GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing regulations.
_______ Words underlined with a solid line indicate insertions in existing regulations.

AMENDMENT TO THE GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965), AS AMENDED

The Minister of Health intends, in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended, in consultation with the Medicines Control Council, to amend the regulations in the Schedule.

Interested persons are invited to submit, within three months after the date of publication of this notice, substantiated comments on or representations regarding the proposed regulations to the Minister of Health, Private Bag X828, PRETORIA (for the attention of the Chief Director: Medicines Regulatory Affairs).

SCHEDULE

Definitions


Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended –

    (a) by the substitution for the definition of "applicant' of the following definition:

    "applicant" means a person who submits or on whose behalf an application for the registration of a medicine, an update or amendment to an existing registration of a medicine is made;"
(b) by insertion after the definition of 'bonded warehouse' of the following definition:

""class of medicine" means a branch or division of medicine or medicinal products or remedies sharing common characteristics, qualities, attributes, properties or discipline".

(c) by insertion after the definition of 'clinical trial' of the following definition:

""Code of Practice" means the code for the marketing of medicines or scheduled substances as contemplated in regulation 52";

(d) by insertion after the definition of 'expiry date' of the following definition:

""health fraud" means the promotion, advertisement, distribution, or sale of medicines or articles, intended for human or animal use, that is represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or to provide a beneficial effect on health, but which has not been proven safe and effective for such purposes and such practice is intended to defraud or mislead the public";

(e) by the substitution for the definition of 'manufacture' of the following definition:

""manufacture" means all operations including purchasing of material, processing, production, packaging, re-packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls";

(f) by insertion after the definition of 'person' of the following definition:

""Pharmaceutical Trade Associations" means:

(a) the Pharmaceutical Manufacturers' Association (PMA);

(b) the National Association of Pharmaceutical Manufacturers (NAPM);
(c) the Self Medication Association of South Africa (SMASA);

(d) Innovative Medicines South Africa [IMSA];

(e) Health Products Association [HPA]; or

(f) Any other trade association or organisation representing persons trading in medicines and which subjects itself to the Code of Practice;

(g) by insertion after the definition of 'proprietary name' of the following definition:

"re-packaging" means packing a medicine or scheduled substance into different containers without making any change in the form of the medicine or scheduled substance."

(h) by the substitution for the definition of 'wholesaler' of the following definition:

"wholesaler" means a dealer or trader who acquires any medicine or medical device from a manufacturer and sells or distributes it to the retail sector and includes a wholesale pharmacy;

Amendment of regulation 4 of the Regulations

3. Regulation 4 of the regulations is hereby amended –

(a) by the substitution for the Heading of regulation 4 of the following heading:

"THE CONDITIONS FOR AND THE QUANTITY NOT TO BE EXCEEDED BY A PHARMACIST IN COMPOUNDING A MEDICINE FOR SALE IN THE RETAIL PHARMACY TRADE"

(b) by the substitution for paragraph (a) of subregulation (1) of the following paragraph:
"(a) related to a treatment regimen of a particular patient under the direct care of an authorised prescriber or pharmacist,".

Amendment of regulation 6 of the Regulations

4. Regulation 6 of the regulations is hereby amended -

(a) by the insertion, before paragraph (a), of the following paragraphs, the existing paragraphs (a), (b), (c), (d), (e), (f), (g), and (h) becoming paragraphs (d), (e), (f), (g), (h), (i), (j) and (k) respectively:

"(a) the class of medicine;
(b) the category of the medicine;
(c) the therapeutic classification of the medicine;"

(b) by the deletion of paragraphs (i) and (j).

Amendment of regulation 7 of the Regulations

5. Regulation 7 of the regulations is hereby amended, in subregulation (5), by the addition of the following paragraph:

"(d) an application in terms of Section 22C(1)(b) of the Act;"

Amendment of regulation 8 of the Regulations

6. Regulation 8 of the Regulations is hereby amended -

(a) by the insertion, in subregulation (1), after paragraph (a), of the following paragraphs and the existing paragraphs (b), (c), (d), (e), (f), (g), (e), (f), (g), (h), (i), (j), (k), (l), (m), (o), (p), (q), (r), (s), (t), (u), (w), (x), (y), (z), (aa), (bb), (cc), becoming paragraphs (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (w), (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff) and (gg) respectively:

(b) The class of the medicine;
(c) The category of the medicine;
(d) The therapeutic classification of the medicine;"
(c) a list of all inactive ingredients contained in the medicine;

(b) by the substitution, in subregulation (1), for paragraph (c) of the following paragraph:

"(c) the registration or application number of the medicine allocated in terms of section 15(6) or section 14(2) of the Act;"

(c) by the substitution, in subregulation (1) for subparagraph (i) of paragraph (h) of the following subparagraph:

"(i) [sugar] glucose contained in the medicine; or"

(d) by the substitution, in subregulation (1), for paragraph (p) of the following paragraph:

"(p) the name of the holder of certificate of registration of the said medicine or in the case of a parallel imported medicine, the name of the holder of the parallel importer permit;"

(e) by the addition, in subregulation (1), of the following paragraphs:

"(2) in the case of a medicine for oral administration which contains a second generation antihistamine, the warnings:

"this medicine lacks significant sedative effects. However a small number of individuals may experience sedation, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants."

(aa) in the case of a medicine intended for oral or parenteral administration which contains glucose, the warning: "Contains glucose."

(f) by the substitution for subregulation (2) of the following subregulation:

"(2) If the medicine package bears both an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label as well: Provided that it shall be sufficient to [give] provide on the immediate container label-"
(i) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the details prescribed in paragraphs (e), (f), (g), (r), (s) and (t) of sub-regulation (1);

(ii) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the details prescribed in paragraphs (e), (f), (h), (i), (r), (s), (t) and (bb) of sub-regulation (1);

(iii) in the case of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the details prescribed in paragraphs (e), (f), (g), (h), (r), (aa), (s), (t) and (bb) of sub-regulation (1);

(iv) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the details prescribed in paragraphs (e) and (f) of sub regulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (e), (f), (s), and (t) of sub-regulation (1), repeated as frequently as is practicable."

Amendment of regulation 9 of the Regulations

7. Regulation 9 of the regulations is hereby amended -

(a) by the insertion, in subregulation(1), after paragraph (a), of the following paragraphs, the existing paragraphs (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), (x), (y), (z) and (aa) becoming paragraphs (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (r), (s), (t), (u), (v), (w), (x), (y), (z), (aa), (bb), (cc) and (dd) respectively:

* (b) The class of the medicine;

(a) The category of the medicine;

(b) The therapeutic classification of the medicine:
(b) by the insertion, in paragraph (c) of subregulation (1), after subparagraph (i), of the following subparagraph and the existing paragraphs (ii), (iii), (iv), (v) and (vi) becoming paragraphs (iii), (iv) (v), (vi) and (vii) respectively:

" (ii) a list of all inactive ingredients contained in the medicine;"

(c) by the substitution for paragraph (e) of subregulation (1) of the following paragraph:

" (d) pharmacological or therapeutic action, [i.e a description of the pharmacological] of the medicine, and where applicable, under a subheading: Pharmacokinetics, pharmacodynamics; summary of clinical studies."

(d) by the substitution for subregulation (2) of the following subregulation:

"(2) The requirements of subsection (1) shall not apply in the case of medicines in respect of which exclusion from the operation of the Act has been granted by the Minister in terms of section 36 of the Act.".

(e) by the substitution for subregulation (5) of the following subregulation:

"(5) The council may modify or withdraw any indication or any other aspect of the package insert if it is of the opinion that the risk and benefit profile of the medicine for the approved indications or suitability for the intended purpose for which the medicine has been registered, is not in the public interest. ".

