

Republic of South Africa

Republiek van Suid-Afrika



Government Gazette

Buitengewone Extraordinary Staatskoerant

(Registered at the Post Office as a Newspaper) (As 'n Nuusblad by die Poskantoor Geregistreer)

(REGULATION GAZETTE No. 877)

Price 10c Prys
Overseas 15c Oorsee
POST FREE - POSVRY

(REGULASIEKOERANT No. 877)

VOL. 30.]

PRETORIA, 15 DECEMBER 1967.
15 DESEMBER

[No. 1916]

GOVERNMENT NOTICE.

DEPARTMENT OF HEALTH.

No. R. 2025.] [15 December 1967.

DRUGS CONTROL ACT, 1965.

The Drugs Control Council, established in terms of section 2 of the Drugs Control Act, 1965 (Act No. 101 of 1965), under the powers conferred upon it by section 35 (1) of the said Act, has made the following regulations:

Definitions.

1. Unless the context otherwise indicates the expression "the Act" means the Drugs Control Act, 1965 (Act No. 101 of 1965), and any expressions which are defined in the Act shall have the same meanings as in the Act, and further—

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

"manufacture" means make, compound, process and, except in regulation 8 (4) and schedule MBR 1 and the annexures thereto, also pack, and manufacturer and manufacturing process have corresponding meanings;

"working formula", in relation to a drug, means the particulars in respect of such drug furnished in annexure 1 of MBR 1 in the schedule hereto;

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

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

"expiry date", in relation to any batch of a drug, means the date up to which a drug 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 drugs of that batch 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;

"outer label", in relation to any drug, means a label as prescribed by the Act which is 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;

GOEWERMENTSKENNISGEWING.

DEPARTEMENT VAN GESONDHEID.

No. R. 2025.] [15 Desember 1967.

WET OP DIE BEHEER VAN MEDISYNE, 1965.

Onderstaande regulasies word hierby kragtens artikel 35 van die Wet op die Beheer van Medisyne, 1965 (Wet No. 101 van 1965), afgekondig deur die Medisyne-beheerraad soos by artikel 2 van genoemde Wet ingestel:—

Definisies.

1. Tensy uit die samehang anders blyk, beteken die uitdrukking "die Wet" die Wet op die Beheer van Medisyne, 1965 (Wet No. 101 van 1965), en het elke uitdrukking waaraan in daardie Wet 'n betekenis toegeskryf is, die betekenis aldus daaraan toegeskryf, en beteken—

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

"vervaardig" maak, berei, verwerk en, behalwe in regulasie 8 (4) en bylae MBR 1 en die aanhangsels daarvan, ook verpak, en het vervaardiger en vervaardigingsproses ooreenstemmende betekenisse;

"bereidingsvoorskrif" met betrekking tot 'n medisyne, die besonderhede in verband met sodanige medisyne verskaf in aanhangsel 1 van vorm MBR 1 in die bylae hiervan;

"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 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;

"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;

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

Application for Registration of a Drug.

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

- (a) a registered chemist and druggist; or
- (b) a body corporate which carries 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), or a person authorised by such a body to apply on its behalf; or

(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, MBR 1 detailed in the schedule and annexures thereto together with the prescribed registration fee to the Registrar of Drugs, Private Bag 88, Pretoria.

Note.—Literature in support of the application for registration may be submitted in single copy. If required by the Council, more copies shall be made available.

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 administration, including packaged preparations where only a vehicle is added to the effective drug or drugs;

(b) *Category B.*—Drugs which can not 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. 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, hypnotics.
- 2.3. Barbiturates.
- 2.4. Non-barbiturates.
- 2.5. Anticonvulsants, including anti-epileptics.
- 2.6. Tranquilizers.
- 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 structure.
- 2.7. Narcotic analgesics.
- 2.8. Non-narcotic analgesics, antipyretics.
- 2.9. Special analgesic combinations.
- 2.10. 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. Local Anaesthetics.

5. Drugs affecting Autonomic Functions.

- 5.1. Adrenomimetics (sympathicomimetics).
- 5.2. Adrenolytics (sympathicolitics).
- 5.3. Cholinomimetics (cholinergics).
- 5.4. Cholinolytics (anticholinergics).

„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;

„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 die registrasie van ’n medisyne kan gedoen word deur—

(a) ’n geregistreerde apteker; of

(b) ’n regspersoon wat as apteker handel dryf kragtens artikel 76 van die Wet op Geneeshere, Tandartse en Aptekers (Wet No 13 van 1928), 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 bepalinge van artikel 37 van die Wet op Geneeshere, Tandartse en Aptekers, daardie persoon.

