Wet omskryf en geheg aan 'n karton, omslag of pakket waarin die onmiddellike houer van 'n medisyne verpak is;

„voubiljet" 'n pamflet waarop die besonderhede voorgeskryf in regulasie 11 gedruk is;

„sakeadres" in die geval van 'n adres in die Republiek, die naam van die stad, dorp of buurt waarin die besigheid gedryf word, die naam van die straat of weg waar die perseel geleë is, en in gevalle waar straat- of wegnommers deur die plaaslike owerheid toegeken is, die straat- of wegnommer van sodanige perseel;

„Wet" die Wet op die Beheer van Medisyne (Wet No. 101 van 1965).

Aansoek om registrasie van 'n medisyne.

2. Elke aansoek om die registrasie van 'n medisyne moet gedoen word deur—

(*a*) 'n geregistreerde apteker;

(*b*) 'n regspersoon wat as apteker handel mag dryf kragtens artikel 76 van die Wet op Geneeshere, Tandartse en Aptekers (Wet No. 13 van 1928, soos gewysig) of 'n persoon wat deur sodanige regspersoon gemagtig is om namens hom aansoek te doen;

(*c*) in die geval van 'n medisyne vervaardig deur 'n persoon wat beskik oor 'n permit uitgereik kragtens die bepalings van artikel 37 van die Wet op Geneeshere, Tandartse en Aptekers, sodanige persoon.

3. Elke aansoek om registrasie van 'n medisyne moet in sesvoud ingedien word by die Registrateur van Medisyne, Privaatsak 88, Pretoria, op die voorgeskrewe vorm M.B.R. I.

Die klassifikasie van medisyne.

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

(*a*) *Kategorie A.*—Medisyne wat sonder verdere verwerking gereed is vir gebruik deur pasiënte; die soorte preparate waar slegs 'n dramiddel gevoeg word by die effektiewe middel of middels, is hierby ingesluit.

(*b*) *Kategorie B.*—Medisyne wat nie normaalweg as sodanig sonder verdere verwerking deur pasiënte gebruik kan word nie.

5. Beide kategorieë A en B moet vir dieselfde doel verder ingedeel word in die volgende farmakologiese klassifikasie:—

Farmakologiese indeling.

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 en epilepsieweermiddels.
2.6. Bedaarmiddels (berustingsmiddels).
2.7. Fenotiasiene en derivate.
2.7.1. Rauwolfia: alkaloïde en samestellings.
2.7.2. Difenielmetaan en derivate daarvan.
2.7.3. Alkieldiole en derivate daarvan.
2.7.4. Diverse strukture.
2.8. Narkotiese analgetika.
2.9. Nie-narkotiese analgetika, antipiretika (koorsweermiddels).
2.10. Spesiale analgetiese samestellings.
2.11. Sentraalwerkende spierverslappers.

3. *Bindweefselmiddels.*
3.1. Rumatiekmiddels (anti-inflammatoriese middels).
3.2. Hormoonvrye middels.
3.3. Jigmiddels.
3.4. Samestellings bevattende kortikosteroïde (skorshormone).

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

"package insert" means a pamphlet on which is printed the particulars as prescribed in regulation 11;

"business address" means, in the case of an address in the Republic, the name of the town, village or locality in which the business is carried on, the name of the street or road in which the premises are situated and in cases where street or road numbers have been allotted by the local authority, the street or road number of such premises;

"Act" means the Drugs Control Act (Act No. 101 of 1965).

Application for Registration of a Drug.

2. Every application for registration of a drug shall be made by—

(*a*) a registered chemist and druggist;

(*b*) a body corporate which may carry on the business as a chemist and druggist in terms of Section 76 of the Medical, Dental and Pharmacy Act (Act No. 13 of 1928, as amended), or a person authorised by such a body to apply on its behalf;

(*c*) in the case of a drug which is manufactured by a person who is the holder of a permit issued under the provisions of Section 37 of the Medical, Dental and Pharmacy Act, that person.

3. Every application for registration of a drug shall be submitted in sextuplicate on the prescribed form, M.B.R. I. to the Registrar of Drugs, Private Bag 88, Pretoria.

The Classification of Drugs.

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

(*a*) *Category A.*—Drugs which are, without further manipulation, ready for use by a patient; types of preparations where only a vehicle is added to the effective drug or drugs are included in this category.

(*b*) *Category B.*—Drugs which can not normally be used by patients without further manipulation.

5. Both categories A and B shall for the same purpose be further subdivided into the following pharmacological classification:—

Pharmacological Classification.

1. *Central Nervous System Stimulants.*
1.1. Central analeptics.
1.2. Psycho-analeptics (antidepressants).
1.3. Special antidepressant combinations.
1.4. Respiratory stimulants.
1.5. Hallucinogenic drugs.

2. *Central Nervous System Depressants.*
2.1. Anaesthetics.
2.2. Sedatives, hynotics.
2.3. Barbiturates.
2.4. Non-barbiturates.
2.5. Anticonvulsants, including anti-epileptics.
2.6. Tranquillizers.
2.7. Phenothiazines and derivatives.
2.7.1. Rauwolfia: alkaloids and combinations.
2.7.2. Diphenylmethane and its derivatives.
2.7.3. Alkyldiols and their derivatives.
2.7.4. Miscellaneous structure.
2.8. Narcotic analgesics,
2.9. Non-narcotic analgesics, antipyretics.
2.10. Special analgesic combinations.
2.11. Centrally-active muscle relaxants.

3. *Connective Tissue Drugs.*
3.1. Antirheumatics (anti-inflammatory agents).
3.2. Non-hormonal preparations.
3.3. Antigout preparations.
3.4. Combinations with corticosteroids.

4. *Plaaslike anestetika.*

5. *Middels met uitwerking op outonome funksies.*

5.1. Adrenomimetika (simpatomimetika).
5.2. Adrenolitika (simpatolitika).
5.3. Cholinomimetika (cholinergiese middels).
5.4. Cholinolitika (anticholinergiese middels).
5.4.1. Middels teen Parkinsonisme.
5.4.2. Algemeen.
5.5. Ganglionblokkeermiddels.
5.6. Histamien.
5.7. Antihistaminika, anti-emetika en antivertigomiddels.
5.7.1. Antihistaminika.
5.7.2. Anti-emetika en antivertigomiddels.
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.
7.1.2. Rauwolfia: diuretiese samestellings.
7.1.3. Ander hipotensiewe middels.
7.1.4. Koronêre vasodilators (kroonvaatverwyders).
7.1.5. Perifere vasodilators.
7.2. Vasokonstriktors (vaatvernouers), pressormiddels.
7.3. Migraine-middels.
7.4. Lipotropiese middels.
7.5. Antiserum-cholesterol-middels.

8. *Middels met uitwerking op bloed en hemopoïetiese 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. Amfetamienpreparate.
11.3.2. 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.
11.9.1. Diarreemiddels in samestelling met anti-infeksiemiddels.
11.9.2. Ander.
11.10. Besondere samestellings.

12. *Wurm-, bilharzia- en filariase-middels.*

13. *Velpreparate.*

13.1. Antiseptika, ontsmettings- en skoonmaakmiddels.
13.1.1. Omgewingsontsmettingsmiddels.
13.2. Middels teen jeuksiekte.
13.3. Oppervlakteverdowingsmiddels.
13.4. Jeukmiddels (antipruritiese middels).