Amendment of regulation 10 of the Regulations

8. Regulation 10 of the regulations is hereby amended-

(a) by the insertion, in subregulation (1), after paragraph (a), of the following paragraphs, the existing paragraphs (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l) and (m) becoming paragraphs (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o) and (p) respectively:

(a) The class of medicine;
(b) The category of the medicine;

(c) The therapeutic classification of the medicine.

(b) by the substitution for paragraph (d) of subregulation (1) of the following paragraph:

"(d) the approved indications, dosage and correct use of the medicine;"

(c) by the substitution for paragraph (h) of subregulation (1) of the following paragraph:

"(h) storage and disposal information, including the following general statement:

"[store] Keep all medicines out of reach of children."

(d) by the substitution for paragraph (l) of subregulation (1) of the following paragraph:

"(l) the name and business address [and telephone number] of the holder of the certificate of registration; and"

Amendment of regulation 11 of the Regulations

9. Regulation 11 of the regulations is hereby amended-

(a) by the substitution for the heading of the following heading:

"PRESCRIPTION BOOK AND RECORD OF SALE"

(b) by the substitution in subregulation (1) for the words preceding paragraph (a) of the following words:

"(1) A prescription book or other permanent record in respect of schedule 1, 2, 3, 4, 5 and 6 medicines or substances shall be kept on
all premises where prescribed medicines or scheduled substances are dispensed or sold and shall contain the following details:

(c) by the substitution in subregulation (2) for the words preceding paragraph (a) of the following words:

"(2) in the case of Schedule 1 and 2 medicine sold without a prescription in terms of section 22A(4) and 22A(5) of the Act, the following shall be recorded:"

(d) by the substitution for paragraph (a) of subregulation (2) of the following paragraph.

(a) the name of the [person] patient to whom it was sold;"

(e) by the substitution for subregulation (3) of the following subregulation:

"(3) A prescription book or other record shall be retained at the business address of the seller for a period of at least five years after the date of the last entry made therein."

(f) by the substitution in subregulation (4) for the words preceding paragraph (a) of the following words:

"(4) The manufacturer or wholesaler shall keep a record of Schedule 1, 2, 3, 4 and 5 medicines and substances in the form of invoices that will reflect:"
(b) by the substitution for paragraph (a) of subregulation (2) of the following paragraph:

(a) is licensed in terms of the Act to import specific medicines or scheduled substance;

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

(c) has a permit to import any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance in terms of section 22A(11)(a) of the Act.

(d) by the addition of the following subregulations:

(3) Any person desiring to import samples for use in an application for registration as referred to in terms of section 15(2) of the Act shall apply to the Director-General for a permit to import such samples.

(4) Any application referred to in subregulation (3) shall contain at least the following information:

(a) The Scheduling status of the medicine;

(b) The class of the medicine;

(c) The category of the medicine;

(d) The therapeutic classification of the medicine;

(e) the name and both the residential and business address of the applicant;

(f) the proprietary name and dosage form of the medicine;

(g) the approved name and quantity of each active ingredient of the medicine;

(h) the approved name of each inactive ingredient of the medicine;
(i) quantity of medicine to be imported;

(j) name and physical address of the manufacturer in the exporting country from whom the medicine will be obtained; and

(k) the port of entry through which importation of the medicine will take place.

Amendment of regulation 16 of the Regulations

11. Regulation 16 of the regulations is hereby amended by the substitution for subregulation (1) of the following subregulation:

"(1) Notwithstanding regulation 12 and subject to subregulation (3) any person entering [or departing from] the Republic may be in possession, for personal medicinal use, of a quantity of a Schedule, 3, 4, 5 or 6 substance, which shall not exceed a quantity required for use for a period of one month: Provided that any person departing from the Republic for a continuous period of up to 3 months may be in possession, for personal medicinal use, of a quantity of a Schedule 3, 4, 5, or 6 substances, which shall not exceed a quantity required for a period of 3 months."

Amendment of regulation 17 of the Regulations

12. Regulation 17 of the regulations is hereby amended-

(a) by the substitution for the heading to regulation 17 of the following heading:

"INFORMATION TO BE FURNISHED ANNUALLY TO THE REGISTRAR BY THE HOLDER OF A PERMIT"

(b) by the substitution in subregulation (1) for the words preceding paragraph (a) of the following words:

(1) A person issued with a permit in terms of regulation 15 shall furnish the [Director-General] Registrar with the following information with regard to the substances referred to in that regulation:"
Amendment of regulation 19 of the Regulations

13. Regulation 19 of the regulations is hereby amended-

(a) by the substitution for the heading to regulation 19 of the following heading:

"LICENCE TO MANUFACTURE, IMPORT OR EXPORT, ACT AS A WHOLESALER OR DISTRIBUTE MEDICINES OR MEDICAL DEVICES"

(b) by the substitution for subparagraphs (i) and (ii) of paragraph (a) of subregulation (1) of the following subparagraphs:

(i) apply to the Council for a licence to manufacture, import or export, act as wholesaler or distributor of any medicine, Scheduled substance or medical device;

(ii) appoint, and designate a pharmacist who will control the manufacturing, import or export, wholesaling or distribution of any medicine, Scheduled substance or medical device;

(c) by the substitution for subparagraph (ii) of paragraph (c) of subregulation (1) of the following subparagraph:

(ii) registration of the responsible pharmacist in terms of the Pharmacy Act 53 of 1974;

(d) by the substitution for item (aa) of subparagraph (iv) of paragraph (c) of subregulation (1) of the following item:

(aa) a copy of a local area plan of the location of the business premises indicating all adjacent properties
and the nature of the business being carried out on such properties;"

(e) by the substitution for item (ee) of subparagraph (iv) of paragraph (c) of subregulation (1) of the following item:

   (ee) a manual or Site Master File of procedures and practices to be implemented and followed to ensure the efficacy, safety and quality of any medicines, Scheduled substances or medical devices to be manufactured, imported or exported, distributed or sold;

(f) by the addition in subparagraph (iv) of paragraph (c) of subregulation (1) of the following item:

   (ff) any other information that the Council may consider necessary in the particular circumstances.

(g) by the substitution for paragraph (d) of subregulation (1) of the following paragraph:

   (d) must specify the medicines, Scheduled substance or medical devices to be manufactured, imported or exported, distributed or sold;"

(h) by the insertion after subregulation (1) of the following subregulation and the existing subregulations (2), (3), (4),(5),(6),(7),(8),(9) and (10) becoming subregulations (3),(4),(5),(6),(7),(8),(9),(10) and (11) respectively.

   "(2) The Council may give the person referred to in sub-regulation (1) written notice to furnish the Council with such additional documentation or information as specified in the notice as the Council may require from time to time or consider necessary in the circumstances."

(i) by the substitution for paragraphs (b) and (c) of subregulation (4) of the following paragraphs:

   "(b) the application for a licence to manufacture, import or export, act as wholesaler, or distribute medicines, Scheduled substances, or medical devices complies with the prescribed requirements;"
(c) the applicant is able to comply with good manufacturing, good wholesale or good distribution practices,

(j) by the substitution for paragraph (b) of subregulation (10) of the following subregulation:

(b) if the responsible pharmacist fails to control the manufacturing, importation or exportation, wholesaling or distribution of medicines, Scheduled substances, or medical devices;

(k) by the substitution in subregulation (1) of the words following upon paragraph (b) of the following words:

"and the licensee has failed to furnish written reasons within 21 days after the date upon which a notice is given of the Council's intention to remove the name of the licensee from the relevant register and [to close such business] as to why the licensee's name should not be removed: [or the business should not be closed] Provided that if the Council is of the opinion that it is in the interest of the public, it may dispense with the required notice."