3. Elke aansoek om registrasie van ’n medisyne moet in sesvoud op die voorgeskrewe vorm MBR 1 uiteengesit in die bylae hiervan en die aanhangsels van daardie bylae saam met die voorgeskrewe registrasiegeld by die Registrateur van Medisyne, Private Bag 88, Pretoria, ingedien word.

Opmerking.—Van literatuur ter ondersteuning van die aansoek om registrasie hoef net een eksemplaar ingedien te word. Indien die Raad daarom vra, moet meer eksemplare beskikbaar gestel word.

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 toediening, met inbegrip van verpakte preparate waar slegs ’n basis by die effektiewe middel of middels 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 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. Stuipeweermiddels en epilepsieweermiddels.
- 2.6. Bedaarmiddels (berustingsmiddels).
- 2.6.1. Fenotiasiene en derivate.
- 2.6.2. Rauwolfia: alkaloiëde en samestellings.
- 2.6.3. Difenielmetaan en derivate daarvan.
- 2.6.4. Alkiöldiële en derivate daarvan.
- 2.6.5. Diverse strukture.
- 2.7. Narkotiese analgetika.
- 2.8. Nie-narkotiese analgetika, antipiretika (koorsweer-middels).
- 2.9. Spesiale analgetiese samestellings.
- 2.10. Sentraalwerkende spierverslappers.

3. Bindweefselmiddels.

- 3.1. Rumatiekmiddels (anti-inflammatoriese middels).
- 3.2. Hormoonvrye middels.
- 3.3. Jigmiddels.
- 3.4. Samestellings bevattende kortikosteroïëde (skors-hormone).

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. 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 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 and other drugs used in angina pectoris.
- 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. 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.

- 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) en ander middels vir gebruik teen angina pectoris.
- 7.1.5. Perifere vasodilators.
- 7.2. Vasokonstriktors (vaatvernouers), pressormiddels.
- 7.3. Migraine-middels.
- 7.4. Lipotropiese middels.
- 7.5. Anti-serumcholesterolmiddels.
8. *Middels met uitwerking op Bloed en Hemopoïetiese Stelsel.*
- 8.1. Bloedstolmiddels, bloedstelpmiddels (hemostatika).
- 8.2. Antistolmiddels.
- 8.3. Eritropoietika.
- 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: spasmoditiese 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-infeksie-middels.
- 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. Oppervlakteverdwingsmiddels.
- 13.4. Jeukmiddels (antipruritiese middels).
- 13.4.1. Kortikosteroïede met of sonder anti-infeksie-middels.
- 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. 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. *Ophthalmic 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. 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. Antileprotics.
- 20.2.5. Germicides.
- 20.2.6. Drugs against protozoa.
- 20.2.7. Spirochaetocides.
- 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. Corticoids.
- 21.5.1. Cortical steroids 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. Progestogens with or without oestrogens.
- 21.9. Androgen-oestrogen combinations.
- 21.10. Tropic (trophic) hormones.
- 21.11. Hyperglycaemic hormones.
- 21.12. Hormone inhibitors.

- 13.9.1. Middels teen psoriase.
- 13.9.2. Swamdoders.
- 13.10. Beskermingsmiddels teen straling.
- 13.11. Melanieninhibitores en -stimuleerders.
- 13.12. Akneemiddels.
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. Oppervlakteverdowningsmiddels.
- 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. 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 mediumspektrum-antibiotika.
- 20.1.2. Penisilliene.
- 20.1.3. Penisillien-streptomisiensamestellings.
- 20.1.4. Antibiotikum-sulfonamiedsamestellings.
- 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. 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 Hipoglukemie-slukmiddels.*
- 21.1. Insulienpreparate.
- 21.2. Hipoglukemie-slukmiddels.
- 21.3. Tiroïedpreparate.
- 21.4. Paratiroïedsamestellings.
- 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. Progestogene met of sonder estrogene.
- 21.9. Androgeen-estrogensamestellings.
- 21.10. Tropiese hormone.
- 21.11. Hiperglukemiehormone.
- 21.12. Hormooninhibitores.

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. Others.
- 22.1.5. B-complex with vitamin C.