4. *Local Anaesthetics.*

5. *Drugs affecting Autonomic Functions.*

5.1. Andrenomimetics (sympathicomimetics).
5.2. Andrenolytics (symhiathicolytics).
5.3. Cholinomimetics (Cholinergics).
54. Cholinolytics (Anticholinergics).
5.4.1. Anti-Parkinsonism preparations.
5.4.2. General.
5.5. Ganglion blockers.
5.6. Histamine.
5.7. Antishistaminics, 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 (sero'onin).
5.10. Serotonin antagonists.

6. *Cardiac Drugs.*

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

7. *Vascular Drugs.*

7.1. Vasodilators, hypotensive drugs.
7.1.1. Rauwolfia and combinations.
7.1.2. Rauwolfia: diuretic combinations.
7.1.3. Other hypotensives.
7.1.4. Vasodilators-coronary.
7.1.5. Vasodilators-peripheral.
7.2. Vasoconstrictors, pressor drugs.
7.3. Migraine preparations.
7.4. Lipotropic agents.
7.5. Serum cholesterol reducers.

8. *Drugs acting on Blood and Haemopoietic System.*

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

9. *Drugs against Alcoholism.*

10. *Drugs acting on Respiratory System.*

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

11. *Drugs acting on Gastro-intestinal Tract.*

11.1. Digestants.
11.2. Gastro-intestinal antispasmodics and cholinolytics (anti-cholinergics).
11.3. Anorexigenics.
11.3.1. Amphetamine preparations.
11.3.2. Others.
11.4. Antacids.
11.4.1. Acid neutralisers.
11.4.2. Acid neutralisers with antispasmodics.
11.4.3. Others.
11.5. Laxatives.
11.6. Lubricants and faecal softeners.
11.7. Cholagogues.
11.8. Suppositories and anal ointments.
11.9. Antidiarrhoeals.
11.9.1. Antidiarrhoeals in combination with anti-infective agents.
11.9.2. Others.
11.10. Special combinations.

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

13. *Dermatological Preparations.*

13.1. Antiseptics, disinfectants, cleansing agents.
13.1.1. Environmental disinfectants.
13.2. Antiscabies drugs.
13.3. Surface anaesthetics.
13.4. Antipruritics.

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. Middels teen psoriase.
13.9.2. Swamdoders.
13.10. Beskermingsmiddels teen straling.
13.11. Melanieninhibitors en -stimuleerders.
13.12. Aknemiddels.

14. *Wondbehandelingsmiddels.*
14.1. Wondontsmettingsmiddels.
14.2. Wonddekkings.

15. *Oogmiddels (oftalmiese middels).*
15.1. Oogmiddels met antibiotika en/of sulfonamiede.
15.2. Oogmiddels met kortikosteroïede (skorshormone).
15.3. Samestellings van antibiotika en/of sulfonamiede en kortikosteroïede.
15.4. Ander.

16. *Oor-, Neus- en Keelmiddels.*
16.1. Neusontstoppingsmiddels.
16.2. Oormiddels, oordruppels.
16.3. Oppervlakteverdowingsmiddels.
16.4. Neus-, mond- en keelantiseptika.

17. *Middels met uitwerking op spierstelsel.*
17.1. Spierverslappers met periferiese 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 middels.
18.7. Voorbehoedmiddels.
18.8. Ovulasiebeheermiddels.
18.9. Uterusspasmolitika.

19. *Oksitosika.*

20. *Antimikrobiese (Chemoterapeutiese) Middels.*
20.1. Antibiotika en antibiotiese samestellings.
20.1.1. Breë- en mediumspektrum-antibiotika.
20.1.2. Penisillien.
20.1.3. Penisillien-, DHS- en streptomisiensamestellings.
20.1.4. Antibiotikum-sulfonamiedsamestellings.
20.1.5. Streptomisien- en DHS-samestellings.
20.1.6. Plaaslik aanwendbare antibiotika.
20.1.7. Swambestrydende antibiotika.
20.2. Nie-antibiotiese middels.
20.2.1. Sulfonamiede.
20.2.2. Swamdoders.
20.2.3. Tuberkulostatika.
20.2.4. Antileprotika.
20.2.5. Kiemdoders.
20.2.6. Middels teen protosoë.
20.2.7. Spirogeetdoders.
20.2.8. Antivirusmiddels.

21. *Hormone en Antihormone, en Hipoglukemiesluk-middels.*
21.1. Insulienpreparate.
21.2. Hipoglukemie-slukmiddels.
21.3. Tiroïedpreparate.
21.4. Paratiroïedsamestellings.
21.5. Kortikosteroïede (skorshormone) en analoga.
21.5.1. Skone kortikosteroïede (skorshormone).
21.5.2. Analgetiese samestelling.
21.5.3. Anti-infeksiesamestellings.
21.5.4. Ander samestellings.
21.6. Anaboliese steroïede.
21.7. Manlike geslagshormone.

13.4.1. Corticosteroids with or without anti-infective agents.
13.4.2. Others.
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. *Wounds Treatment.*
14.1. Wound disinfectants.
14.2. Wound dressings.

15. *Opthalmic Preparations.*
15.1. Ophthalmic preparations with antibiotics and/or sulphonamides.
15.2. Ophthalmic preparations with corticoids.
15.3. Combination antibiotics and/or sulphonamides and corticoids.
15.4. Others.

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. *Drugs acting on Muscular System.*
17.1. Peripherally-acting muscle relaxants.
17.2. Muscle activators.

18. *Drugs 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. Penicillin.
20.1.3. Penicillin—DHS and streptomycin combinations.
20.1.4. Antibiotic-sulphonamide combinations.
20.1.5. Streptomycin and DHS 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. Antileprotics.
20.2.5. Germicides.
20.2.6. Drugs 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. Cortical steroids and analogues.
21.5.1. Plain corticoids.
21.5.2. Analgesic combinations.
21.5.3. Anti-infective combinations.
215.4. Other combinations.
21.6. Anabolic steroids.
21.7. Male sex hormones.

21.8. Vroulike geslagshormone.
21.8.1. Estrogene.
21.8.2. Progestogene met of sonder estrogene.
21.9. Androgeen-estrogeensamestellings.
21.10. Tropiese hormone.
21.11. Hiperglukemiehormone.
21.12. Hormooninhibitors.
22. *Vitamiene.*
22.1. Multivitamiene, skoon en met minerale.
22.1.1. Vitamiene vir pediatriese gebruik.
22.1.2. Vitamiene vir voorgeboortelike gebruik.
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. *Spesiale Voedsel.*
25.1. Babavoedsel en ander samestellings.
25.2. Ander voedingstowwe.
26. *Sitostatika.*
27. *Chelaatvormende middels veral dié teen swaarmetaalvergiftigings.*
28. *Kontrasmedia.*
29. *Diagnostiese Hulpmiddels.*
30. *Biologiese Middels.*
31. *Ensiempreparate.*
32. *Ensieminhibitors.*
33. *Tonika.*
34. *Ander.*

6. Die bepalings van artikel 14 (1) van die Wet geld kragtens artikel 14 (2) ten opsigte van medisyne in die farmakologiese klassifikasie 20 van kategorie A.

Monsters saam met aansoek om registrasie.