Amendment of regulation 22 of the Regulations

14. Regulation 22 of the regulations is hereby amended-

(a) by the substitution for subregulation 4 of the following subregulation:

"(4) The information referred to in subregulation (3) shall be in English. [and at least one other official language."

(b) by the substitution in subregulation (5) for the words preceding subparagraph (i) of paragraph (a) of the following words:

(a) Particulars of the Applicant [and] or the prospective holder of certificate of registration:

(c) by the substitution for subparagraph (vi) of paragraph (b) of subregulation (5) of the following subparagraph:

(vi) class, category and therapeutic classification;"
Amendment of regulation 23 of the Regulations

15. Regulation 23 of the regulations is hereby amended by the insertion before paragraph (a) of the following paragraphs, the existing paragraphs (a), (b), (c), (d), (e), (f), (g), (h), (i) and (j) becoming paragraphs (d), (e), (f), (g), (h), (i), (j), (k), (l) and (m) respectively.

(a) the class of the medicine;

(b) the category of the medicine;

(c) the therapeutic classification of the medicine;”

Substitution of regulation 25 of the Regulations

16. The following regulation is hereby substituted for regulation 25 of the Regulations:

"CLASS, CATEGORIES AND CLASSIFICATION OF MEDICINES

25 (1). The following are the classes of medicines:

African traditional medicine
Anthroposophical medicine
Aromatherapy medicine
Ayurvedic medicine
Biochemic tissue salts
Chinese medicine
Conventional medicine
Flower remedies
Gemmotherapy medicine
Herbal medicine
Homeopathic medicine
Homotoxicological medicine
Naturopathy
Nutraceuticals
Other traditional medicines – to be specified
Plant Herbs
Sowa Riapa
Unani medicine
25.[(1)] (2) The following are the basic categories of medicines:

(a) Category A = Medicines which are intended for use in humans and which are, without manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;

(b) Category B = Medicines which can not normally be administered without further manipulation; and

(c) Category C = Medicines intended for veterinary use which are, without further manipulation, ready for administration, including packaged preparations where only vehicle is added to the effective medicine.

[(2)] (3) Medicines in category A are subdivided into the following therapeutic classifications:

1. Central nervous system stimulants

   1.1 Central analeptics

   1.2 Psychoanaleptics or antidepressants

   1.3 Special antidepressant combinations

   1.4 Respiratory stimulants

   1.5 Hallucinogenic medicines

   1.6 Central Nervous System Support

   1.7 Other Central nervous system stimulants

2. Central nervous system depressants

   2.1 Anaesthetics

   2.2 Sedatives, hypnotics

   2.3 Barbiturates
2.4 Non-barbiturates

2.5 Anticonvulsants, including anti-epileptics

2.6 Tranquillisers
   2.6.1 Phenothiazines and their derivatives
   2.6.2 Rauwolfia: Alkaloids and combinations
   2.6.3 Diphenylmethane and its derivatives
   2.6.4 Alkyl diols and their derivatives
   2.6.5 Miscellaneous structures

2.7 Antipyretics or antipyretic and anti-inflammatory analgesics

2.8 Analgesic combinations

2.9 Other analgesics

2.10 Centrally acting muscle relaxants and

2.11 Other central nervous system depressants.

3. Connective Tissue Medicines
   3.1 Antirheumatics (anti-inflammatory agents)
   3.2 Non-hormonal preparations
   3.3 Anti-gout preparations
   3.4 Combinations with corticosteroids and
   3.5 Other connective tissue medicines
4. Local anaesthetics

5. Medicines affecting autonomic function

5.1 Adrenomimetics (sympathomimetics)

5.2 Adrenergics (sympathoergic)

5.3 Cholinomimetics (cholinergics)

5.4 Cholinolytics (anticholinergics)

5.4.1 Anti-Parkinsonism preparations

5.4.2 General cholinolytics

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

5.9 Hydroxytryptamine (serotonin)

5.10 Serotonin antagonists

5.11 Other medicines affecting autonomic function

6. Cardiac medicines

6.1 Cardiac stimulants

6.2 Cardiac depressants
6.3 Cardiac glycosides

6.4 Other cardiac medicines

7. Vascular medicines

7.1 Vasodilators, hypotensive medicines

7.1.1 Rauwolfia and combinations

7.1.2 Rauwolfia: Diuretic combinations

7.1.3 Other hypotensives

7.1.4 Vasodilators - coronary and other medicines used in angina pectoris

7.1.5 Vasodilators - peripheral

7.2 Vasoconstrictors, pressor medicines

7.3 Migraine preparations

7.4 Lipotropic agents

7.5 Serum-cholesterol reducers and

7.6 Other vascular medicines

8. Medicines acting on blood and haemopoietic system

8.1 Coagulants, haemostatics

8.2 Anticoagulants

8.3 Erythropoietics (haematinics)

8.4 Plasma expanders and

8.5 Other medicines acting on blood and haemopoietic system
9. Medicines against alcoholism and substance abuse

10. Medicines acting on respiratory system

10.1 Antitussives and expectorants

10.2 Bronchodilators

10.2.1 Inhalants

10.3 Other medicines acting on the respiratory system

11. Medicines acting on gastro-intestinal tract

11.1 Digestants

11.2 Gastro-intestinal antispasmodics and cholinolytics - anticholinergics

11.3 Anorexigenics

11.4 Antacids

11.4.1 Acid neutralisers

11.4.2 Acid neutralisers with antispasmodics

11.4.3 Other antacids

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 Special combinations

11.10 Other medicines acting on gastro-intestinal tract

12. Anthelmintics, bilharzia medicines, filaricides and anti-parasitic medicines

13. Dermatological preparations

13.1 Antiseptics, disinfectants and cleansing agents

13.2 Antiscabies medicines

13.3 Surface anaeasthetics

13.4 Antipruritics

13.4.1 Corticosteroids with or without anti-infective agents

13.4.2 Other antipruritics

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
13.13 Other dermatological preparations