23. Amino-acids.

24. Mineral Substituents, 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. Others.

6. The provisions of section 14 (1) of the Act shall come into operation in terms of section 14 (2) in respect of drugs in the pharmacological classification 20 of category A which were available for sale in the Republic or the Territory immediately prior to the promulgation of these regulations.

Samples with Application for Registration.

7. An application for registration of a drug shall 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 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 active ingredient of the drug per unit;
- (11) the country of manufacture 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 Application Form MBR 1 in the attached schedule.

22. Vitamiene.

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

23. Aminosure.

24. Aanvullende Mineralepreparate, Elektroliete.

25. Spesiale Voedsel.

25.1. Babavoedsel en ander samestellings uitsluitende voedingsmiddels wat slegs gebruik word as 'n vervangmiddel vir moedersmelk.

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.

6. Die bepalings van artikel 14 (1) van die Wet tree ooreenkomstig artikel 14 (2) in werking ten opsigte van medisyne in die farmakologiese klassifikasie 20 van kategorie A wat onmiddellik voor die afkondiging van hierdie regulasies in die Republiek of in die Gebied vir verkoop beskikbaar was.

Monsters saam met Aansoek om Registrasie.

7. 'n Aansoek om registrasie van 'n medisyne moet versamel 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 sodanige monsters van die grondstowwe soos deur die Raad versoek mag word.

Gegewens wat in die Medisyne-register moet voorkom.

8. Wanneer 'n medisyne geregistreer word, moet die volgende gegewens ingeskryf word in die medisyne-register 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 aktiewe 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 inspeksieverlag vermeld in registrasievorm MBR 1 in die bylae hiervan.

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 active 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.

Pretoria _____ 19____ Registrar of Drugs.

- (1) Active 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. (1) The package in which a drug 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 drug 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 drug;

(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 drug as a preservative;

(e) the batch number of the drug;

(f) the expiry date of the drug, where applicable;

(g) where practicable, the dose of the drug.

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

(2) In the case of a package of a drug of 5 ml. or less, it will be adequate to record the information required by paragraphs (a), (b), (c) and (d) of subregulation (1) on the outer label.

(3) The provisions of paragraphs (a), (c), (d), (e), (g) and (h) of subregulation (1) shall not apply to drugs dispensed by a chemist and druggist or medical practitioner or dentist if such a drug is labelled with the name and address of the person or the body corporate by whom, or on whose behalf, the sale has been effected and data including the name and quantity of the drug sold, the name of the person to whom it is sold and the date of sale are kept by the seller as a record.

(4) 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. (1) Each package of a drug shall contain a package insert on which is printed prominently in both official languages—

(a) all the information which shall in terms of section 18 (1) of the Act, and regulations 10 (1) (c) and 10 (1) (d) appear on labels;

(b) directions for use;

(c) 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;

Vorm van Registrasiesertifikaat.

9. 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 aktiewe bestanddele bevat⁽¹⁾ _____

in die bereidingsvorm van⁽²⁾ _____
en bemark onder die handelsnaam van⁽³⁾ _____
en vervaardig 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.

Pretoria _____ 19____ Registrateur van Medisyne.

- (1) Aktiewe 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. (1) Die pakket waarin 'n medisyne verkoop word, moet voorsien wees van 'n etiket 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, indien enige, betreffende die metode van opberging of ander voorsorgmaatreëls wat nodig is vir die preservering van die medisyne;

(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 gevoeg word;

(e) die lotnommer van die medisyne;

(f) die verstrykingsdatum van die medisyne, waar van toepassing;

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

(h) die hoeveelheid van die medisyne in die pakket.

(2) In die geval van 'n verpakking van medisyne van 5 ml. en minder is dit voldoende om die gegewens vereis by paragrafe (a), (b), (c) en (d) van subregulasie 1 op 'n buite-etiket aan te bring.

(3) Die bepalinge van paragrafe (a), (c), (d), (e), (g) en (h) van subregulasie 1, is nie ten opsigte van medisyne voorberei deur 'n apteker, geneesheer of tandarts, van toepassing nie as dié medisyne van 'n etiket bevattende die naam en adres van die persoon of regspersoon deur of namens wie die verkoop plaasgevind het, voorsien is en gegewens, insluitende die naam en hoeveelheid van die medisyne verkoop, die naam van die persoon aan wie dit verkoop is en die datum van verkoop, deur die verkoper vir rekorddoeleindes gehou word.

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

Voubiljette.

11. (1) Elke medisynepakket moet 'n voubiljet inhê waarop in prominente letters in beide amptelike tale gedruk is—

(a) alle gegewens wat ingevolge die bepalinge van artikel 18 (1) van die Wet en regulasies 10 (1) (c) en 10 (1) (d) op etikette moet voorkom;

(b) gebruiksaanwysings;

(c) enige noodsaaklike waarskuwings in verband met die onveilige gebruik van die medisyne deur kinders, ou mense of swanger vrouens, en moontlike gevare verbonde aan langdurige gebruik van die medisyne of die toediening van die medisyne;

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

(e) 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.

(2) The provisions of subregulation (1) shall not apply to any drug intended in regulation 10 (3) in respect of which the provisions of that subregulation are complied with.

Advertisements.

12. When a drug 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 11, shall simultaneously be given to the person to whom the oral advertisement is directed, and when advertised orally on subsequent occasions such information shall be available on request.

Composition, Therapeutic Suitability and Effect, Purity, etc., to which a Drug shall comply.

13. (a) All drugs shall comply with the standard, if any, laid down in the British Pharmacopoeia or the British Pharmaceutical Codex 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 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 active 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.

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) 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 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, given by telegram or telephone. If all members agree, a specific meeting can be convened at shorter, 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 shall be kept by the Registrar of all the members attending a meeting.

(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;

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

(2) Die bepalings van subregulasie (1) is nie van toepassing in die geval van 'n medisyne waarop in regulasie 10 (3) gedoel en ten opsigte waarvan aan die vereistes van daardie subregulasie voldoen word nie.

Advertensies.

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

Samestelling, Terapeutiese Geskiktheid en Uitwerking, Suiwerheid, ens., waaraan 'n Medisyne moet voldoen.

13. (a) Alle medisyne moet voldoen aan die standaarde, indien enige, bepaal in die British Pharmacopoeia of die British Pharmaceutical Codex na die geval mag wees, of aan standaarde wat die Raad bevredig.

(b) Elke applikant moet die Raad sonder versuim verwittig van enige afwyking van die besonderhede deur hom verstrekk 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 aktiewe 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.

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) 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 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 in 'n voortsetting is, uitgesonderd sake wat voorgebring word soos in die voorgaande reël bepaal.

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

(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 in consecutive order with the other business to be brought before the Council.

(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 order 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) 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 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.

(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.

(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 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.

(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, daarvoor 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 komitee-vergaderings.

(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 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 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.

(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 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 daarvoor 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) 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.

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 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.

(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 to any period of the debate.

(20) If an amendment be proposed, it may be followed by the 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 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) the closure, namely, "that the question be not 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".

(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";
- (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.

'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 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.

(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 in 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.”;
- (c) die beëindiging van die bespreking, nl. „ dat die saak nou in stemming gebring word.”;
- (d) die verdagting van die bespreking, nl. „ dat die bespreking van die mosie verdaag word.”;
- (e) die verdagting 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 verdagting van die bespreking, nl. „ dat die bespreking van die mosie nou verdaag word.”;
- (d) die verdagting 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 verdagting 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 verdagting het by hervatting van die bespreking die reg om eerste te praat.

(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 only be considered if notice thereof has been given in terms of rule (6). 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.

(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) 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.

(32) 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.

(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, 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.

(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.

CONFIDENTIAL.

SCHEDULE.

(FORM MBR 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 _____

	FOR OFFICE USE ONLY.
*1. Name of applicant _____	Date of registration _____
2. Business address of applicant _____	Registration number _____
3. Postal address of applicant _____	Classification _____
Telephone No. _____	Approved name _____
*4. Approved name of drug (if any) _____	Inspection report No. _____
*5. Trade name of drug (if any) _____	Conditions of registration _____
*6. Form of preparation _____	
7. Country of origin _____	
8. Name and business address of manufacturer _____	
*9. Classification _____	

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

Signature of applicant.

(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 sitting van die Raad mag egter ondanks bostaande bepaling tydens dieselfde sitting van die Raad oorweeg word, mits skriftelike kennis gegee word dat die aanleentheid op die daaropvolgende dag van daardie sitting 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 beslissings van die Voorsitter betreffende 'n vertolking van hierdie reglement opneem as 'n lid, wanneer die beslissing gegee word, daarom vra.

(31) 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.

(32) 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 daarvoor 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 2 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.

(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.

VERTROULIK.

BYLAE.

(VORM MBR 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 _____	SLEGS VIR KANTOORGEBRUIK.
2. Sakeadres van applikant _____	Datum van registrasie _____
3. Posadres van applikant _____	Registrasienommer _____
Telefoonnommer _____	Klassifikasie _____
*4. Goedgekeurde naam van medisyne (indien enige) _____	Goedgekeurde naam _____
*5. Handelsnaam van medisyne (indien enige) _____	Inspeksieverslagnummer _____
	Voorwaardes van registrasie: _____
*6. Bereidingsvorm _____	
7. Land van herkoms _____	
8. Naam en sakeadres van vervaardiger _____	
*9. Klassifikasie _____	

Die ondergetekende verklaar hierby dat al die inligting hierin en in die aanhangsels hiervan waar en juis is.

Handtekening van applikant.

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. Application for registration of drugs of which only the strength vary, may be made on the same form.
- *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.

ANNEXURE 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).		

ANNEXURE 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 annexure 1 (approved or other name).	(1) Chemical name.	(2) Structural formula.

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

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

ANNEXURE 3.

Name of applicant _____
 Name of drug _____
 Form of preparation _____

The nature of the packaging materials in immediate contact with the drug and the specifications for raw materials used in the manufacturing process of the drug are as follows:—*

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

ANNEXURE 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 annexure 2, will be acceptable.

ALGEMENE INLICHTING.

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 hy 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. Aansoeke om die registrasie van medisyne waarvan slegs die sterkte verskil, kan op dieselfde vorm gedoen word.
- *6. Die bereidingsvorm, soos byvoorbeeld oplossings in water, suspensies, oogdruppels, oordruppels, emulsies, salwe, setpille, tablette, kapsules, inspuitings moet hier vermeld word.
- *9. Die klassifikasie van die medisyne soos omskryf in regulasies 4 en 5 moet hier vermeld word.

AANHANGSEL 1.

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 doserings-eenheid bevat:—

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

AANHANGSEL 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 aanhangsel 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, aanvaarbaar wees:—

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

AANHANGSEL 3.

Naam van applikant _____
 Naam van medisyne _____
 Bereidingsvorm _____

* Die aard van die verpakkingsmateriaal in direkte kontak met die medisyne en die spesifikasies vir die grondstowwe wat in die vervaardigingsproses van die medisyne gebruik word, is soos volg:—

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

AANHANGSEL 4.

Naam van applikant _____
 Naam van medisyne _____
 Bereidingsvorm _____

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

* Waar dit van toepassing is, sal verwysings na die publikasies genoem in die voetnoot van aanhangsel 2, aanvaarbaar wees.

ANNEXURE 5.

Name of applicant.....
 Name of drug.....
 Form of preparation.....
 The analytical control procedures which are performed during the manufacturing process are as follows:—

ANNEXURE 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 annexure 2 will be acceptable.

ANNEXURE 7.

Name of applicant.....
 Name of drug.....
 Form of preparation.....
 Full specifications for the drug and the analytical control procedures used to determine the compliance with specifications and the data and reasoning on which the stability of the drug is predicted, are as follows:—

ANNEXURE 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.

ANNEXURE 9.

The drug will be advertised to—

- *(a) the general public;
- *(b) the general public through point of sale displays in retail pharmacies;
- *(c) the professions.

* Delete whichever is inapplicable.

ANNEXURE 10.

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.

ANNEXURE 11.*

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:—

* With regard to drugs which have been available for sale in the Republic or the Territory before promulgation of these regulations, the above particulars shall be supplied only if requested by the Council.

AANHANGSEL 5.

Naam van applicant.....
 Naam van medisyne.....
 Bereidingsvorm.....
 Die analitiese kontroleprosedures wat gedurende die vervaardigingsproses gevolg word, is soos volg:—

AANHANGSEL 6.

Naam van applicant.....
 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 aanhangsel 2 sal, waar dit van toepassing is, aanvaarbaar wees.

AANHANGSEL 7.

Naam van applicant.....
 Naam van medisyne.....
 Bereidingsvorm.....
 Volledige spesifikasies vir die medisyne en die analitiese kontroleprosedures wat gebruik word om die nakoming van spesifikasies te bepaal, en die besonderhede en beredenering waarvolgens die stabiliteit van die medisyne voorspel is, is soos volg:—

AANHANGSEL 8.

Naam van applicant.....
 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.

AANHANGSEL 9.

Reklame vir die medisyne sal gemaak word by—

- *(a) die algemene publiek;
- *(b) die algemene publiek deur middel van verkooppuntuitstalings en kleinhandelsapteke;
- *(c) die beroepe.

* Skrap wat nie van toepassing is nie.

AANHANGSEL 10.

Naam van applicant.....
 Naam van medisyne.....
 Bereidingsvorm.....

Die volgende verslag ten opsigte van registrasie in die land van herkoms is uitgereik deur die statutêre lisensie- of registrasie-oowerheid 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.

AANHANGSEL 11.*

Naam van applicant.....
 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:—

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

ANNEXURE 12.*

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:—

* With regard to drugs which have been available for sale in the Republic or the Territory before promulgation of these regulations, the above particulars shall be supplied only if requested by the Council.
† Any known synergistic or modifying effects of the drug shall also be mentioned here.

ANNEXURE 13.

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.

ANNEXURE 14.*

Name of applicant _____
Name of drug _____
Form of preparation _____

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

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

* With regard to drugs which have been available for sale in the Republic or the Territory before promulgation of these regulations, the above particulars shall be supplied only if requested by the Council.

ANNEXURE 15.

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 and the advertising material as prescribed in regulation 7 (b).

* Delete whichever is inapplicable.

No. _____ Date _____

DRUGS CONTROL ACT, 1965.

The following regulations are hereby made by the Minister of Health, under the powers conferred upon him by section 35 (4) of the Drugs Control Act, 1965 (Act No. 101 of 1965):—

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

1. 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 _____

AANHANGSEL 12.*

Naam van applikant _____
Naam van medisyne _____
Bereidingsvorm _____

(a) Die volgende is besonderhede van die farmakologiese proewe wat alle aspekte van 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 die farmakologiese proewe wat alle aspekte van 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:—

* Met betrekking tot medisyne wat in die Republiek of die Gebied vir verkoop beskikbaar was voor die afkondiging van hierdie regulasies moet bogenoemde besonderhede slegs verskaf word indien die Raad daarom vra.

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

AANHANGSEL 13.

Naam van applikant _____
Naam van medisyne _____
Bereidingsvorm _____

Hieronder volg 'n beskrywing van die doel waarvoor die medisyne aangebied word, met vermelding van die werking, nuwe-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.

AANHANGSEL 14.*

Naam van applikant _____
Naam van medisyne _____
Bereidingsvorm _____

(a) Die volgende aangehegte verbandhebbende wetenskaplike dokumente het oor die medisyne en die grondstowwe van die medisyne verskyn:—

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

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

AANHANGSEL 15.

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 en die advertensiemateriaal soos bepaal in regulasie 7 (b).

* Skrap wat nie van toepassing is nie.

No. _____ Datum _____

WET OP DIE BEHEER VAN MEDISYNE, 1965.

Onderstaande regulasies word hierby deur die Minister van Gesondheid uitgevaardig kragtens die bevoegdheid hom verleen by artikel 35 (4) van die Wet op die Beheer van Medisyne, 1965 (Wet No. 101 van 1965):—

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

1. Onderstaande sertifikaat moet deur inspekteurs uitgereik word wanneer monsters van medisyne geneem word:—

MEDISYNE-BEHEERRAAD.

SERTIFIKAAT VAN INSPEKTEUR WAT 'N MONSTER VAN 'N MEDISYNE NEEM.

Hierby sertifiseer ek dat meegaande (n) monster(s) is wat op _____
te (1) _____
van 'n medisyne verkry uit voorraad onder toesig van (2) _____
geneem is 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) 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 _____

Witness.

Inspector.

Date _____

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.

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

2. 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 subjoined.

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

REGISTRATION FEES.

3. An amount of R60 shall be paid by the applicant to the Registrar in respect of the registration of a drug.

- (e) Die naam en sakeadres van die verkoper van die medisyne _____
- (f) Die beraamde 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 _____

Getuie.

Inspekteur.

Datum _____

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.

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

2. 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 OOR 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 my bevindings is soos hieronder aangedui.
 Opmerkings in verband met resultate _____

Ontleder, Farmakoloog, Patoloog.

- (1) Naam van inhoud soos dit op die etiket voorkom.
 (2) Naam van persoon van wie monster ontvang is.
 (3) Naam van vervaardiger, lotnommer en enige ander besonderhede wat op die etiket voorkom.
 (i) } Skrap wat nie van toepassing is nie.
 (ii) }
 (iii) }

REGISTRASIEGELDE.

3. Daar moet ten opsigte van die registrasie van 'n medisyne 'n bedrag van R60 deur die applikant aan die Registrateur betaal word.

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