7. 'n Aansoek om registrasie moet vergesel wees van—

(*a*) 'n monster van die finale produk in die kleinste van elk van die verpakkingsvorms waarin dit op die mark beskikbaar gestel word;

(*b*) monsters van alle advertensiemateriaal en voubiljette wat by die verkoop of verspreiding van die medisyne gebruik word of sal word en sodanige monsters van die grondstowwe soos deur die Raad versoek mag word.

Gegewens wat in die medisyneregister moet voorkom.

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

(1) Die datum van aansoek om registrasie;
(2) die datum van registrasie;
(3) die naam en adres van die applikant;
(4) die naam en adres van die vervaardiger;
(5) die goedgekeurde naam van die medisyne;
(6) die handelsnaam van die medisyne, indien enige;
(7) die registrasienommer van die medisyne;
(8) die voorwaardes waaraan die registrasie onderworpe gestel is, indien enige;
(9) die bereidingsvorm van die medisyne;
(10) die naam en hoeveelheid van elke bestanddeel van die medisyne per eenheid;
(11) die land van vervaardiging van die medisyne;
(12) die klassifikasie van die medisyne ooreenkomstig regulasies 4 en 5;
(13) die nommer wat toegeken is aan die aansoek om registrasie;
(14) die nommer wat toegeken is aan die inspeksieverslag vermeld in registrasievorm M.B.R. I.

21.8. Female sex hormones.
21.8.1. Oestrogens.
21.8.2. Progestogens with or without oestrogens.
21.9. Androgen-oestrogen combinations.
21.10. Tropic (trôphic) hormones.
21.11. Hyperglycaemic hormones.
21.12. Hormone inhibitors.
22. *Vitamins.*
22.1. Multivitamins, plain and 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. Others.
22.1.5. B-Complex with vitamin C.
23. *Amino-acids.*
24. *Mineral Substituents, Electrolytes.*
25. *Special Foods.*
25.1. Infant and other formulas.
25.2. Other nutrients.
26. *Cytostatic Agents.*
27. *Chelating Agents (versenates) especially as Heavy Metal Antidotes.*
28. *Contrast Media.*
29. *Diagnostic Agents.*
30. *Biologicals.*
31. *Enzymatic Preparations.*
32. *Enzyme Inhibitors.*
33. *Tonics.*
34. *Others.*

6. The provisions of section 14 (1) of the Act shall come into operation in terms of section 14 (2) and shall apply in respect of drugs in the pharmacological classification 20 of Category A.

Samples with Application for Registration.

7. An application for registration shall be accompanied by—

(*a*) a sample of the final product in the smallest of each of the package forms available on the market;

(*b*) samples of all advertising material and package inserts which are, or will be, used in the selling or distribution of the drug and such samples of the raw materials as the Council may request.

Information which shall Appear in the Drugs Register.

8. When a drug is registered the following information shall be written in the drugs register which shall be kept in terms of section 13 of the Act:—

(1) The date of application for registration;
(2) the date of registration;
(3) the name and address of the applicant;
(4) the name and address of the manufacturer;
(5) the approved name of the drug;
(6) the trade name of the drug, if any;
(7) the registration number of the drug;
(8) the conditions of registration, if any;
(9) the form of preparation of the drug;
(10) the names and quantities of each ingredient of the drug per unit;
(11) the country of production of the drug;
(12) the classification of the drug in terms of regulations 4 and 5;
(13) the number allocated to the application for registration;
(14) the number allocated to the inspection report referred to in Registration Form, M.B.R. I.

Vorm van Registrasiesertifikaat.

9. Die onderstaande registrasiesertifikaat moet uitgereik word nadat 'n medisyne geregistreer is kragtens artikel 15 (4) van die Wet:—

MEDISYNE-BEHEERRAAD.

REGISTRASIESERTIFIKAAT.

Kragtens artikel 15 (4) van die Wet op die Beheer van Medisyne word hiermee gesertifiseer dat 'n medisyne wat die volgende bestanddele bevat (1)_____

in die bereidingsvorm van (2)_____
en bemark word onder die handelsnaam van (3)_____
en vervaardig word deur (4)_____
onder die volgende voorwaardes geregistreer is (5)_____

en geregistreer is op die naam van (6)_____

en dat die registrasienommer (7)_____
en die goedgekeurde naam (8)_____
daaraan toegewys is.

Registrateur van medisyne.

Pretoria_____ 19____

(1) Bestanddele en hoeveelhede per eenheid.
(2) Bereidingsvorm.
(3) Handelsnaam.
(4) Naam en sakeadres van vervaardiger.
(5) Voorwaardes waaronder medisyne geregistreer is.
(6) Naam en adres van applikant.
(7) Die toegewese registrasienommer kragtens artikel 15 (6) van die Wet.
(8) Die goedgekeurde naam kragtens artikel 15 (5) van die Wet.

Die etikettering van medisyne.

10. Behoudens die bepalings van subregulasie (9) moet die pakket waarin 'n medisyne verkoop word benewens nakoming van die bepalings van ander wette en regulasies, van 'n etiket voorsien wees waarop in duidelike en onuitwisbare letters die volgende besonderhede vermeld word:—

(1) 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;

(2) die vereistes, indien enige, betreffende die metode van opberging of ander voorsorgmaatreëls wat nodig is vir die bewaring van die medisyne;

(3) sodanige besonderhede as wat deur die Raad gespesifiseer word kragtens artikel 15 (7) van die Wet;

(4) die naam en persentasie van enige bakteriostatiese of bakteriedodende middel wat as preserveermiddel by 'n medisyne gevoeg word;

(5) die lotnommer van die medisyne;

(6) die verstrykingsdatum van die medisyne;

(7) die normale dosisse van die medisyne vir die verskillende ouderdomsgroepe;

(8) die hoeveelheid van die medisyne in die houer.

(9) (*a*) In die geval van verpakkings van medisyne van 5 ml. en minder hoef die gegewens vereis by subregulasies (1), (2), (3) en (4) slegs op 'n buite-etiket aangebring te word.

(*b*) Die bepalings (1)-(8) van hierdie regulasie en die bepalings in regulasie 11 is nie van toepassing nie op medisyne wat toeberei is deur 'n apteker, geneesheer of tandarts as die aldus toebereide medisyne van 'n etiket bevattende die naam en adres van die persoon of regspersoon deur of namens wie die verkoop of lewering plaasgevind het, voorsien is en die naam en hoeveelheid van elke bestanddeel asook die naam van die persoon aan wie dit gelewer of verkoop is en die dag van verkoop of lewering, opgeteken word in 'n boek wat die „resepteboek" genoem en deur die verkoper of leweransier vir die doel gehou moet word.

Form of Certificate of Registration.

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

DRUGS CONTROL COUNCIL.

REGISTRATION CERTIFICATE.

In terms of section 15 (4) of the Drugs Control Act it is hereby certified that a drug which contains the following ingredients (1)_____

in the form of preparation (2)_____
and marketed under the trade name of (3)_____
and manufactured by (4)_____
has been registered under the following conditions (5)_____

in the name of (6)_____

and that the registration number (7)_____
and the approved name (8)_____
have been allotted thereto.

Registrar of Drugs.

Pretoria_____ 19____

(1) Ingredients and quantities per unit.
(2) Form of preparation.
(3) Trade name.
(4) Name and business address of manufacturer.
(5) Conditions subject to which drug is registered.
(6) Name and address of applicant.
(7) The allotted registration number in terms of section 15 (6) of the Act.
(8) The approved name in terms of section 15 (5) of the Act.

The Labelling of Drugs.