14. Preparations for treatment of wounds

14.1 Wound disinfectants

14.2 Wound dressings and

14.3 Other preparations for treatment of wounds

15. Ophthalmic preparations

15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

15.2 Ophthalmic preparations with corticosteroids

15.3 Combination antibiotics and/or sulphonamides and corticosteroids

15.4 Other ophthalmic preparations

16. Ear, nose and throat preparations

16.1 Nasal decongestants

16.2 Aural preparations

16.3 Surface anaesthetics

16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

16.5 Other ear, nose and throat preparations

17. Medicines acting on musculo-skeletal system

17.1 Peripherally acting muscle relaxants

17.2 Muscle activators

17.3 Medicines acting on the skeletal system
17.4 Other medicines acting on musculo-skeletal system

18. Medicines acting on genito-urinary system

18.1 Diuretics

18.2 Antidiuretics

18.3 Iod-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 and

18.10 Other medicines acting on genito-urinary system

19. Oxytocics

20. Anti-infective, Antimicrobial (chemotherapeutic) agents

20.1 Antibiotics and antibiotic combinations

20.1.1 Broad and medium spectrum antibiotics

20.1.2 Penicillins

20.1.3 Penicillin-streptomycin combinations

20.1.4 Antibiotic-sulphonamide combinations

20.1.5 Streptomycin and combinations
20.1.6 Topical antibiotics

20.1.7 Antifungal antibiotics

20.2 Other than antibiotics

20.2.1 Sulphonamides

20.2.2 Fungicides

20.2.3 Tuberculostatics

20.2.4 Leprostatics

20.2.5 Germicides

20.2.6 Medicines against protozoa

20.2.7 Spirochaeticides

20.2.8 Antiviral agents and

20.3 Other anti-infective agents

21. Hormones, antihormones and oral hypoglycaemics

21.1 Insulin preparations

21.2 Oral hypoglycaemics

21.3 Thyroid preparations

21.4 Parathyroid preparations

21.5 Corticosteroids

21.5.1 Corticosteroids and analogues

21.5.2 Analgesic combinations
21.5.3 Anti-infective combinations

21.5.4 Other corticosteroid combinations

21.6 Anabolic steroids

21.7 Male sex hormones

21.8 Female sex hormones

21.8.1 Oestrogens

21.8.2 Progesterones with or without oestrogens

21.9 Androgen-oestrogen combinations

21.10 Trophic hormones

21.11 Hyperglycaemic hormones

21.12 Hormone inhibitors and

21.13 Others hormones, antihormones and oral hypoglycaemics

22 Vitamins and minerals

22.1 Multivitamins and multivitamins with minerals

22.1.1 Vitamins for paediatric use

22.1.2 Vitamins for prenatal use

22.1.3 Vitamins for geriatric use

22.1.4 Vitamin B-complex with Vitamin C and

22.2 Other vitamin combinations

23. Amino-acids and metabolites
24. Mineral substitutes, electrolytes and fluid replacement

25. Special foods

25.1 Infant foods and other formulae, excluding foods used solely as a substitute for human milk

25.2 Specialised whole foods, functional foods and macronutrients

25.3 Special foods for convalescence and fatigue states

25.4 Body building preparations

25.5 Energy tonics and drinks

25.6 Other special foods

26. Cytostatic agents

27. Chelating agents (versenates) as heavy metal antidotes

28. Contrast media

29. Diagnostic agents

30. Biologicals

30.1 Antigens [Antibodies]

30.2 Antibodies [Antigens]

30.3 Blood fractions

30.4 Specialised Anti-allergy products and vaccines

31. Enzymatic preparations

32. Enzyme inhibitors

33. Tonics - general
34. Other medicines, substances or agents

34.1 Tonics - other

34.2 Weight gain

34.2.1 Appetite stimulants

34.2.2 High kilojoule meal additions

34.2.3 Other weight gain preparations

34.3 Slimming preparations

34.3.1 Appetite suppressants

34.3.2 Insulin and blood sugar stabilisers

34.3.3 Low kilojoule meal substitutes

34.3.4 Food absorption inhibitors

34.3.5 Metabolic rate stimulants

34.3.6 Stored fat catabolics

34.3.7 Other slimming preparations

34.4 Water for injection

34.5 Artificial tear and contact lens solutions

34.6 Preparations of boracic acid, borax and zinc, starch and boracic powder

34.7 Topical applications of delousing agents

34.8 Topical applications of insect repellents

34.9 Intra-uterine devices
34.10 Dental preparations

34.11 Solutions for haemo- or peritoneal dialysis

34.12 Preparations for which the expressions "medicated", "medicinal", "for medical use" or expressions with similar connotations are used

34.13 Preparations intended to promote hair growth

34.14 Sales packs containing two or more medicines with different indications

35. Radiopharmaceuticals

36. Nutraceuticals

36.1 Probiotics

36.2 Prebiotics

36.3 Synbiotics

36.4 Fats, fatty acids and phospholipids

36.5 Bioflavonoids and isoflavones

36.6 Adaptogens

36.7 Antioxidants

36.8 Biochemicals

36.9 Other nutraceuticals

37. Immune and Lymphatic Systems

37.1 Adjuvant immune system therapy

37.2 General immune system support
37.3 Lymphatic system disorders

37.4 Other Immune and Lymphatic Systems

38. Others, where the abovementioned therapeutic classifications are not applicable and no biomedical but only discipline or traditional claims are made for the preparation.

Medicines in category C are subdivided into the following pharmacological classes:

1. Central [And Peripheral] Nervous System

   1.1 Central nervous system stimulants

      1.1.1 Central analeptics

      1.1.2 Respiratory Stimulants

   1.2 Anaesthetics

      1.2.1 Inhalation anaesthetics

      1.2.2 Parenteral anaesthetics

      1.2.3 Local anaesthetics

   1.3 Narcoic analgesics

      1.3.1 Opioid agonists

      1.3.2 Opioid antagonists

   1.4 Sedatives

      1.4.1 Sedative hypnotics

      1.4.2 Sedative angesics

      1.4.3 Sedative antagonists
1.5 Anticonvulsants including anti-epileptics

1.6 Tranquillisers

1.6.1 Phenothiazine derivatives

1.6.2 Butyrophenone derivatives

1.7 Neuroleptanalgesics

1.8 Analgesic antipyretics

1.9 Drugs used for euthanasia

2. Autonomic Nervous System

2.1 Sympathomimetics

2.2 Sympatholytics

2.3 Cholinergics

2.4 Antimuscarinics

3. Musculo-Skeletal System and Joints

3.1 Anti-inflammatory

3.1.1 Steroidals

3.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)