10. Save as provided in sub-regulation (9), the package in which a drug is sold, shall bear a label on which is stated, in addition to the compliance with the provisions in order acts and regulations, in clear and indelible letters the following information:—

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

(2) the requirements, if any, for the method of storage or other necessary precautions for the preservation of the drug;

(3) such particulars as may be stipulated by the Council in terms of section 15 (7) of the Act;

(4) the name and percentage of any bacteriostatic or bactericidal agent which is added to the drug as a preservative;

(5) the batch number of the drug;

(6) the expiry date of the drug;

(7) the normal dose of the drug for the different age groups;

(8) the quantity of the drug in the package.

(9) (*a*) In the case of a package of a drug of 5 ml or less, the information in sub-regulations (1), (2), (3) and (4) may be recorded on the outer label only.

(*b*) The provisions (1)-(8) of this regulation and the provisions of regulation 11 shall not apply to drugs contained in medicine dispensed by a chemist and druggist or medical practitioner or dentist if the medicine so dispensed is labelled with the name and address of the person or the body corporate by whom, or on whose behalf, the sale or supply has been effected and the name and quantity of each ingredient are entered together with the name of the person to whom it is sold or supplied and the date of the sale or supply in a book called " prescription book " to be kept by the seller or supplier for the purpose.

(*c*) 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 en voubiljette goedkeur.

Voubiljette.

11. Elke medisynepakket moet 'n voubiljet inhê waarop in prominente letters gedruk is—

(*a*) alle gegewens wat volgens hierdie regulasies op etikette van medisyne moet voorkom;

(*b*) in die geval van 'n medisyne met twee of meer bestanddele, duidelike aanduidings van watter die aktiewe bestanddele is en watter slegs as oplosmiddels, geurstowwe of kleurstowwe, ens., gebruik word;

(*c*) volledige gebruiksaanwysings;

(*d*) enige noodsaaklike waarskuwings in verband met die onveilige gebruik van die medisyne deur kinders, ou mense of swanger vrouens en enige moontlike nadelige gevolge wat mag ontstaan as gevolg van langdurige gebruik van die medisyne of in verband met die toediening van die medisyne;

(*e*) alle beskikbare gegewens betreffende die doel van gebruik, die voordelige uitwerking en enige skadelike of nadelige of ander uitwerking van die medisyne;

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

Advertensies.

12. Wanneer 'n medisyne mondeling geadverteer word by lede van die mediese, tandheelkundige en farmaseutiese beroepe moet skriftelike gegewens, wat ten minste die gegewens insluit wat verskyn op die voubiljet waarna verwys is in regulasie 11, terselfdertyd gegee word aan die persoon aan wie die mondelinge advertensie gerig is.

Samestelling, terapeutiese bruikbaarheid en uitwerking, suiwerheid, ens., waaraan 'n medisyne moet voldoen.

13. Geen medisyne sal geregistreer word nie, tensy die applikant die Raad daarvan oortuig—

(i) dat die medisyne doeltreffend is vir die doel waarvoor dit aangebied word;

(ii) dat die medisyne veilig is wanneer toegedien in die aanbevole dosis en vir die doel waarvoor dit gebruik moet word;

(iii) dat die medisyne voldoen aan die standaarde, indien enige, bepaal in die British Pharmacopoeia of die British Pharmaceutical Codex, na die geval mag wees, en aan standaarde wat die Raad bevredig.

Opmerking.—Elke applikant moet die Raad sonder versuim verwittig van enige afwyking van die besonderhede deur hom verstrek saam met enige 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.*

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

(*a*) Die naam van die medisyne;

(*b*) die handelsnaam van die medisyne, indien enige;

(*c*) in die geval van 'n mengsel van verskillende stowwe, die naam en hoeveelheid van elke bestanddeel van die medisyne;

(*d*) die naam en sakeadres van die applikant;

(*e*) die naam en sakeadres van die vervaardiger van die medisyne;

(*f*) die bereidingsvorm en sterkte van die medisyne.

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

Package Inserts.

11. Each package of a drug shall contain a package insert on which is printed prominently—

(*a*) all the information which shall according to these regulations appear on labels;

(*b*) in the case of a drug with two or more constituents, a clear statement indicating which of the constituents are the active ingredients and which are used only as solvents, aromatics, colouring agents, etc.;

(*c*) complete directions for use;

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

(*e*) all available information concerning the purpose and the beneficial, detrimental, injurious or other effects of the drug;

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

Advertisements.

12. When a drug is advertised verbally to any member of the medical, dental and pharmaceutical professions, written information which shall include at least the information appearing on the package insert referred to in regulation 11, shall simultaneously be given to the person to whom the verbal advertisement is directed.

Composition, Therapeutic Suitability and Effect, Purity, Etc., to which a Drug shall Comply.

13. No drug shall be registered unless the applicant satisfies the Council—

(i) that the drug is efficacious for the purpose for which it is presented;

(ii) as to the safety of the drug when administered in the recommended dosage and for the purpose for which it is intended to be used;

(iii) that the drug complies with the standard, if any, laid down in the British Pharmacopoeia or the British Pharmaceutical Codex, as the case may be and with standards which satisfy the Council.

NOTE.—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 drug irrespective of whether such alteration is made before or after such drug was registered.

Particulars which shall be Published in the Government Gazette *in Terms of Section* 15 (11) *of the Act.*

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

(*a*) The name of the drug;

(*b*) the trade name of the drug, if any;

(*c*) in the case of a mixture of different substances, the name and quantity of each ingredient of the drug;

(*d*) the name and business address of the applicant;

(*e*) the name and business address of the manufacturer of the drug;

(*f*) the form of preparation and strength of the drug.

Reglement betreffende die verrigting van die sake van die Medisyne-beheerraad.

15. Behoudens die Wet se bepalings betreffende die verrigting van die sake van die Raad geld die volgende bykomende bepalings:—

(1) Ampshalwe is die voorsitter van die Raad lid van al die komitees van die Raad, maar hy mag nie op vergaderings van enige komitee voorsit nie tensy hy voorsitter van die komitee is. As die Voorsitter nie in staat is om 'n vergadering van 'n komitee by te woon nie, is die Vise-voorsitter geregtig om dit by te woon, en wanneer hy dit aldus bywoon, word hy gedurende die afwesigheid van die Voorsitter geag 'n lid van daardie komitee te wees. Die Vise-voorsitter mag nie op 'n vergadering van die komitee voorsit nie tensy hy voorsitter van die komitee is nie.

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

(3) 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.

(4) 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 voorgebring word soos in die voorgaande reël bepaal.

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

(6) Om die bepaalde uur moet die Voorsitter die voorsitterstoel inneem, en indien na verloop van 'n kwartier geen kworum aanwesig is nie, kan hy die vergadering as verdaag verklaar tot 'n datum en uur wat hy bepaal.

(7) By die voortsetting van sodanige verdaagde vergadering maak die lede teenwoordig op dáárdie vergadering 'n kworum uit en moet hulle die werksaamhede afhandel waarvoor die vergadering oorspronklik belê is.

(8) 'n Lid wat 'n saak aan die Raad wil voorlê, moet minstens dertig dae voor die datum waarvoor 'n vergadering belê moet word, 'n skriftelike kennisgewing van sy voorstel aan die Registrateur stuur, en die kennisgewing van sy voorstel 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.