3.1.2.1 Non-selective COX2 inhibitors

3.1.2.2 Selective COX2 inhibitors

3.1.3 Topical agents

3.1.4 Combinations
3.1.5 Other

3.2 Analgesics

3.2.1 Opioids

3.2.2 NSAIDs

3.2.3 Topical agents

3.2.4 Combinations

3.3 Muscle relaxants

3.3.1 Centrally acting

3.3.2 Peripherally-acting

4. Autacoids

4.1 Histamine inhibitors

4.1.1 Antihistamines

4.1.2 Histamine release inhibitors

4.2 Serotonin antagonists

4.3 Others

5. Cardio-Vascular System

5.1 Positive inotropic agents

5.1.1 Cardiac glycosides

5.1.2 Methylxanthines

5.1.3 Others
5.2 Anti-arrhythmics

5.3 Vasodilators

5.3.1 Peripheral-acting vasodilators

5.3.2 Angiotensin inhibitors

5.3.3 Calcium channel inhibitors

6. Blood And Haemopoietic System

6.1 Coagulants, haemostatics

6.2 Anticoagulants

6.3 Haematinics

6.4 Plasma expanders

7. Respiratory System

7.1 Antitussives and expectorants

7.2 Mucolytics

7.3 Bronchodilators

7.4 Combinations

8. Gastro-Intestinal System

8.1 Mouth washes

8.2 Emetics

8.3 Anti-emetics

8.4 Acid-reducers
8.4.1 Antacids and combinations

8.4.2 Histamine-2 receptor antagonists

8.4.3 Proton pump inhibitors

8.4.4 Cytoprotective agents

8.5 Motility enhancers

8.5.1 Lubricants and Faecal softeners

8.5.2 Laxatives and Purgatives

8.6 Antispasmodics

8.7 Antidiarrhoeals

8.7.1 Plain

8.7.2 With anti-microbial agents

8.7.3 Antimicrobial agents

8.7.4 Biologicals

8.8 Analgesics

8.9 Digestants

8.10 Preparations used in the rumen

8.10.1 Ruminotorics

8.10.2 Anti-bloat remedies

8.10.3 Others
9. Hepatic System

9.1 Cholagogues and cholerectics

9.2 Liver protectants and lipotropics

10. Urinary System

10.1 Diuretics

10.2 Urolitholytics and antispasmodics

10.3 Urinary tract antiseptics

10.4 pH modifiers

10.4.1 Urinary acidifiers

10.4.2 Urinary alkalinisers

10.5 Others

11. Reproductive System

11.1 Intravaginal and intra-uterine preparations

11.2 Sex hormones

11.2.1 Testosterone

11.2.2 Oestrogens

11.2.3 Progestrones & Progestogens

11.2.4 Combinations

11.3 Prostaglandins

11.4 Trophic hormones
11.5 Myometrial stimulants (Ecbolics)

11.6 Myometrial relaxants (Tocolytics)

11.7 Ovulation controlling agents

12. Endocrine System

12.1 Insulin preparations

12.2 Thyroid preparations

12.3 Corticosteroids

12.4 Growth Hormone

12.5 Anabolic steroids

13. Dermatologicals

13.1 Disinfectants and cleaning agents

13.2 Antiseptic and antimicrobial preparations

13.3 Antipuritics

13.3.1 Topical corticosteroids with or without anti-infective agents

13.3.2 Topical antihistamines with or without anti-infective agents

13.4 Emollients and protectives

13.5 Rubefacients and counter irritants

13.6 Keratolytics

13.7 Antifungals

13.8 Anti-parasitics
14. Ophthalmic And Aural Preparations

14.1 Anti-infectives

14.2 Corticosteroids

14.3 Combinations (anti-infective with corticosteroids)

14.4 Others

15. Wounds

15.1 Wound antiseptics

15.2 Wound dressings

15.3 Desloughing agents

16. Mammary Gland

16.1 Intra-mammary preparations

16.2 Preparations for the care of teats and udders

17. Antimicrobials

17.1 Antibacterials

17.1.1 Beta-lactams

17.1.1.1 Penicillins

17.1.1.2 Cephalosporins

17.1.2 Tetracyclines

17.1.3 Aminoglycosides

17.1.4 Macrolides and Lincosamides
17.1.5 Amphenicol

17.1.6 Quinolones

17.1.7 Sulphonamides and potentiatots

17.1.8 Nitrofurans

17.1.9 Polypeptides

17.1.10 Other

17.1.11 Antibacterial combinations

17.2 Antifungals

17.3 Antivirals

17.4 Anti protozoals

17.4.1 Anticoccidials

17.4.2 Antibabesials

17.4.3 Spirochaeticides

17.4.4 Others

18. Antiparasitic Agents

18.1 Endoparasiticides

18.1.1 Benzimidazoles and Probenzimidazoles

18.1.2 Macrocyclic lactones

18.1.3 Halogenated salicylanilides and Nitrophenols

18.1.4 Imidazoles
18.1.5 Tetrahydropyrimidines

18.1.6 Piperazines

18.1.7 Organophosphores

18.1.8 Others

18.1.9 Combinations

18.2 Endectocides

18.3 Ectoparasiticides

18.3.1 Organochlorines

18.3.2 Organophosphores

18.3.3 Pyrethrin and Pyrethroids

18.3.4 Formamidines

18.3.5 Nitroquanidines

18.3.6 Phenylpyrazoles

18.3.7 Insect growth hormones

18.3.8 Chitin inhibitors

18.3.9 Others

18.3.10 Combinations

19. Vitamins, Minerals And Geriatric Preparations

19.1 Vitamins only

19.2 Vitamin and mineral combinations
19.3 Minerals and electrolytes

19.4 Vitamins, electrolytes and amino acid combinations

20. Cytostatic Agents

21. Immune Modulating Agents

22. Chelating Agents

23. Contrast Media

24. Biologicals

  24.1 Dogs vaccines

  24.2 Cats vaccines

  24.3 Poultry vaccines

  24.4 Other vaccines

  24.5 Other biologicals

25 Production Enhancers

  25.1 Antimicrobials

  25.2 Hormones

      25.2.1 Sex hormones

  25.3 Beta agonists

  25.4 Other

26. Fish Medicines". 
Amendment of regulation 26 of the Regulations

17. Regulation 26 of the regulations is hereby amended by the deletion of items 7, 8 and 9 on the certificate of registration.

Amendment of regulation 28 of the Regulations

18. Regulation 28 of the regulations is hereby amended-

(a) by the substitution for the heading to regulation 28 of the following heading:

"PARTICULARS WHICH MUST APPEAR ON A PRESCRIPTION FOR A MEDICINE OR ORDER FOR A SCHEDULE 6 SUBSTANCE [MEDICINE]

(b) by the substitution for the words preceding paragraph (a) of subregulation (1) of the following words:

"(1) Every prescription for a medicine or order for a Schedule 6 substance [medicine] must be written in legible print, typewritten or computer generated and signed in person by a medical practitioner, dentist, veterinarian or authorised prescriber or in the case of an order for a Schedule 6 substance, an authorised person, and must at least state the following:

(c) by the substitution for paragraph (b) of subregulation (1) of the following paragraph:

"(b) the name and address of the patient in the case of a prescription or the name and address of the person to whom the medicines are delivered in the case of a prescription issued by a veterinarian: Provided that where the authorised prescriber who issued the prescription has omitted to insert thereon the address of the patient or person to whom the medicine are delivered in the case of a prescription issued by a veterinarian such address may be inserted by the person by whom the prescription is made;"

(d) by the substitution for paragraph (b) of subregulation (1) of the following paragraph:

"(b) the approved name of the Schedule 6 substance or of the medicine or the proprietary name of the medicine;"
(e) by the substitution for paragraph (f) of subregulation (1) of the following paragraph:

"(f) the strength of the dosage form and the quantity of the medicine to be supplied: Provided that in the case of Schedule 6 substance the quantity to be supplied shall be expressed in figures as well as in words; Provided further that in the case of a prescription where the prescriber has failed to express the quantity in figures as well as in words, the person dispensing the prescription may, after obtaining confirmation from the prescriber, insert the words or figures that have been omitted."

Deletion of regulation 29 of the Regulations

19. Regulation 29 of the regulations is hereby deleted.

Amendment of regulation 30 of the Regulations

20. Regulation 30 of the regulations is hereby amended by the substitution for subregulation (1) of the following subregulation:

"(1) A person importing, exporting, manufacturing or selling specified Schedule 5, [Schedules 5] or Schedule 6 medicines or substances shall keep a register of such medicines or substances."

Amendment of regulation 31 of the Regulations

21. Regulation 31 of the Regulations is hereby amended –

(a) by the substitution for subregulation (1) of the following subregulation:

"(1) An inspector may take a sample or any quantity of samples of a medicine or Scheduled substance for purposes of evidence, testing, examination or analysis in terms of the Act by a person designated as an analyst, pharmacologist or pathologist.

(b) by the substitution for subregulation (4) of the following subregulation:

(4) An inspector referred to in subregulation (1) may take a sample during a routine inspection from a manufacturer, a wholesaler or...
Amendment of regulation 32 of the Regulations

22. Regulation 32 of the Regulations is hereby amended –

(a) by the substitution for subregulation (1) of the following subregulation:

"SEIZURE OF MEDICINES

32 (1) A medicine may be seized if it:

(a) does not comply with any or all of the requirements of the Act, regulations and guidelines as determined by the Council;

(b) is on reasonable grounds suspected of committing health fraud;

(c) is suspected to be a counterfeit and includes but not limited to a medicine or product that is deliberately and fraudulently mislabelled with respect to identity or source; and includes a product with incorrect ingredients, without active ingredients or with insufficient quantity of active ingredients or with fake packaging, which may also contain unauthorised substances or excipients, be they toxic or not;

(d) is misbranded and includes but not limited to a medicine or product that is coloured, coated, powdered or polished in a way that conceals the damage or makes the product to appear to be better or of greater therapeutic value than it really is; or not labelled in the prescribed manner; or not kept in the approved package or any article or thing accompanying the medicine which bears any statement or meaning, design or device that is misleading;
(e) is adulterated which includes but not limited to a medicine or product that:

(i) Consists in whole or in part, of any filthy, putrid or decomposed substance except in homoeopathy where the use of such material may be desirable, or foreign substances;

(ii) Has been prepared, packed, stored under unsanitary conditions;

(iii) Is kept in a container that is composed, in whole or in part of any poisonous or deleterious substance that may render the contents harmful to health;

(iv) Contains colouring matter other than the one that has been approved for use by the Medicines Control Council in the documentation submitted to it in the course of registration of the applicable medicine;

(v) Contains any harmful or toxic substance that may render it harmful to health;

(vi) Is not manufactured in accordance with the approved method, using approved equipment, at the approved
site and using raw materials from approved sources;

(vii) Is not stored in accordance with the recommendations on the label;

(viii) Is manufactured using a different formula without the necessary authorisation from the Medicines Control Council;

(ix) The product's physical attributes are not the same as those contained in the registration dossier as approved by Council;

(x) Is not manufactured in accordance with current good manufacturing practices;

(xi) Has exceeded its expiry date;

(xii) Is on reasonable grounds, suspected stolen;

(xiii) Is possessed by an unauthorised person or by an authorised person but in unexplained excessive quantities;

(xiv) Has been declared undesirable or defective in terms of section 23 of the Act;

(xv) Is on reasonable grounds suspected to be or is the property of the State and is
found in the possession of an unauthorised person;

(xvi) is used in an unauthorised clinical trial;

(xvii) any other grounds considered placing the health of the public at risk.

(b) by the insertion after subregulation (2) of the following subregulation, the existing subregulations (3) and (4) becoming subregulations (4) and (5) respectively:

(3) Medicines or substances seized in terms of this regulation must be removed from the premises by an inspector and:

(a) Seizure of larger batches must be effected by any reasonable suitable means;

(b) In the event that a whole warehouse is to be seized, a police seal may be used to seal the whole warehouse and access to this area may be restricted; and

(c) Seized medicines or substances must be stored at the premises approved by the Registrar or at a police station and a record must be kept of such storage at such premises or police station by the person receiving such medicines or substances.

Amendment of regulation 33 of the Regulations

23. Regulation 33 of the Regulations is hereby amended by the addition after paragraph (e) of the following paragraph:

"(f) at the premises licensed in terms of Section 22C(1)(b)."
Amendment of regulation 37 of the Regulations

24. Regulation 37 of the regulations is hereby amended by the substitution for subregulations (1) and (2) of the following subregulations:

"(1) The applicant or holder of a certificate of registration in respect of a medicine or Scheduled substance shall inform the Council, in the manner and within the time frame as determined by the Council, of suspected adverse drug reactions reported to him, her or it occurring as a result of the use of such a medicine or scheduled substance: Provided that any prescriber or dispenser of any medicine must inform the Council of suspected adverse drug reactions reported to him, her or it occurring as a result of the use of any medicine or scheduled substance.

(2) Subregulation (1) with the necessary changes also applies in the case of unregistered medicines; [used in terms of sections 14(4), 15C, and 21 of the Act]."

Substitution of regulation 39 of the Regulations

25. The following regulation is hereby substituted for regulation 39 of the Regulations:

"INVESTIGATIONS BY THE DIRECTOR GENERAL OR COUNCIL

39 (1) The Director General or Council may conduct an investigation into any activity that is considered a risk to public health or safety or necessary for the proper enforcement of the Act or relating to any medicine or medical device if -

(a) such a medicine or medical device is recalled in South Africa or any other country;

(b) an adverse reaction is reported;

(c) there is an international alert with regard to such a medicine or medical device;

(d) for any other reason, the Director General or the Council deems it fit to conduct an investigation on the medicine or medical device."
Amendment of regulation 40 of the Regulations

26. Regulation 40 of the regulations is hereby amended-

(a) by the substitution for the words preceding paragraph (a) of subregulation (1) of the following words:

"(1) Save as provided in subregulations (2) and (3), each package of a medicine shall be accompanied by a package insert, either as a separate entity or as an integral part of the package, on which are printed in English and at least one other official language and in type having a minimum legibility as defined in regulation 1, under the headings and in the format specified in this regulation, and which shall contain the following particulars [The immediate container of a veterinary medicine that is sold must have the following information with regard to the medicine which is in at least one official language and in minimum legibility]:"

(b) by the insertion in subregulation (1) before paragraph (a) of the following paragraph, the existing paragraphs (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o) and (p) becoming paragraphs (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), and (q) respectively.

  (a) The words "Veterinary Medicine"

(c) by the substitution for paragraph (d) of subregulation (1) of the following paragraph:

  (d) composition, using generic or approved names, contained in a dosage unit or per suitable mass or volume or unit of the medicine, as well as the approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative (expressed as a percentage);

(d) by the substitution for paragraph (g) of subregulation (1) of the following paragraph:

  (g) pharmacokinetic properties and pharmacodynamic properties, where applicable;

(e) by the substitution for paragraphs (i), (j) and (k) of subregulation (1) of the following paragraphs:
"(i) warnings and [or] withdrawal period in the case of food producing animals;

(j) side-effects and special precautions for use per species;

(k) known signs of overdose and particulars of its treatment per species;"

(f) by the substitution for paragraphs (m) and (n) of subregulation (1) of the following paragraphs:

"(m) storage instructions including, where applicable, the storage temperature thereof and particulars of the stability thereof after opening of the original package;"

(n) registration number, i.e.

(i) the number allocated in terms of section 15(6) of the Act; or

(ii) in the case of a medicine the registration of which has been applied for, the reference number allocated to such application, followed by the expression "Act 101/1965";

(g) by the insertion in subregulation (1) before paragraph (p) of subregulation (1) of the following paragraphs, the existing paragraph (p) becoming paragraph (v):

(q) date of publication of this package insert;

(r) dosage and directions for use, including age and species dosage;

(s) conditions of registration; and

(t) identification;

(u) presentation and

(h) by the addition of the following subregulations:

(3) The requirements of subregulation (1) shall not necessarily apply to -
(a) any veterinary medicine sold in accordance with the provisions of section 14(4) of the Act;

(b) any medicine compounded and sold by a veterinarian or pharmacist or any other person who is authorised to dispense medicines in the course of his or her professional activities for the treatment of a particular patient;

(c) any medicine sold by a pharmacist in accordance with a prescription issued by a veterinarian for the treatment of a particular patient.

(4) The council may withdraw any indication if it is of the opinion that the risk and benefit profile of the medicine for the approved indications for which they have been registered is not in the public interest."

Amendment of regulation 42 of the Regulations

27. Regulation 42 of the regulations is hereby amended by the insertion after paragraph (t) of the following paragraph, the existing paragraph (u) becoming paragraph (v):

"(u) Regulation 52 with regard to the Code of Practice, or".

Amendment of regulation 43 of the Regulations

28. Regulation 43 of the Regulations is hereby amended -

(a) by the substitution of subregulation (1) of the following subregulation:

"(1) Every registered medicine shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 22 and which have been accepted by the Council with regard to such medicine."

(b) by the addition of the following subregulation:
"(3) Unregistered medicines, whether they have been subjected to a resolution in terms of section 14(2) of the Act or not, must comply with all the applicable requirements of the regulations as determined by Council including the requirements for quality, safety and efficacy and suitability of the medicine for its intended purpose."