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

(10) Die meerderheid van die amptelike lede van 'n komitee wat kragtens artikel 9 (1) (*b*) van die Wet saamgestel word, sal 'n kworum van sodanige komitee uitmaak.

(11) Enige komitee kan 'n saak om ondersoek en verslag na 'n subkomitee van sy lede verwys.

Rules Relating to the Conduct of Business of the Drugs Control Council.

15. Except for the provisions about the conducting of the business of the Council as prescribed in the Act, the following additional rules shall apply:—

(1) The Chairman of the Council shall be *ex officio* a member of all committees of the Council, but shall not preside at meetings of any committee unless he is chairman of the committee. If the Chairman is unable to attend any meeting of a committee, the Vice-chairman shall be entitled to attend such meeting, and if so attending, he shall be deemed to be a member of that committee in the absense of the Chairman. The Vice-chairman shall not preside at any meeting of a committee unless he is chairman of the committee.

(2) Notices convening ordinary and special meetings 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 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 at the Chairman may deem sufficient, and, if necessary, given by telegram or telephone. If all members agree, a specific meeting can be convened at shorter, or without written notice.

(3) 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.

(4) 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.

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

(6) The Chairman shall take the chair at the appointed hour, and if at the expiration of a quarter of an hour a quorum is not present, he may declare the meeting postponed to a day and hour to be fixed by him.

(7) At the resumption of such a postponed meeting, the members present at that meeting, shall form a quorum and shall dispose of the business for which the meeting was originally called.

(8) Any member desirous of bringing any matter before the Council shall forward in writing to the Registrar at least thirty 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 in consecutive order with the other business to be brought before the Council.

(9) 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.

(10) The quorum of any committee established under section 9 (1) (*b*) of the Act shall consist of the majority of the official members of the relevant committee.

(11) Any committee may refer a matter to a sub-committee of its members for investigation and report to it.

(12) 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 roetineaangeleenthede of op sodanige sake waarvan die beginsel reeds by regulasie of besluit van die Raad bepaal is nie.

(13) 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.

(14) Enige lid van die Raad kan enige vergadering van 'n vaste komitee waarvan hy nie lid is nie, bywoon maar is nie geregtig op die betaling van gelde en toelaes vir die bywoon van sodanige vergaderings nie; en enige lid van die Raad kan by die Registrateur 'n algemene of spesifieke versoek indien om betyds in kennis gestel te word van die datum, plek en agenda van enige vergadering of alle vergaderings van 'n vaste komitee en moet, indien die tyd dit toelaat, van sodanige kennisgewing voorsien word. Die voorsitter van die komitee kan sodanige besoekende lid toelaat om te praat maar nie om te stem nie.

(15) 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.

(16) 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.

(17) (*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 sodanige mosies en amendemente as 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 notules 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 aangeneem is maar kommentaar of opmerkings van lede moet nie vermeld word nie.

(18) 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.

(19) 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.

(20) By die opening van elke afsonderlike sitting 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.

(21) Die agenda vir elke vergadering moet deur die Registrateur in oorleg met die Voorsitter opgestel word en moet vir elke vergadering die volgende items insluit:—

(*a*) Bekragtiging van die notule van die vorige vergadering;

(*b*) sake voortspruitend uit die notule van die vorige vergadering;

(*c*) verslae van vaste komitees;

(*d*) mosies;

(*e*) korrespondensie;

(*f*) algemeen.

(12) 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.

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

(14) Every member of the Council may attend any meeting of a standing committee of which he is not a member, but shall not be entitled to be paid fees and allowances for attending such meetings and every member of the Council may register with the Registrar a general or specific request to be furnished with timely notice of the date, place and agenda of any meeting or all meetings of a standing committee, and shall, whenever time permits, be so supplied; the chairman of the committee may permit a member so attending, to speak, but not to vote.

(15) 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.

(16) 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.

(17) (*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 metings 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.

(18) 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.

(19) 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.

(20) At the opening of each separate sitting 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 sitting by the Chairman or by such office-bearer or official as the Chairman may direct. No discussion thereon shall be permitted.

(21) The agenda for every meeting 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.

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

(22) 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 toestemming van die Voorsitter voorgelees en gesekondeer 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 die bedoeling 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.

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

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

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

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

(27) 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.

(28) 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 sakelys.";
(*c*) die beëindiging van die bespreking, nl. „Dat die saak nou in stemming gebring word.";
(*d*) die verdaging van die bespreking, nl. „Dat die die bespreking van die mosie verdaag word.";
(*e*) die verdaging van die Raad, nl. „Dat die Raad nou verdaag word."

(29) 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.";
(*d*) die verdaging van die Raad, nl. „Dat die Raad nou verdaag word.".

(30) 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.

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.

(22) 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 framed so 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.

(23) 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.

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

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

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

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

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

(29) 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";
(*d*) the adjournment of the Council, namely, "that the Council do now adjourn".

(30) 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.

(31) 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.

(32) 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.

(33) As die voorstel vir die verdaging van die Raad voorgestel 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.

(34) 'n Mosie tot herroeping van 'n besluit geneem op 'n vorige vergadering word alleen oorweeg indien kennis daarvan gegee is ingevolge reël (8). Dit word aangeneem indien 'n meerderheid van stemme ten gunste daarvan is.

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

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

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

(37) Kennis kan gegee word van 'n mosie om enige 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.

(38) 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, 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.

(39) 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.

(31) 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.

(32) 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.

(33) 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.

(34) A motion to rescind a resolution which has been passed at a previous meeting shall only be considered if notice thereof has been given in terms of rule (8). It shall be passed if a majority of the votes recorded, are 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 only be passed if two-thirds of the votes recorded are in its favour.

(35) 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.

(36) Notices of motion may be given 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.

(37) Notices of motion may be given 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.

(38) 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, who may, if it thinks fit, direct that such ruling shall be cancelled or amended, and the decision of the 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 can be discussed or reviewed during the meeting of the committee at which it has been given.

(39) 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.

VERTROULIK. (M.B.R. 1.)

MEDISYNE-BEHEERRAAD.

AANSOEK OM REGISTRASIE VAN 'N MEDISYNE.

[Kragtens artikel 13 van die Wet op die Beheer van Medisyne (Wet No. 101 van 1965).]

Datum.....

*1. Naam van applikant.....
2. Sakeadres van applikant.....
3. Posadres van applikant.....
Telefoonnommer.....
*4. Goedgekeurde naam van medisyne (indien enige).....
*5. Handelsnaam van medisyne (indien enige).....
*6. Bereidingsvorm.....
7. Land van herkoms.....
8. Naam en sakeadres van vervaardiger
*9. Klassifikasie.....
10. Besonderhede van verkope van die medisyne gedurende afgelope twaalf maande:
Hoeveelheid.....
Waarde R.....

Die ondergetekende verklaar hierby dat al die inligting hierin en in die aangehegte bylaes waar en juis is.

Handtekening van applikant.

SLEGS VIR KANTOORGEBRUIK.

Datum van registrasie.....
Registrasienommer.....
Klassifikasie.....
Goedgekeurde naam.....
Inspeksieverslagnommer.....
Voorwaardes van registrasie.....

ALGEMENE INLIGTING.

Verwysing—

*1. Indien die applikant nie 'n apteker of die besturende direkteur van 'n regspersoon wat as apteker mag handel dryf, is nie, moet hy die gesag waarvolgens by aansoek doen, vermeld en skriftelik staaf.

*4. Indien geen goedgekeurde naam deur 'n verbandhebbende internasionale liggaam toegeken is nie, moet die naam wat vir goedkeuring voorgestel is of gaan word, hier aangedui word.

*5. 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 as dieselfde medisyne beskou word nie, en afsonderlike aansoeke moet ten opsigte van elke sodanige medisyne ingedien word.

*6. Die bereidingsvorm, soos byvoorbeeld oplossings in water, suspensies, oogdruppels, oordruppels, emulsies, salwe, setpille, tablette, kapsules, inspuitings, ens., moet hier vermeld word.

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

BYLAE I.

Naam van applikant.....

Naam van medisyne.....

Bereidingsvorm.....

Die volgende is 'n lys van die bestanddele en hoeveelhede van elke aktiewe en nie-aktiewe bestanddeel wat die medisyne per doseringseenheid bevat:—

Bestanddeel.		Hoeveelheid.	Aktief of nie-aktief.
Naam.	Goedgekeurde naam indien enige).		

CONFIDENTIAL. (M.B.R. 1.)

DRUGS CONTROL COUNCIL.

APPLICATION FOR REGISTRATION OF A DRUG.

[In terms of section 13 of the Drugs Control Act (Act No. 101 of 1965).]

Date.....

*1. Name of applicant.....
2. Business address of applicant.....
3. Postal address of applicant.....
Telephone No.....
*4. Approved name of drug (if any).....
*5. Trade name of drug (if any).....
*6. Form of preparation.....
7. Country of origin.....
8. Name and business address of manufacturer.....
*9. Classification.....
10. Particulars of sales of the drug during past twelve months.
Quantity.....
Value R.....

The undersigned hereby declare that all the information contained herein and in the subjoined appendices are correct and true.

Signature of Applicant.

FOR OFFICE USE ONLY.

Date of registration.....
Registration number.....
Classification.....
Approved name.....
Inspection report No.....
Conditions of registration.

GENERAL INFORMATION.

Reference—

*1. If the applicant is not a chemist and druggist or the managing director of a body corporate entitled to carry on the business of a chemist and druggist, he shall quote and prove in writing the authority on which application is made.

*4. If no approved name has been allocated to the drug by an appropriate international body, the name which was, or will be, submitted for approval, shall be mentioned here.

*5. Attention is drawn to section 1 (2) of the Act. Furthermore it should be noted that drugs which are not identical in composition or strength are not regarded as the same drug and separate applications must be submitted in respect of each such drug.

*6. The form of preparation, i.e. solutions in water, suspensions, eye drops, ear drops, emulsions, ointments, suppositories, tablets, capsules, injections, etc., shall be mentioned here.

*9. The classification of the drug as described in regulations 4 and 5 shall be mentioned here.

APPENDIX 1.

Name of applicant.....

Name of drug.....

Form of preparation.....

The following is a schedule of the ingredients and quantities of each active and non-active ingredient contained in a dosage unit of the drug:—

Ingredient.		Quantity.	Active or non-active.
Name.	Approved name (if any).		

BYLAE 2.

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

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

Name van aktiewe bestanddele soos in Bylae 1 (goedgekeurde of ander naam).	(1) Chemiese naam.	(2) Struktuurformule.

(1) Die chemiese naam moet sover moontlik volgens die gepubliseerde lys van 'n verbandhebbende internasionale liggaam verstrek word.
(2) Verwysing na die volgende publikasies sal, waar van toepassing, aanvaar word:—

British Pharmacopoeia, British Pharmaceutical Codex, Pharmacopoeia of the United States, Merck Index, Remington's Pharmaceutical Sciences and Pharmacopoeia Internationalis.

BYLAE 3.

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

Die spesifikasies vir die grondstowwe en verpakkingsmateriaal wat in die vervaardigingsproses gebruik word, is soos volg:—*

* Alle grondstowwe en verpakkingsmateriaal moet vermeld word. Indien geen spesifikasies bestaan nie, moet dit vermeld word.

BYLAE 4.

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

Die analitiese kontroleprosedures wat met grondstowwe voor gebruik word in die vervaardigingsproses gevolg word, is soos volg:—*

* Waar dit van toepassing is, sal verwysings na die publikasies genoem in die voetnoot van Bylae 2, aanvaar word.

BYLAE 5.

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

Die analitiese kontroleprosedures wat gedurende die vervaardigingsproses uitgevoer word, is soos volg:—

BYLAE 6.

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

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

* Verwysings na die publikasies genoem in die voetnoot van Bylae 2 sal, waar dit van toepassing is, aanvaar word.

BYLAE 7.

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

Die analitiese en ander kontroleprosedures om die verstrykingstydperk te bepaal en te verseker, is soos volg:—

BYLAE 8.

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

Die klassifikasie van die medisyne kragtens die Wet op Geneeshere, Tandartse en Aptekers, No. 13 van 1928, is soos volg:—

	*	
Vergif, afd. I.....	Ja	Nee
Vergif, afd. II.....	Ja	Nee
Moontlik nadelige medisyne (Bylae VI).....	Ja	Nee
Terapeutiese stof.....	Ja	Nee
Verslaafmiddel.....	Ja	Nee
Giftige stof.....	Ja	Nee

* Skrap wat nie van toepassing is nie.

APPENDIX 2.

Name of applicant.....
Name of drug.....
Form of preparation.....

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

Names of the active ingredients as in Appendix 1 (approved or other name).	(1)Chemical name.	(2)Structural formula.

(1) The chemical name shall, wherever possible, be given in terms of the published list of an appropriate international body.
(2) Reference to the following publications will, where applicable, be be accepted:—

British Pharmacopoeia, British Pharmaceutical Codex, Pharmacopoeia of the United States, Merck Index, Remington's Pharmaceutical Sciences and Pharmacopoeia Internationalis.

APPENDIX 3.

Name of applicant.....
Name of drug.....
Form of preparation.....

The specifications for raw materials and packaging materials used in the manufacturing process are as follows:—*

* All raw materials and packaging materials shall be mentioned. Where no specifications exist, this shall be mentioned.

APPENDIX 4.

Name of applicant.....
Name of drug.....
Form of preparation.....

The analytical control procedures which are performed on raw materials before they are used in the manufacturing process are as follows:—*

* Where appropriate, reference to the publications mentioned in the footnote to Appendix 2, will be accepted.

APPENDIX 5.

Name of applicant.....
Name of drug.....
Form of preparation.....

The analytical control procedures which are performed during the manufacturing process are as follows:—

APPENDIX 6.

Name of applicant.....
Name of drug.....
Form of preparation.....

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

* Reference to the publications mentioned in the footnote to Appendix 2 will be accepted.

APPENDIX 7.

Name of applicant.....
Name of drug.....
Form of preparation.....

The analytical and other control procedures used to ascertain and ensure the expiry period are as follows:—

APPENDIX 8.

Name of applicant.....
Name of drug.....
Form of preparation.....

The classification of the drug in terms of the Medical, Dental and Pharmacy Act, No. 13 of 1928 is as follows:—

	*	
Poison, Div. I.....	Yes	No
Poison, Div. II.....	Yes	No
Potentially harmful drug (Sixth Schedule)...	Yes	No
Therapeutic substance.....	Yes	No
Habit forming drug.....	Yes	No
Poisonous substance.....	Yes	No

* Delete whichever is inapplicable.

BYLAE 9.

Reklame vir die medisyne sal gedoen word by—

*(*a*) die algemene publiek;
(*b*) slegs die beroepe.

* Skrap wat nie van toepassing is nie.

BYLAE 10.

Die prys vir die medisyne aan die publiek is soos volg:—

(Die pryse vir alle handelsverpakkings moet verstrek word.)

BYLAE 11.

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

Die volgende verslag ten opsigte van registrasie in die land van herkoms is uitgereik deur die statutêre lisensie- of registrasieowerheid van die land van herkoms van die medisyne:—*

* Indien geen verslag beskikbaar is nie, moet alle verbandhebbende besonderhede verstrek word met betrekking tot die vordering wat reeds in verband met die registrasie van die medisyne gemaak is in die land van herkoms.

BYLAE 12.

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

(*a*) Die volgende is besonderhede van die proewe wat op diere uitgevoer is met betrekking tot die veiligheid van die gebruik van die medisyne, veral met betrekking tot die verband tussen die uitgevoerde proewe en die doel waarvoor die medisyne gepropageer word of sal word, en die wyse van werking van die medisyne:—

(*b*) Die volgende is besonderhede van die proewe wat op mense uitgevoer is met betrekking tot die veiligheid van die gebruik van die medisyne, veral met betrekking tot die verband tussen die uitgevoerde proewe en die doel waarvoor die medisyne gepropageer word of sal word, en die wyse van werking van die medisyne:—

BYLAE 13.

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

(*a*) Die volgende is besonderhede van die farmakologiese proewe wat alle aspekte van die stofwisseling in verband met die medisyne dek en op diere uitgevoer is met betrekking tot die doeltreffendheid van die gebruik van die medisyne, veral met betrekking tot die verband tussen 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:—

(*b*)* Die volgende is besonderhede van farmakologiese proewe wat alle aspekte van die stofwisseling in verband met die medisyne dek en op mense uitgevoer is met betrekking tot die doeltreffendheid van die gebruik van die medisyne, veral met betrekking tot die verband tussen 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:—

* Waar enige sinergistiese of modifiserende uitwerking van die medisyne bekend is, moet dié ook hierin aangedui word.

BYLAE 14.

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

Hieronder volg 'n beskrywing van die doel waarvoor die medisyne aangebied word, met vermelding van sy werking, newe effekte, kontra-indikasies en dosisse van die medisyne vir die onderskeie ouderdomsgroepe:—*

* Waar enige sinergistiese of modifiserende uitwerking van die medisyne bekend is, moet dié ook hierin aangedui word.

APPENDIX 9.

The drug will be advertised to—

*(*a*) the general public;
(*b*) only the professions.

* Delete whichever is inapplicable.

APPENDIX 10.

The price of the drug to the public is as follows:—

(The prices of all trade packs must be given.)

APPENDIX 11.

Name of applicant.....
Name of drug.....
Form of preparation.....

The following report with regard to registration in the country of origin was issued by the statutory licensing or registering body of that country:—*

* If no such report is available, all relevant particulars with regard to the progress already made concerning the registration of the drug in the country of origin, shall be furnished.

APPENDIX 12.

Name of applicant.....
Name of drug.....
Form of preparation.....

(*a*) The following are particulars of the tests performed on animals with regard to the safety of the use of the drug with special reference to the relationship between the tests done and the purpose for which the drug is, or will be, propagated and the mode of action of the drug:—

(*b*) The following are particulars of the tests performed on humans with regard to the safety of the use of the drug with special reference to the relationship between the tests done and the purpose for which the drug is, or will be, propagated and the mode of action of the drug:—

APPENDIX 13.

Name of applicant.....
Name of drug.....
Form of preparation.....

(*a*) The following are particulars of the pharmacological tests concerning all aspects of the metabolism with regard to the drug, which were performed on animals concerning the efficacy of the use of the drug with special reference to the relationship between the tests and the purpose for which the drug is, or will be, propagated and with further reference to the dosage and method of administration of the drug:—

(*b*)* The following are particulars of the pharmacological tests concerning all aspects of the metabolism with regard to the drug, which were performed on humans concerning the efficacy of the use of the drug with special reference to the relationship between the tests and the purpose for which the drug is, or will be, propagated and with further reference to the dosage and method of administration of the drug:—

* Any known synergistic or modifying effects of the drug shall also be mentioned here.

APPENDIX 14.

Name of applicant.....
Name of drug.....
Form of preparation.....

The following is a description of the purpose for which the drug is presented with reference to the mode of action, side-effects, contra-indications and dosage of the drug for the different age groups:—*

* Where any synergistic or modifying effects of the drug are known, it shall also be mentioned here.

BYLAE 15.

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

(*a*) Die volgende aangehegte wetenskaplike dokumente het verskyn in verband met die medisyne of die grondstowwe van die medisyne:—

(*b*) Die volgende literatuur het betrekking op die medisyne:—

BYLAE 16.

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

Monsters van die volgende is per geregistreerde pos/per hand by die Registrateur ingedien:—

*(*a*) Die medisyne;
(*b*) die voubiljet wat die medisyne vergesel;
(*c*) die advertensiemateriaal wat gebruik word of gaan word vir die advertering van die medisyne.

* Skrap wat nie van toepassing is nie.

No. R. 447.] [31 Maart 1967.

WET OP DIE BEHEER VAN MEDISYNE, 1965.

KONSEPREGULASIES.

Hierby word vir algemene inligting ingevolge artikel 35 (6) van die Wet op die Beheer van Medisyne, 1965 (Wet No. 101 van 1965), bekendgemaak dat die Minister van Gesondheid na oorlegpleging met die Medisyne-beheerraad ingestel kragtens artikel 2 van genoemde Wet, voornemens is om die volgende regulasies kragtens artikel 35 (4) van genoemde Wet uit te vaardig.

Belanghebbende persone en organisasies word uitgenooi om binne drie maande na die datum hiervan opmerkings oor of vertoë in verband met die konsepregulasies by die Registrateur van Medisyne, Privaatsak 88, Pretoria, in te dien.

VORM VAN DIE SERTIFIKAAT WAT DEUR INSPEKTEURS UITGEREIK MOET WORD BY MONSTERNEMING.

16. Onderstaande sertifikaat moet deur inspekteurs uitgereik word wanneer 'n monster van medisyne geneem word: —

MEDISYNE-BEHEERRAAD.

SERTIFIKAAT VAN INSPEKTEUR WAT MONSTERS VAN 'N MEDISYNE NEEM.

Hierby sertifiseer ek dat meegaande ('n) monster(s) is wat op ..... te (1).....
geneem is van 'n medisyne verkry uit voorrade onder toesig van (2).....in die teenwoordigheid van (3).....

Die volgende is besonderhede in verband met die monster(s):—

(*a*) Die goedgekeurde naam van die medisyne:.....

(*b*) die handelsnaam van die medisyne, indien enige:.....

(*c*) die registrasienommer van die medisyne:.....

(*d*) die naam en sakeadres van die vervaardiger van die medisyne:.....

(*e*) die naam en sakeadres van die verkoper van die medisyne:.....

(*f*) die geraamde hoeveelheid van die medisyne:.....

(*g*) die lotnommer wat op die etiket voorkom:.....

(*h*) die verstrykingsdatum wat op die etiket voorkom:.....

(*i*) ander besonderhede wat op die etiket voorkom:.....

(*j*) die besonderhede wat in die voubiljet voorkom:.....