Amendment of regulation 45 of the Regulations

29. Regulation 45 of the regulations is hereby amended -

(a) by the substitution for paragraph (a) of subregulation (2) of the following paragraph:

"(a) Medicines that do not contain a scheduled substance and medicines which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public except when indicated directly or indirectly for all forms of the following conditions unless the Council has expressly agreed otherwise in writing. This restriction is not applicable when the aforementioned conditions are advertised for the information of dentists, medical practitioners, pharmacists, practitioners, veterinarians, and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein:

- Acne Vulgaris
- Acquired Immunodeficiency Syndrome (AIDS)
- Age-Related Macular Degeneration (ARMD)
- Age-Related Memory Impairment (Alzheimer's, senile dementia)
- Alcohol Dependence
- Alcohol Intoxication
- Alcohol Withdrawal
- Alcoholism
- Alopecia (baldness)
- Alzheimer's Disease
- Amenorrhoea
- Anaemia, other than that caused by dietary deficiency
- Angina
- Angina Pectoris
- Ankylosing Spondylitis
- Anorexia Nervosa
Anorgasmia (Sexual dysfunction in women)
Anthrax
Anxiety disorders
Aphthous ulcers
Appendicitis
Arrhythmia
Arteriosclerosis
Arthritis
Asthma, except for products advertised solely for the alleviation of an attack of mild asthma, and the advertisement should contain a recommendation that sufferers should seek medical advice.
Atherosclerosis
Attention Deficit Disorder
Attention Deficit Hyperactivity Disorder (ADHD)
Auditory systems, any structural or organic ailment
Autism
Auto-immune diseases
Backache where the reference is to chronic or persistent
Barber's Rash (Sycosis)
Benign Prostatic Hyperplasia/Hypertrophy
Beriberi
Bilharzia (Schistosomiasis)
Biliary Stones
Binge Eating
Bipolar Disorders
Bladder Cancer
Bleeding Disorders
Blocked uterine (Fallopian) tubes
Blood Pressure
Bradyardia
Brain Cancer
Breast Cancer
Breast Diseases of or development of
Breast milk enhancers or strengtheners
Bronchitis, chronic
Bruxism (teeth grinding)
Bubonic Plaque
Bursitis (including "Tennis elbow")
Bust Developers
Cachexia
Cancer
Cancer (non-specific)
Candidiasis, including Thrush
Carbuncles
Cardiac Arrhythmia
Cardiac Failure
Cardiac symptoms, Heart Troubles
Cardiomyopathy
Carpal Tunnel Syndrome
Cataracts
Cellulitis
Cerebral Ataxia
Cerebral Haemorrhage
Cerebral Insufficiency
Cerebral Ischaemia
Cerebral Palsy
Cerebrovascular Disease
Cervical Cancer
Cervical Dysplasia
Chest Pain
Chlamydia
Cholecystitis
Chorea
Chronic Brain Syndrome
Chronic Fatigue Syndrome
Chronic Lead Poisoning
Chronic Obstructive Pulmonary / Airways Disease (COPD/COAD)
Chronic Venous Insufficiency
Chronic venous stasis ulcers
Circulatory Conditions
Cirrhosis
Classic migraine
Cluster Headache
Coeliac Disease
Cognitive Impairment
Colic including Infantile Colic
Colon or Colorectal Cancer
Complex seizures
Condylomata Acuminata
Congestive Heart Failure
Conjunctivitis (allergic, infective)
Convulsions (fits)
Cor Pulmonale
Coronary Heart Disease
Coxsackie infections
Crohn's Disease
Deep Vein Thrombosis
Dementia
Dengue Fever
Depression
Dermatitis (see Skin diseases)
Diabetes type I and type II
Diabetic Foot Ulcers
Diabetic Neuropathy
Diabetic Retinopathy
Diarrhoea, non-acute
Diphtheria
Dirty blood
Disseminated (or multiple) sclerosis
Diverticulitis
Diverticulosis
Dizziness
Down Syndrome
Dropsy
Dyspnoea
Dysuria
Ears, any structural or organic defect of the auditory system
Eczema
Emphysema
Empyema
Endometrial Hyperplasia
Endometriosis
Enlarged Glands (lymphadenopathy)
Epilepsy
Epistaxis, recurring
Erectile Dysfunction
Erysipelas
Eyes, any structural or organic defect of the optical system
Facial Neuralgia
Facial Paralysis
Familial hyperlipidaemias
Fatigue
Febrile Convulsions
Female Infertility
Fibrocystic Breast disease including fibroadenoids
Fibromyalgia
Fits (convulsions)
Food allergies
Fungal infections, except athlete's foot
Gallstones
Gangrene
Gastric or Stomach Cancer
Gastro-oesophageal Cancer
Generalised Seizures
Genital herpes
Genital Tumour
Genital Ulcers
Genital Warts
Gingival Hyperplasia
Gingivitis
Glands, enlarged, or glandular conditions
Glaucoma
Goitre
Gonorrhoea
Gout
Haemophilia
Haemorrhagic diseases
Haemorrhoids
Hair Growth
Hair Loss
Hairy leukoplakia
Halitosis
Hallucinations
Hangovers
Head and Neck Cancer
Headache, cluster
Headache, migraine
Headache, non-acute
Headache, tension
Heart Attack
Heart block
Heart Disease
Heart Failure
Heart Troubles, cardiac symptoms
Heartburn
Helicobacter pylori infection
Hepatitis
Hepatomegaly
Herpes simplex
Herpes zoster (shingles)
High Blood Pressure
High Cholesterol
HIV infection
HIV/AIDS-Related Anorexia
HIV/AIDS-Related Dementia
HIV/AIDS-Related Diarrhoea
HIV/AIDS-Related Myelopathy
HIV/AIDS-Related Peripheral Neuropathy
HIV/AIDS-Related Wasting
Homocysteine – raised levels of
Homocysteinuria
Human papilloma virus
Hyperacidity (Superacidity)
Hyperactivity
Hypercholesterolaemia
Hyperglycaemia
Hyperkalaemia
Hyperkinesis
Hyperlipidaemia
Hyperparathyroidism
Hypertension
Hypertension, or symptoms thereof
Hyperthyroidism
Hypertriglyceridaemia
Hypoglycaemia
Hypokalaemia
Hypomagnesaemia
Hypotension
Hypothyroidism
Impetigo
Impotence
Indigestion, where the reference is to chronic or persistent
Infertility
Inflammatory Bowel Disease
Influenza
Insomnia, where the reference is to chronic or persistent
Intermittent Claudication
Irritable Bowel Syndrome (IBS)
Ischaemic Stroke
Itch, the (see Scabies)
Jaundice
Kaposi’s Sarcoma and HIV/AIDS-related tumours
Kidney Cancer
Kidney Stones
Kidneys, disorder or diseases of the
Lazy Eye
Leg Trouble
Leg Ulcers
Leishmaniasis
Leprosy
Lethargy
Leukaemia
Leukoplakia
Leukorrhea
Lichen Planus
Liver Cancer
Liver Cirrhosis
Liver function abnormalities
Locomotor Ataxia
Low Blood Pressure
Low Blood Sugar
Lung cancer
Lupus
Lupus Erythematosus
Lymphadenitis
Lymphadenopathy (enlarged glands)
Lymphangitis
Lymphoedema
Macular Degeneration
Malaria, unless expressly approved by Council
Male Climacteric
Male Impotence
Male Infertility
Mammary Dysplasia
Mania
Manic-Depressive Disorders
Mastitis
Mastodynia
Mastoiditis
Meconium Ileus
Meniere's Syndrome
Menopausal Ailments, except minor associated conditions
Menorrhagia
Mental Retardation
Metabolic Disorders
Metrorrhagia
Microcytic Anaemia
Migraine
Minimal Brain Dysfunction
Mitral Valve Prolapse
Mononucleosis
Motor Neurone Disease
Mouth Cancer
Mucous Colitis
Multiple (or disseminated) Sclerosis
Multiple Sclerosis
Muscular Dystrophy
Myasthenia Gravis
Myelodysplastic Syndrome
Myelopathy
Myocardial Infarction
Myocardial Ischaemia
Myocarditis
Myoclonus Epilepsy
Myopathy
Myositis Ossificans Generalis
Myxoedema
Nasopharyngeal Carcinoma
Neonatal Apnoea
Nephritis
Nervous irritability
Nervousness
Neurasthenia
Neuropathy
Night Blindness
Nightmares
Nodulocystic Acne
Non-Hodkin's Lymphoma
Obesity or over mass
Obstructive Jaundice
Oedema
Oesophageal Cancer
Oligomenorrhea
Oliguria
Oral Leukoplakia
Oral Mucocoeles
Orchitis
Orthostatic hypotension
Osteoarthritis
Osteogenesis Imperfecta
Osteomalacia
Osteoporosis except when an adequate dose of calcium and vitamin D are suggested as an adjuvant to treatment
Osteosarcoma
Ovarian Cancer
Palpitations
Pancreatic Cancer
Pancreatitis
Paralysis
Parkinson's Disease
Partial seizures
Pelvic inflammatory Disease
Penis enlargement
Peptic Ulcer Disease (PUD)
Peptic Ulcers
Peripheral Neuritis
Peripheral Neuropathy
Peripheral Vascular Disease
Pernicious Anaemia
Pertussis
Phlebitis
Plantar warts (verrucae of the feet)
Pleurisy
Pneumocystis Carinii Pneumonia
Pneumonia
Polyneuropathy
Porphyria
Postherpetic Neuralgia
Postirradiation Dermatitis
Postmenopausal symptoms
Post-partum Depression
Post-Partum Diarrhoea
Post-Partum Haemorrhage
Post-Traumatic Stress Disorder
Pre-Eclampsia
Premature Ejaculation
Preoperative Anxiety
Priapism
Proctitis
Progressive Systemic Sclerosis
Prolapse
Prostate Cancer
Prostate Enlargement
Prostatitis
Protozoal Infections
Pruritus
Psoriasis, except for temporary relief
Pubic lice (“Crabs”)
Pulmonary Tuberculosis
Purpura
Pyelonephritis
Pyogenic granuloma
Pyorrhoea
Rabies
Radiation Burns
Radiation Sickness
Raynaud's Disease
Red Blood Cell Aplasia
Reiter's Syndrome
Renal Calculus
Renal Gravel
Renal Insufficiency
Renal Osteodystrophy
Retinal Haemorrhage
Reye's Syndrome
Rheumatism (and backache) where the reference is too chronic or persistent
Rheumatoid arthritis
Rhinitis (seasonal, allergic, perennial)
Rickets
Ringworm
Scabies (the Itch)
Scarlet Fever
Schistosomiasis (Bilharzia)
Schizophrenia including all schizophreniform disorders
Scleroderma
Scurvy
Seasonal affective disorder
Seborrhoea, except for the relief of
Secondary Amenorrhea
Seizure Disorders
Septicaemia
Sexual Dysfunction in Men
Sexual Dysfunction in Women (Anorgasmia)
Sexual weakness and loss of libido
Sexually transmitted infections
Shingles
Shock
Short Bowel Syndrome
Sickle cell anaemia
Silicone Breast Disease
Sinusitis
Sjögren's Syndrome
Skin Cancer
Skin Diseases, except those of minor nature, where the reference is to "all or most" or skin ailments in general
Skin Lighteners
Skin Ulcerations
Sleep apnoea  
Sleeplessness, where the reference is to chronic or persistent  
Slimming except when used in conjunction with a kilojoule reduced diet  
Smallpox  
Social phobias  
Spastic colon  
Spermatorrhea  
Splenomegaly  
Squint  
Stomach Cancer  
Streptococcal Pharyngitis  
Stroke Prevention  
Sycosis (Barber's rash)  
Syphilis  
Systemic Lupus Erythematosus (SLE)  
Systemic Sclerosis  
Tachycardia  
Tapeworm Infestation  
Tenosynovitis  
Tension  
Tetanus  
Thrombocytopenia  
Thrombosis  
Thrush (see Candidiasis, Candida infections)  
Thyroid Cancer  
Tiredness  
Tourette's Syndrome  
Tremors  
Trigeminal Neuralgia  
Tuberculosis  
Typhoid Fever  
Typhus  
Ulcereative Colitis  
Ulcers (all except non-aphthous mouth ulcers)  
Urethritis  
Urinary Calculi  
Urinary Incontinence  
Urinary Infections  
Urinary Retention  
Urinary Stones
Urinary Tract Infections
Uterine Cancer
Uterine Fibroids (myomata)
Vaginal discharge
Varicella
Varicose Veins (except where the reference is confined to relief by elastic stockings)
Vascular conditions
Vasculitis
Venereal Diseases (Sexually transmitted infections)
Venereal Warts (Human papilloma virus)
Venous Stasis
Verrucae of the Feet (Plantar warts)
Viral Diseases, serious
Vitiligo
Warts
Weight loss except when used in conjunction with a kilojoule reduced diet
Whooping Cough, except for the alleviation of symptoms
Wilson's Disease
Yuppie Flu