(*k*) enige ander verbandhebbende besonderhede:.....

.....

Inspekteur.

..... Datum.....
Getuie.

OPMERKING.—'n Afskrif van die sertifikaat moet aan die eienaar of verkoper van die medisyne of sy agent oorhandig of per geregistreerde pos gestuur word.

(1) Volledige adres.
(2) Naam en volledige adres.
(3) Naam en volledige adres van getuie.

APPENDIX 15.

Name of applicant.....
Name of drug.....
Form of preparation.....

(*a*) The following attached scientific documents with regard to the drug or the raw materials of the drug have been published:—

(*b*) The following are references to literature about the drug:—

APPENDIX 16.

Name of applicant.....
Name of drug.....
Form of preparation.....

Samples of the following have been submitted per registered post/by hand to the Registrar:—

*(*a*) The drug;
(*b*) the package insert;
(*c*) the advertising material which is, or will be, used for the advertising of the drug.

* Delete whichever is inapplicable.

No. R. 477.] [31 March 1967.

DRUGS CONTROL ACT, 1965.

DRAFT REGULATIONS.

It is hereby notified for general information in terms of section 35 (6) of the Drugs Control Act, 1965 (Act No. 101 of 1965), that the Minister of Health, in the exercise of the powers conferred upon him by section 35 (4) of the said Act, and after consultation with the Drugs Control Council established in terms of section 2 of the said Act, intends to make the following regulations.

Interested persons and organisations are invited to submit comments or representations on the draft regulations within three months from the date hereof to the Registrar of Drugs, Private Bag 88, Pretoria.

FORM OF CERTIFICATE TO BE ISSUED BY INSPECTORS WHEN A SAMPLE IS TAKEN.

16. When taking a sample of a drug the inspector shall issue the following certificate: —

DRUGS CONTROL COUNCIL.

CERTIFICATE OF INSPECTOR TAKING A SAMPLE OF A DRUG.

I hereby certify that the accompanying is (are) a sample(s) of a drug taken on.....at (1).....
from stock in charge of (2).....in the presence of (3).....

The following are particulars in connection with the sample(s):—

(*a*) The approved name of the drug:.....

(*b*) the trade name of the drug, if any:.....

(*c*) the registration number of the drug:.....

(*d*) the name and business address of the manufacturer of the drug:.....

(*e*) the name and business address of the seller of the drug:.....

(*f*) the estimated quantity of the drug:.....

(*g*) the batch number appearing on the label:.....

(*h*) the expiry date appearing on the label:.....

(*i*) other particulars appearing on the label:.....

(*j*) the particulars appearing on the package insert:.....

(*k*) any other appropriate particulars:.....

.....

Inspector.

..... Date.....
Witness.

NOTE.—A copy of this certificate shall be handed or forwarded by registered post to the owner or seller of the drug or to his agent.

(1) Full address.
(2) Name and full address.
(3) Name and full address of witness.

VORM VAN SERTIFIKAAT WAT UITGEREIK MOET WORD IN VERBAND MET DIE TOETS, ONDERSOEK OF ONTLEDING VAN MONSTERS.

17. Onderstaande sertifikaat moet uitgereik word deur 'n ontleder, farmakoloog of patoloog nadat 'n monster van 'n medisyne deur hom ontleed, getoets of ondersoek is kragtens die Wet: —

MEDISYNE-BEHEERRAAD.

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

Ek, (volle naam)_____
'n behoorlik aangestelde (i) ontleder, (ii) farmakoloog of (iii) patoloog _____kragtens artikel 27 van die Wet op die Beheer van Medisyne (Wet No. 101 van 1965), verklaar hierby dat ek op (datum)_____'n monster van (1)_____
van (2)_____vir (i) ontleding, (ii) toets, (iii) ondersoek ontvang het; dat die monster soos volg gemerk was: (3)_____
dat ek die monster ontleed en/of getoets het en dat ek die resultate gevind het wat aangeheg is.
Opmerkings in verband met resultate_____

Ontleder, Farmakoloog, Patoloog.

(1) Naam van inhoud soos dit op die etiket voorkom.
(2) Naam van persoon van wie ontvang.
(3) Naam van vervaardiger, lotnommer en enige ander besonderhede wat op die etiket voorkom.

(i), (ii), (iii) } Skrap wat nie van toepassing is nie.

No. R. 478.] [31 Maart 1967.

WET OP DIE BEHEER VAN MEDISYNE, 1965.

KONSEPREGULASIE.

Hierby word vir algemene inligting ingevolge artikel 35 (6) van die Wet op die Beheer van Medisyne, 1965 (Wet No. 101 van 1965), bekendgemaak dat die Minister van Gesondheid in oorleg met die Minister van Finansies en na oorlegpleging met die Medisyne-beheerraad ingestel kragtens artikel 2 van genoemde Wet, voornemens is om die volgende regulasie kragtens artikel 35 (4) van genoemde Wet uit te vaardig.

Belanghebbende persone en organisasies word uitgenooi om binne drie maande na die datum hiervan opmerkings oor of vertoë in verband met die konsepregulasie by die Registrateur van Medisyne, Privaatsak 88, Pretoria, in te dien.

REGISTRASIEGELDE.

18. 'n Bedrag van R100 is betaalbaar wanneer aansoek om registrasie van 'n medisyne gedoen word.

FORM OF CERTIFICATE WHICH SHALL BE ISSUED WITH REGARD TO THE TESTING, EXAMINATION OR ANALYSIS OF SAMPLES.

17. The following certificate shall be issued by an analyst, pharmacologist or pathologist after he analysed, tested or examined a sample of a drug in terms of the Act: —

DRUGS CONTROL COUNCIL.

CERTIFICATE BY ANALYST, PHARMACOLOGIST OR PATHOLOGIST OF RESULT OF ANALYSIS OR TEST OR EXAMINATION OF SAMPLE OF A DRUG.

I, (full name)_____
a duly appointed (i) analyst, (ii) pharmacologist or (iii) pathologist in terms of section 27 of the Drugs Control Act (Act No. 101 of 1965), hereby declare that on (date)_____ I received a sample of (1)_____ from (2)_____for (i) analysis, (ii) test, (iii) examination; that the sample was marked as follows: (3)_____
that I have analysed and/or tested the sample and found the results which are subjointed.
Remarks with regard to results_____

Analyst, Pharmacologist, Pathologist.

(1) Name of contents as described on the label.
(2) Name of person from whom sample was received.
(3) Name of manufacturer, batch number and any other particulars on the label.

(i), (ii), (iii) } Delete whichever is not applicable.

No. R. 478.] [31 March 1967.

DRUGS CONTROL ACT, 1965.

DRAFT REGULATION.

It is hereby notified for general information in terms of section 35 (6) of the Drugs Control Act, 1965 (Act No. 101 of 1965), that the Minister of Health, in the exercise of the powers conferred upon him by section 35 (4) of the said Act, in consultation with the Minister of Finance and after consultation with the Drugs Control Council established under section 2 of the said Act, intends to make the following regulation.

Interested persons and organisations are invited to submit comments or representations on the draft regulation within three months from the date hereof to the Registrar of Drugs, Private Bag 88, Pretoria.

REGISTRATION FEES.

18. A fee of R100 shall be payable when application is made for the registration of a drug.

INHOUD.

CONTENTS.

Die Staatsdrukker, Pretoria. | The Government Printer, Pretoria.