(b) by the substitution for subregulation (3) of the following subregulation:

"(3)(a) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Council in respect of such medicine and incorporated into the approved package insert of such medicine.

(b) Any unregistered medicine must not contain a statement in its advertisement, labeling or packaging which deviates from, is in conflict with or goes beyond the evidence concerning its safety, quality or efficacy that has been published in peer reviewed medical or scientific journals or other reference books that the Council considers to be authoritative."
Insertion of regulations 49, 50, 51 and 52 of the Regulations

30. The following regulations are hereby inserted in the Regulations after regulation 48, the existing regulation 49 becoming regulation 53:

“ACQUISITION AND USE OF MEDICINES BY EMERGENCY SERVICES, MASTERS OF SHIPS AND OFFICERS IN CHARGE OF ANY AIRCRAFT

49. The Regional Director, State Health Services of the area concerned or a medical practitioner designated by him or her may, notwithstanding section 22A of the Act and the regulations, on the written request of a person in charge of emergency services, the master of the ship or the officer in charge of an aircraft, authorise the purchase, acquisition, keeping or use of a Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5, or Schedule 6 substance: Provided that the quantity shall be within reasonable limits and subject to the condition that such medicine is intended for emergency medicinal use only.

USE OF MEDICINES FOR EXHIBITION PURPOSES

50. A manufacturer, importer, wholesaler or distributor and other marketers of medicines may use a medicine or scheduled substance sample for exhibition purposes or to introduce such medicine or scheduled substance to healthcare providers or the public or to remind practitioners about such medicine or scheduled substance: Provided that such samples:

(a) are reasonably required for purposes of such exhibition or the launch of such medicine or scheduled substance; and

(b) may not be handed out or given to any healthcare provider or member of the public and must be accounted for in writing after the exhibition, or launch of the medicine or scheduled substance.

PURCHASE OF MEDICINES BY WHOLESALERS FROM OTHER WHOLESALERS

51. (1) A wholesaler desiring to purchase medicines from another wholesaler shall apply to the Director General to be exempted from the provisions of Section 22H(1) of the Act.
(2) An application referred to in sub-regulation (1) shall be accompanied by an application fee as determined by the Director General and contain at least the following information –

(a) the name and business address (both physical and postal) of the applicant;

(b) proof of licensing as contemplated in Section 22C(1) of the Act;

(c) telephone and fax numbers of the applicant;

(d) reasons for seeking the exemption;

(e) specification of the medicines, scheduled substances or medical devices which are to be the subject of the application;

(f) the geographic area to be served by the applicant in respect of the medicines, scheduled substances or medical devices which are the subject of the application;

(g) the estimated number of healthcare users in the geographic area referred to in paragraph (f); and

(h) details of how the healthcare users in the geographic area referred to in paragraph (f), would benefit from the exemption.

(3) The Director General may grant such exemption.

CODE OF PRACTICE

52 (1) The Minister has, after consultation with the pharmaceutical industry, made this regulation and the Code of Practice ("the Code") annexed hereto.

(2) The pharmaceutical industry shall, in marketing medicines, adhere to the Code.
(3) The Code shall be administered by the Council through one of its committees appointed in terms of section 9 of the Act.

(4) The committee contemplated in subregulation (3) shall monitor compliance with the Code by members of the pharmaceutical industry.

(5) A breach of the Code contemplated in subregulation (5) shall be regarded as non-compliance with the regulations as provided for in regulation 43.

Deletion of regulation 50 of the regulations

31. Regulation 50 of the regulations is hereby deleted.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH