GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 844 **16 July 2004**

GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions form 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

1. In this Schedule, "the Regulations" means the regulations published under Government Notice No. R 510 of 10 April 2003 as amended by Government Notices No. R 539 of 25 April 2003 and 1506 of 16 October 2003. "The Act" means the Medicines and Related Substances Act, 1965 (Act No 101 of 1965).

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 <u>or on whose behalf</u> an application for the registration of a medicine, an update or amendment to an existing registration <u>of a medicine is made</u>";

(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), (v), (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), (v), (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) <u>a list of all inactive ingredients contained in the medicine;</u>

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

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

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

" (i) **[sugar]** <u>glucose</u> 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<u> or in the case of a parallel imported medicine, the name of the holder of the parallel importer permit</u>;"

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

" (z) <u>in the case of a medicine for oral administration which contains a second generation antihistamine, the warnings:</u>

"<u>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."</u>

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

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

" (2) If the medidicine 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]** <u>provide</u> 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), (h), (q), (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), (j), (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 (r) of sub regulation (1);

(v) in the case of a medicine packed in blister or similar packaging, the details prescribed in paragraphs (e), (r), (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 <u>list of all inactive ingredients contained in the medicine</u>;

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

" (d) pharmacological <u>or therapeutic</u> action, **[i.e a description of the pharmacological]** of the medicine, and where applicable, under a sub-heading: 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 <u>of the</u> 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 <u>modify or</u> withdraw any indication <u>or any other aspect of the package insert</u> if it is of the opinion that the risk and benefit profile of the medicine for the approved indications <u>or suitability for the intended purpose</u> for <u>which the medicine</u> 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) <u>The class of medicine;</u>

(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:"

Amendment of regulation 12 of the Regulations

10. Regulation 12 of the regulations is hereby amended-

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

(1) No person shall import any medicine or specified Schedule 5, 6, 7 or 8 substance, including medicines imported in terms of section 15C of the Act, read together with regulation 7, into the Republic except through one of the following ports of entry:

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

(a) is licensed in terms of the Act to import the specified 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:"

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

(c) the quantity of such substance used during the preceding calendar year in the production of any other Schedule 6 or Schedule 7 substance or a specified substance referred to in section 22A(12)(a)(ii) and (iii) of the Act <u>or any substance listed in another Schedule</u>;"

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, <u>IMPORT OR EXPORT</u>, ACT AS A WHOLESALER OR DISTRIBUTE MEDICINES <u>OR MEDICAL DEVICES</u>

(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 <u>distributor of any medicine</u>, Scheduled substance or medical device;

(ii) appoint, and designate a pharmacist who will control the manufacturing, <u>import or export, wholesaling or</u> 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 <u>pharmacist in terms of the Pharmacy Act 53 of 1974;</u>

(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,]** 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 Rigpa
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 Adrenolytics (sympatholytics)

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 <u>and substance abuse</u>

10. Medicines acting on respiratory system

10.1 Antitussives and expectorants

10.2 Bronchodilators

10.2.1 Inhalants

10.3 <u>Other medicines acting on the respiratory system</u>

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 <u>antacids</u>

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 anaesthetics

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 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 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.

25**[(3)]** (4) 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 Narcotic analgesics

1.3.1 Opioid agonists

1.3.2 Opioid antagonists

1.4 Sedatives

1.4.1 Sedative hypnotics

1.4.2 Sedative analgesics

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 Haemopoeitic 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 Antispasmotics

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 Progesterones & 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

1 3.6 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 potentiators

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 paraghraph:

"(f) the strength of the dosage form and the quantity of the medicine to be supplied: <u>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;"</u>

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 <u>Schedule</u> 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 <u>evidence,</u> 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

retailer for evidence testing, examination or analysis in terms of these regulations.".

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 away 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 products 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

Bradycardia

Brain Cancer

Breast Cancer

Breast Diseases of or development of

Breast milk enhancers or strengtheners

Bronchitis, chronic

Bruxism (teeth grinding)

Bubonic Plague

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

Cholera

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-Hodgkin'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

Sjőgren'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

Thrombocytopaenia

Thrombosis

Thrush (see Candidiasis, Candida infections)

Thyroid Cancer

Tiredness

Tourette's Syndrome

Tremors

Trigeminal Neuralgia

Tuberculosis

Typhoid Fever

Typhus

Ulcerative 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.".

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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

CODE OF PRACTICE

PART 1A MARKETING AND PROMOTION OF MEDICINES TO HEALTH CARE PROFESSIONALS

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Guidance on the interpretation of the Code appears as supplementary information to the text in italics

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1. Registration

1.1 A medicine must not be promoted prior to the product being registered by the MCC, which permits its sale, supply and use in South Africa.

Clause 1.1 Note 1: Registration

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited, provided that any such information or activity does not constitute promotion, which is prohibited under this or any other clause.

Clause 1.1 Note 2: Promotion at International Conferences

The display and provision of promotional material for unregistered medicines is not permitted in South Africa, whether the meeting is national or international in nature.

1.2 The promotion of a medicine must be in accordance with the terms of its registration, and must not be inconsistent with the particulars listed in its package insert.

Clause 1.2 Unauthorised Indications

The promotion of "off-label" indications, unregistered in South Africa, is prohibited. This does not preclude discussing the merits of such unregistered, "off-label" indications in proper scientific discussions.

2. Prescribing Information and other Obligatory Information

2.1 The prescribing information listed in Clause 2.2 must be provided in a clear and legible manner in all promotional material for a medicine aimed at healthcare professionals, except for abbreviated advertisements (see Clause 3) and for promotional aids, which meet the requirements of Clause 16.3.

The prescribing information must be positioned for ease of reference and must not be presented in a manner such that the reader has to turn the material round in order to read it, for example by providing it diagonally or around the page borders.

The prescribing information must form part of the promotional material and must not be separate from it.

Clause 2.1 Note 1: Prescribing Information and Package inserts

Each promotional item for a medicine must be able to stand-alone. For example, when a 'Dear Doctor' letter on a medicine is sent in the same envelope with a brochure about the same medicine, each item must include the prescribing information. It does not suffice to have the prescribing information on only one of the items. The inclusion of a package insert moreover does not suffice to conform to the provisions of this clause.

The prescribing information must be consistent with the approved package insert for the medicine.

Clause 2.1 Note 2: Prescribing Information at Exhibitions

The prescribing information for medicines promoted on posters and exhibition panels at meetings must either be provided on the posters or panels themselves or must be available at the company stand. If the prescribing information is made available at the company stand, this should be

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referred to on the posters or panels.

Clause 2.1 Note 3: Legibility of Prescribing Information

The prescribing information is the essential information that must be provided in promotional material. It follows therefore that the information must be given in a clear and legible manner that assists readability.

Legibility is not simply a question of type size. The following recommendations will help to achieve clarity:

- *minimum type size as defined in legislation i.e. 6 point Helvetica type face;*
- *lines should be no more than 100 characters in length, including spaces;*
- *sufficient space should be allowed between lines to facilitate easy reading;*
- *a clear font should be used;*
- *there should be adequate contrast between the colour of the text and the background;*
- *dark print on a light background is preferable;*
- *emboldening headings and starting each section on new line aid legibility.*

Clause 2.1 Note 4: Electronic Journals

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information can be found. This should be in the form of a direct link. The first Part is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement.

If the first part mentions the product name, then this is the most prominent display of the brand name and the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name. The size must be such that the information is easily readable. The requirement of Clause 8 that promotional material and activities should not be disguised, should also be borne in mind.

2.2 The prescribing information consists of the following:

- the name of the medicine (both the proprietary name and the approved name);
- a quantitative list of the active ingredients, using approved names where such exist;
- at least one registered indication for use, consistent with the package insert;

NOTE:
Regulation 45 of Act 101 of 1965 as amended, requires any written advertisement for a medicine to contain both the proprietary name and the approved name.

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- a succinct statement of the information in the package insert relating to the dosage and method of use relevant to the indications quoted in the advertisement and, where not otherwise obvious, the route of administration;
- a succinct statement of the side-effects, precautions and contra-indications relevant to the indications in the advertisement, giving, in an abbreviated form, the substance of the relevant information in the package insert;
- any warning issued by the Medicines Control Council, which is required to be included in advertisements;
- the scheduling status and pharmacological classification of the product (as determined by the MCC) ;
- the registration number and the name and address of the registered licence holder or the name and address of the part of the business responsible for its sale or supply.

The information specified above in relation to dosage, method of use, side effects, precautions and contra-indications and any warning, which is required to be included in advertisements, must be placed in such a position in the advertisement that its relationship to the claims and indications for the product can be appreciated by the reader.

2.3 In addition, the approved name of the medicine or a list of the active ingredients using approved names, where such exist, must appear immediately adjacent to the most prominent display of the proprietary name in bold type of a size of 6 point Helvetica* typeface in black ink on white cartridge paper or the equivalent thereof or in type of such a size that the approved name or list of active ingredients occupies a total area no less than that taken up by the proprietary name.

2.4 In the case of audio-visual material such as films, video recordings and such like and in the case of interactive data systems, the prescribing information may be provided either:

- by way of a document that is made available to all persons to whom the material is shown or sent, or
- by inclusion on the audio-visual recording or in the interactive data system itself.

When the prescribing information is included in an interactive data system, instructions for

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Clause 2.3 Approved Name

'Immediately adjacent to...' means immediately before, immediately after, immediately above or immediately below.

It should be noted that in a promotional letter, the most prominent display of the proprietary name would usually be that in the letter itself, rather than that in prescribing information provided on the reverse of the letter.

Clause 2.4 Prescribing Information on Audio-visual Material

Where prescribing information is shown in the audio-visual material as part of the recording, it must be of sufficient clarity and duration so that it is easily readable. The prescribing information must be an integral part of the advertisement and must appear with it. It is not acceptable for the advertisement and the prescribing information to be separated by any other material.

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accessing it must be clearly displayed.

2.5 In the case of audio material, i.e. material that consists of sound only, the prescribing information must be provided by way of a document that is made available to all persons to whom the material is played or sent.

2.6 In the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found. In the case of an advertisement included in an independently produced electronic journal on the Internet, there must be a clear and prominent statement in the form of a direct link between the first page of the advertisement and the prescribing information. The approved name of the medicine or the list of active ingredients, as required by Clause 2.3, must appear immediately adjacent to the proprietary name at its first appearance in a size such that the information is readily readable.

2.7 In the case of a journal advertisement where the prescribing information appears overleaf, at either the beginning or the end of the advertisement, a reference to where it can be found must appear on the outer edge of the other page or double page spread of the advertisement in a type size such that a lower case 'x' is no less than 2mm in height.

2.8 In the case of printed promotional material consisting of more than four pages, a clear reference must be given to where the prescribing information can be found.

2.9 Promotional material other than advertisements appearing in professional publications must include the date on which the promotional material was drawn up or last revised.

3. Abbreviated Advertisements

3.1 Abbreviated advertisements are advertisements that are exempt from the requirement to include prescribing information for the advertised medicine, provided that they satisfy the requirements of this clause.

3.2 Abbreviated advertisements may only appear in professional publications, i.e. publications sent or delivered wholly or mainly to members

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Clause 2.9 Dates on Loose Inserts

A loose insert is not regarded as an integral part of the professional publication or journal with which it is sent. It must therefore bear the date on which it was drawn up or last revised.

Clause 3.2 Abbreviated Advertisements – Professional Publications

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of the health professions and/or appropriate administrative staff. A loose insert in such a publication cannot be an abbreviated advertisement.

Abbreviated advertisements are not permissible in relation to any medicine where the MCC has issued a direction that abbreviated advertisements must not be issued.

Abbreviated advertisements are not permitted in audio-visual material or in interactive data systems or on the Internet, including journals on the Internet.

3.3 Abbreviated advertisements must be no larger than an A4 page in size.

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Abbreviated advertisements are restricted to journals and other such professional publications sent or delivered wholly or mainly to members of the health professions.

A promotional mailing or piece left by a medical representative cannot be an abbreviated advertisement, and an abbreviated advertisement cannot appear as part of another promotional item, such as in a brochure consisting of a full advertisement for another medicine.

Diaries and desk pads bearing a number of advertisements are considered to be professional publications and may include abbreviated advertisements for medicines.

Similarly, audio-visual material and such like sent to healthcare professionals may be considered professional publications and an abbreviated advertisement may be affixed to the side of the video cassette or included on the box containing the audio-visual material. The prescribing information must, however, be made available for any advertisement for a medicine appearing on audio-visual material or in an interactive data system or on the Internet, including journals on the Internet. Such advertisements cannot be deemed abbreviated advertisements.

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3.4 Abbreviated advertisements must contain the following information in a clear and legible manner:

- the name of the medicine (which must contain both the proprietary name and the approved name);
- the approved name of the medicine or a list of the active ingredients, using approved names where such exist;
- at least one indication for use consistent with the package insert;
- the scheduling status and the pharmacological classification of the product (as determined by the MCC);
- any warning issued by the MCC that is required to be included in advertisements;
- the name, address and telephone number of the registered licence holder or the name, address and telephone number of the part of the business responsible for its sale or supply;
- a statement that further information is available on request to the holder of the registration or that it may be found in the package insert.

3.5 Abbreviated advertisements may, in addition, contain a concise statement consistent with the package insert, giving the reason why the medicine is recommended for the indication or indications given.

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Clauses 3.4 and 3.5 Abbreviated Advertisements – Permitted Information

The contents of abbreviated advertisements are restricted as set out in Clauses 3.4 and 3.5 and the following information should therefore not be included in abbreviated advertisements:

- *registration numbers*
- *references*
- *dosage particulars*
- *details of pack sizes*

Artwork used in abbreviated advertisements must not convey any information about a medicine that is additional to that permitted under Clauses 3.4 and 3.5.

Telephone numbers may be included in abbreviated advertisements.

4. Journal Advertising

4.1 An advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.

Clause 4 Note 1: Journal Advertisements

See Clause 2 and in particular Clause 2.7 regarding the requirements for prescribing information in journal advertisements.

Clause 4.1 Note 2: Journals with an International Distribution

Part IA of the Code applies to the advertising of medicines in professional journals that are produced in South Africa and/or intended for a South African audience. International journals that are produced in South Africa are subject to the Code even if only a small proportion of their circulation is to a South African audience. It is helpful in these circumstances to indicate that the information in the advertisement is consistent with the South African registration of the product.

4.2 An advertisement taking the form of a loose insert in a journal may not be of a size larger

Clause 4.2 Note 1: Advertising on the Outside of Journals

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than the page size of the journal itself.

Advertising such as cards stapled to a journal and 'wraparounds' must not have a greater surface area than that outlined for loose inserts under Clause 4.2.

Clause 4.2 Note 2: Inserts

A package insert is permitted as an Insert. Inserts and supplements that are not advertisements as such, though they may be regarded as promotional material, for example reports of conference proceedings, are permitted subject to the size restriction of Clause 4.2.

5. Information, Claims and Comparisons

5.1 Upon reasonable request, companies must promptly provide members of the health professions and appropriate administrative staff with accurate and relevant information about the medicines that the company markets.

Clause 5.1 General

The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, inter alia, information or claims relating to pricing and market share. Thus, for example, any claim relating to the market share of a product must be substantiated without delay upon request, as required under Clauses 5.4 and 5.5.

5.2 Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence, and must reflect that evidence clearly. They must not mislead either directly or by implication.

Clause 5.2 Misleading Information, Claims and Comparisons

- ***claims for superior potency in relation to weight*** *are generally meaningless and best avoided unless they can be linked with some practical advantage, for example, reduction in side-effects or cost of effective dosage;*
- ***use of data derived from in-vitro studies, studies in healthy volunteers and in animals.*** *Care must be taken with the use of such data so as not to mislead as to its significance. The extrapolation of such data to the clinical situation should only be made where there is data to show that it is of direct relevance and significance;*
- ***economic evaluation of medicines.*** *Care must be taken that any claim involving the economic evaluation of a medicine is borne out by the data available and does not exaggerate its significance. To be acceptable as the basis of promotional claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the product registration;*
- ***emerging clinical or scientific opinion.***

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Where a clinical or scientific issue exists

that has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a balanced manner in promotional material. A systematic review of the debate must be available upon request;

- ***hanging comparisons**, whereby a medicine is described as being better or stronger or suchlike without stating with which criterion the medicine is compared, must not be made;*
- ***price comparisons.** Price comparisons, as with any comparison, must be accurate, fair and must not mislead. A valid comparison can only be made where a price comparison is made on the basis of the therapeutically equivalent dosage requirement for the same indications. For example, to compare the cost per ml for topical preparations is likely to mislead unless it can be shown that their usage rates are similar, or, where this is not possible, for the comparison to be qualified in such a way as to indicate that usage rates may vary;*
- ***Statistical information.** Care must be taken to ensure that there is a sound statistical basis for all information, claims and comparisons in promotional material. Differences that do not reach statistical significance must not be presented in such a way as to mislead. Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect. Accordingly, before statistical information is included in promotional material it must have been subjected to statistical appraisal. Care should also be taken if there is statistical significance but no obvious clinical significance.*

5.3 A comparison is only permitted in promotional material if:

- it is not misleading;
- medicines or services for the same needs or intended for the same purpose are compared;
- one or more material, relevant, substantiable and representative feature is compared;
- no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, proprietary names, other distinguishing marks and those of a competitor;

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• the trademarks, proprietary names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated. Trade marks/ proprietary names of a competitor may only be mentioned with written permission from the competitor; • no unfair advantage is taken of the reputation of a trade mark, proprietary name or other distinguishing marks of a competitor; • medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.	
5.4 Any information, claim or comparison must be capable of substantiation.	
5.5 Substantiation for any information, claim or comparison must be provided without delay at the request of members of the health professions or appropriate administrative staff. It need not be provided, however, in relation to the validity of indications approved in the product registration.	
5.6 When promotional material refers to published studies, clear and complete references must be given.	
5.7 When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay at the request of members of the health professions or appropriate administrative staff, and a stamp with the text "unpublished data" must be placed on each page of the data.	
5.8 All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.	***Clause 5.8 Note 1: Artwork, Illustrations, Graphs and Tables*** *Care must be taken to ensure that artwork does not mislead as to the nature of a medicine or any claim or comparison and that it does not detract from any warnings or contra-indications.* *For example, anatomical drawings used to show results from a study must not exaggerate those results. Depictions of children should not be used in relation to products not authorised for use in children.* *Particular care should be taken with graphs and tables to ensure that they do not mislead, for example by their incompleteness or by the use of suppressed zeros or unusual scales.*

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	Differences that do not reach statistical significance must not be presented in such a way as to mislead. *Graphs and tables must be adequately labelled so that the information presented can be readily understood. If a graph, table or suchlike is taken from a published paper but has not been reproduced in its entirety, the graph must clearly be labelled as having been adapted from the paper in question (See also Clause 5.5). Any such adaptation must not distort or mislead as to the significance of that graph, table etc. It should also be noted that if a table, graph etc in a paper is unacceptable in terms of the requirements of the Code, because, for example, it gives a visually misleading impression as to the data shown, then it must not be used or reproduced in promotional material.* ***Clause 5.8 Note 2: Trade dress*** *Logos and trade dress must be subordinate in size, concentration of colours and visual impact to the trade name of the medicine.*
5.9 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, toxic hazards or risks of addiction. The word 'safe' must not be used without qualification.	***Clause 5.9 Use of the word 'safe'*** *The restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this Clause.*
5.10 Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.	***Clause 5.10 Note 1: Superlatives*** *Superlatives are those grammatical expressions that denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was 'the best' treatment for a particular condition, for example, could not be substantiated as there are too many variables to enable such a sweeping claim to be proven. The use of a superlative which could be substantiated is a simple statement of fact that can be very clearly demonstrated, such as that a particular medicine is the most widely prescribed in South Africa for a certain condition, if this is not presented in a way that misleads as to its significance.* ***Clause 5.10 Note 2: Use of the Words 'The' and 'Unique'*** *In certain circumstances, the use of the word 'the' can imply a special merit, quality or property for a medicine that is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is 'The analgesic' implies that it is, in effect, the best, and might not be acceptable under this clause.*

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Similarly, great care needs to be taken with the use of the word 'unique'. Although in some circumstances the word unique may be used to describe some clearly defined special feature of a medicine, in many instances it may simply imply a general superiority. In such instances it is not possible to substantiate the claim, as the claim itself is so ill defined.

5.11 The word 'new' must not be used to describe any product or presentation, which has been generally available, or any therapeutic indication, which has been available for more than twelve months in South Africa.

5.12 Proprietary names of other companies' products must not be used unless the prior consent of the proprietors has been obtained.

6. Disparaging References

6.1 The medicines, products and activities of other pharmaceutical companies must not be disparaged.

Clause 6.1 Disparaging References

Much pharmaceutical advertising contains comparisons with other products and, by the nature of advertising, such comparisons are usually made to show an advantage of the advertised product over its comparator. Provided that such critical references to another company's products are accurate, balanced, fair, objective and unambiguous, based on an up to date evaluation of all the evidence, and can be substantiated, they are acceptable under the Code. Such references must not mislead, either directly or by implication or omission.

Unjustified knocking copy, in which the products or activities of a competitor are unfairly denigrated, is prohibited under this clause.

Attention is drawn to the requirements for comparisons set out in Clauses 5.2 to 5.5

6.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

7. Format, Suitability and Causing Offence, Sponsorship

7.1 All material and activities must recognise the special nature of medicines and the professional standing of the audience to which they are directed and must not be likely to cause offence. High standards must be

Clause 7.1 Suitability and Taste

The special nature of medicines and the professional audience to which the material is directed require that the standards set for the

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maintained at all times.

7.2 The name or photograph of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.

7.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

7.4 Promotional material must not include any reference to the MCC unless this is specifically required by the MCC.

7.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

7.6 Extremes of format, size or cost of promotional material must be avoided.

7.7 The telephone, SMS, e-mail, telex or facsimile machines must not be used for promotional purposes, except with the prior permission of the recipient.

7.8 All material relating to medicines and their uses, which is sponsored by a pharmaceutical company, must clearly indicate that it has been sponsored by that company.

7.9 The only exception to clause 7.8 is market research material that need not reveal the name of the company involved but must state that it is sponsored by a pharmaceutical company.

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promotion of medicines are higher than those that might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of promotion, even where they might be acceptable for the promotion of products other than medicines, are unacceptable.

These include:
- *The use or display of sexual imagery for the explicit purpose of attracting attention to the material;*
- *The provision of rubber stamps to doctors for use as aids to prescription writing;*
- *The provision of private prescription forms pre-printed with the name of a medicine.*

Clause 7.7

This does not preclude representatives from making genuine appointments with healthcare professionals by telephone or fax.

Clause 7.8 Declaration of Sponsorship

The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

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8. Disguised Promotion

8.1 Promotional material and activities must not be disguised.

Clause 8.1 Disguised Promotional Material

Promotional material sent in the guise of personal communications, for example by using envelopes or postcards addressed in real or facsimile handwriting, is inappropriate. Envelopes must not be used for the dispatch of promotional material if they bear words implying that the contents are non-promotional, for example that the contents provide information relating to safety or "dear doctor" letters.

Advertisements in journals must not resemble editorial matter unless clearly identified as advertorial or as a sponsored feature. Care must also be taken with company-sponsored reports on meetings and the like to ensure that they are not disguised promotion. Sponsorship must be declared in accordance with Clause 7.8.

Trademarks considered misleading by MCC

The MCC may not accept a proposed trade name and/or related artwork (even though it is a valid trademark) if it considers it misleading in any way in terms of the Medicines Act.

8.2 Market research activities, post-marketing surveillance studies, clinical assessments and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products.

Clause 8.2 Note 1: Guidelines for Clinical Trials in South Africa

The "Guidelines for good practice in the conduct of clinical trials in human participants in South Africa" (DOH 2000 or later versions) shall be adhered to. Clinical trials or safety studies should not be undertaken solely for the purpose of promotion.

Clause 8.2 Note 2: Market Research

Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional. The two phases must be kept distinct. Approval by Ethics Committee and, where required, approval by the MCC, must be obtained for post-marketing trials.

Market research material should be examined before publication or use to ensure that it does not contravene the Code.

9. Provision of Reprints and the Use of Quotations

9.1 Reprints of articles in journals must not be provided unsolicited unless the articles have

Clause 9.1 Provision of Reprints

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been refereed. If a non-refereed article is requested by a healthcare professional, a copy may be provided on written request, provided that each page is stamped with the text "non-refereed article".	*The provision of an unsolicited reprint of an article about a medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed.* *Particular attention must be paid to the requirements of Clause 1.* *When providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information.*
9.2 Quotations from medical and scientific literature must accurately reflect the meaning of the author(s). If unpublished, "personal communications" shall not be used unless the company, organisation or individual is able to supply written substantiation upon request.	***Clause 9.2 Quotations*** *Any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself. For example, to quote from a paper that stated that a certain medicine was 'safe and effective' would not be acceptable even if it were an accurate reflection of the meaning of the author of the paper, as it is prohibited under Clause 5.9 of the Code to state without qualification in promotional material that a medicine is safe.* *Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance. (See Clause 5.2 which prohibits misleading information, claims etc in promotional material).* *Attention is drawn to the provisions of Clause 5.6, which requires that when promotional material refers to published studies, clear references must be given to where they can be found.*
9.3 Quotations relating to medicines taken from public broadcasts, for example radio, television or Internet, and from private occasions, such as medical conferences or symposia, must not be used without the written permission of the speaker.	
9.4 The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.	***Clause 9.4 Current Views of Authors*** *If there is any doubt as to the current view of an author, companies, organisations or individuals should check with the author prior to its use in promotional material..*

10. Distribution of Promotional Material

10.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.	***Clause 10.1 Distribution of Promotional Material*** *Promotional material should be tailored to the audience to whom it is directed.*

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10.2 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.

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Clause 10.2 Frequency of Mailings

The style of mailings is relevant to their acceptability to doctors and criticism of their frequency is most likely to arise where their informational content is limited or where they appear to be elaborate and expensive. A higher frequency rate will be accepted for mailings on new products than for others.

10.3 Mailing lists must be kept up-to-date. Requests from healthcare professionals to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at their request or with their permission.

11. Scientific Information Service

11.1 All companies must compile and collate all information about the medicines that they market, and must be able to provide such information to authorities, members of health care professions or the general public, where appropriate. This may include information about adverse drug reactions.

12. Certification of Promotional Material and Other Activities

12.1 Promotional activities must not be approved nor promotional material issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company, or by the individual, in the manner provided by this clause. Each company or individual should have a Standard Operating Procedure for this process, which must be available for audit by MCC or the Authority.

One of the two persons in a company, or the individual, must be a registered medical practitioner or a responsible pharmacist or, in the case of a product for dental use only, a registered medical practitioner, a responsible pharmacist or a dentist. The other must be an appropriate senior official of the company.

Clause 12.1 Note 1: Certification

An acceptable way to comply with Clause 12.1 is for the final proof to be certified but this is not obligatory provided that that which is certified is in its final form to which no subsequent amendments will be made.

All promotional material or activities must be certified in this way, including promotional aids, audio-visual material, promotional material on databases, Internet websites and medical representatives' technical briefing materials, or arrangements for meetings, hospitality and the like.

Other material issued by companies that relates to medicines but which is not intended as promotional material for those medicines per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange and the like, and educational material for patients etc, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and can therefore fall within the scope of the Code.

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In certifying audio, audio-visual material and material used on interactive data systems or Internet, all companies must ensure that a written transcript of the material is certified, including reproductions of any graphs, tables and the like that appear in the recording. In the event of a complaint, a copy of the written transcript of the material will be requested.

The guidelines on company procedures relating to the Code give further information on certification.

See also the supplementary information to Clause 1 on promotion at international conferences regarding the certification of such material.

Clause 12.1 Note 2: Joint Ventures and Co-Promotion

In a joint venture in which a third party provides a service on behalf of a number of pharmaceutical companies, or other organisations, the responsibility for any activity carried out by that third party on their behalf remains that of the pharmaceutical companies, or other organisations or individuals.

It follows therefore that the pharmaceutical companies or organisations involved should be aware of all aspects of the service carried out on their behalf and should take this into account when certifying the material or activity involved. Similarly, if two or more pharmaceutical companies or other organisations organise a joint meeting, each company should ensure that the arrangements for the meeting are acceptable.

Under co-promotion arrangements whereby companies jointly promote the same medicine and the promotional material bears both company names, each company should certify the involved promotional material or activity, as they will be held jointly responsible for it under the Code.

12.2 All meetings that involve travel outside South Africa which is sponsored for the professionals or appropriate administrative staff, must be certified in advance in a manner similar to that provided for by Clause 12.1.

The certificate for meetings involving travel outside South Africa must certify that the signatories have examined all the proposed arrangements for the meeting and that, in their opinion, the arrangements are in accordance with the relevant advertising regulations and the Code.

Clause 12.2 Meetings involving Travel outside South Africa

When certifying meetings that involve travel outside South Africa, the signatories should ensure that all the arrangements are examined, including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

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12.3 The MCC Inspectorate and the Authority shall be notified in advance of the names of those nominated as authorised signatories in 12.1, together with their qualifications. Changes in the names of nominees must be submitted within 30 days.

12.4 The certificate must state that the signatories have examined the final form of the material and that, in their opinion, it is in accordance with the requirements of the relevant advertising regulations and this Code, is not inconsistent with the product registration and the package insert and is a fair and truthful presentation of the facts about the medicine.

Material that is still in use must be re-certified at intervals of no more than two years to ensure that it continues to conform to the relevant advertising regulations and the Code.

12.5 Companies, organisations or individuals shall preserve all certificates. In relation to certificates for promotional material, the material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved.

In relation to certificates for meetings involving travel outside South Africa, details of the programme, the venue, the reasons for using the venue, the audience, the anticipated and actual costs and the nature of the hospitality and the like must also be preserved.

Companies, organisations or individuals shall preserve certificates and the relevant accompanying information for not less than three years after the final use of the promotional material or the date of the meeting and produce them on request from MCC or the Authority.

Clause 12.5 Retention of Documentation

Companies, organisations or individuals, should note that the Medicines Control Council is entitled to request particulars of an advertisement, including particulars as to the content and form of the advertisement, the method of dissemination and the date of first dissemination, and that such a request is not subject to any time limit. This does not apply to the certificates themselves, in respect of which the three-year limit in Clause 12.5 is applicable.

13. Medical Representatives

13.1 Medical representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines that they promote.

Clause 13.1 Note 1: Medical Representatives

All provisions in the Code relating to the need for accuracy, balance, fairness, good taste etc apply equally to oral representations as well as to printed material. Medical representatives must not make claims or comparisons that are in any way inaccurate, misleading, disparaging, in poor taste etc, or which are outside the terms of the product

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registration for the medicine, or are inconsistent with the package insert. Indications for which the medicine does not have a product registration must not be promoted. Attention is also drawn to the provisions of Clause 7.7, which prohibits the use of the telephone, SMS, e-mail, telex or facsimile machines for promotional purposes except with the prior permission of the recipient.

Clause 13.1 Note 2: Contract Representatives

Companies employing or using contract representatives are responsible for their conduct and must ensure that they comply with the provisions of this and all other relevant clauses in the Code, and in particular the training requirements under Clauses 13.1, 14.1, 14.2 and 14.3.

13.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all relevant requirements of the Code.

13.3 Medical representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the granting of an interview.

Clause 13.3 Note 1: Hospitality and Payments for Meetings

Attention is drawn to the requirements of Clauses 16 and 17 which prohibit the provision of any financial inducement for the purposes of sales promotion and require that any hospitality provided is secondary to the purpose of a meeting, is not out of proportion to the occasion and does not extend beyond members of the health professions or appropriate administrative staff.

Meetings organised for groups of doctors, other healthcare professionals and/or appropriate administrative staff, should be of a professional nature. Medical Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs, which may have been incurred. For example, if the refreshments have been organised and paid for by a medical practice, the cost may be reimbursed as long as it is reasonable in relation to what was provided and the refreshments themselves were appropriate for the occasion. Donations in lieu of hospitality are unacceptable as they are inducements for the purpose of holding a meeting. If hospitality is not required at a meeting, there is no obligation or right to provide some benefit of an equivalent value.

Clause 13.3 Note 2: Donations to Charities

Donations to charities in return for medical representatives gaining interviews are prohibited under Clause 13.3.

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Clause 13.3 Note 3: Items Delivered by Medical Representatives

Reply paid cards, which refer to medical representatives delivering items, which have been offered to healthcare professionals or appropriate administrative staff, should explain that there is no obligation to grant the medical representative an interview when the item is delivered. This is to avoid the impression that there is such an obligation, which would be contrary to Clause 13.3, which prohibits the use of any inducement to gain an interview.

Clause 13.3 Note 4: Statutory Health Professions Councils

There are various statutory health professions Councils regulating health care professions. These bodies provide guidance on standards of professional conduct and ethical behaviour.
Guidance is mainly set out in the relevant Acts pertaining to the professions concerned and the Regulations made in terms of these Acts.
Policy statements and rulings by the statutory Councils give further guidance to the professions. One such guideline, relevant to this code, is the Policy Statement pertaining to Perverse Incentives and Related Matters, which was developed by the Forum of Statutory Health Professions Councils and adopted by the individual Councils.
A copy of this Policy is available on www.hpcsa.co.za or www.samedical.org and cognisance should be taken of its contents.

13.4 Medical representatives must ensure that the frequency, timing and duration of calls on healthcare professionals, administrative staff in hospitals and health authorities and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom medical representatives wish to call, and the arrangements in force at any particular establishment, must be observed.

Clause 13.4 Frequency and Manner of Calls on Doctors

The number of calls made on a doctor and the intervals between successive visits are relevant to the determination of frequency.

Companies should arrange that intervals be visits do not cause inconvenience.

Medical representatives must always endeavour to treat healthcare professionals' time with respect and give them no cause to believe that their time might have been wasted. If, for any unavoidable reasons, an appointment cannot be kept, the longest possible notice must be given.

13.5 In an interview, or when seeking an appointment for one, medical representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or the company that they represent.

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13.6 Medical representatives must transmit forthwith to the scientific service referred to in Clause 11 any information that they receive in relation to the use of the medicines that they promote, particularly reports of side effects.

13.7 When medical representatives introduce medicine to the healthcare professional for the first time, they should provide a copy of the package insert or another relevant document containing the same text. On subsequent occasions, such information should be available on request.

13.8 If discussion on a medicine is initiated by the person or persons on whom a medical representative calls, the medical representative is not obliged to have available the information on that medicine referred to in clause 13.7, but shall ensure the speedy delivery of the requested material.

13.9 Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine that they will promote. A copy of such material must be made available to the MCC or the Authority upon request. Briefing material must comply with the relevant requirements of the Code, with the exception of Clause 5.10, and, in particular, is subject to the certification requirements of Clause 12. Briefing material must not advocate, either directly or indirectly, any course of action that would be likely to lead to a breach of the Code.

13.10 Companies are responsible for the activities of their medical representatives if these are within the scope of their employment even if they are acting contrary to the instructions that they have been given.

14. Training

14.1 All personnel, including members of staff concerned in any way with the preparation or approval of promotional material or of information to be provided to members of South African health professions and to appropriate administrative staff or of information to be provided to the public, must be fully conversant with the requirements of the Code.

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Clause 13.9 Briefing Material

The detailed briefing material referred to in this clause consists of both the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

Clause 14.1 Training

Extensive in-house training on the Code should be given by companies and/or PMA, NAPM and SMASA. In addition, the Authority will run seminars on the Code, which are open to all interested parties including personnel from advertising agencies, public relations agencies and the like. Details of these seminars can be obtained from the Authority.

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14.2 Medical representatives must pass appropriate examinations, in line with SAQA requirements, within 2 years of commencing employment as a medical representative. Upon completion of such training, medical representatives will receive a certificate and their names will be entered into a Register.

Clause 14.2 Time Allowed to Pass Examination

Prior to passing the appropriate examination, representatives may be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether those two years have been spent with one company or with more than one company. A representative cannot, for example, work for eighteen months for one company and eighteen months with another and so on, thus avoiding the examination entirely.

In the event of extenuating circumstances, such as prolonged illness, the Authority may agree to the continued employment of a person as a representative past the end of the two-year period, subject to the representative's passing the examination within a reasonable time.

Companies are reminded about the Labour Relations Act. It is suggested that the requirement of passing the medical representative exam within a specified time period, should be mentioned in their contracts.

14.3 The following exemptions apply in relation to Clause 14.2:

- Persons who were employed as medical representatives on **1 January 2003 are exempt from the need to take the Medical Representatives Examination
- Persons with an acceptable professional qualification, for example in pharmacy, medicine or nursing, who were employed as medical representatives at any time before **1 January 2003, are exempt from the need to take the Medical Representatives Examination

***** dates to be adjusted depending on time taken to approve and implement the Code.***

Clause 14.3 Medical Representatives

The examinations for medical representatives will be based on SAQA requirements.
The syllabus should be complementary to, and may be incorporated within, the company's induction training, which is provided to representatives as a prerequisite to carrying out their function. Normally, representatives should be entered for the appropriate examination within their first year of employment.

15. Samples

15.1 The Medicines Act does not permit sampling

Clause 15

The supply of samples for promotional purposes is not permitted under the Medicines Act. The supply of medicines for exhibition purposes may be permitted under Act 101 (1965). Provision of samples to MCC or drug inspectors is, however, permitted in the normal function of their duties and samples for clinical trial purposes are permitted.

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Donations of medicines may also be made to the public sector.

16. Gifts and Inducements

16.1 No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials, or the general public as an inducement to prescribe, supply, stock, dispense, administer or buy any medicine, subject to the provisions of Clause 16.2.

Clause 16.1 Note 1: Provision of Medical and Educational Goods and Services

Clause 16.1 does not prevent the provision of medical and educational goods and services, which will enhance patient care or benefit the South African Health System. The provision of such goods or services must not be done in such a way as to be an inducement to prescribe, supply, administer or buy any medicine. They must not bear the name of any medicine but may bear a corporate name.

The following guidance is intended to assist companies in relation to medical and educational goods and services.

1. *The role of medical representatives in relation to the provision of goods and services supplied in accordance with the supplementary information to Clause 16.1 needs to be in accordance with the principles set out below. In this context, companies should consider using staff other than medical representatives.*

2. *If medical representatives provide, deliver or demonstrate medical and educational goods and services, this must not be linked in any way to the promotion of products.*

3. *The acceptability of the role of medical representatives will depend on the nature of the goods and services provided and the method of provision.*

4. *The nature of the service provider, the person associated with the provision of medical and educational goods and services, is important. E.g. is the service provider a medical representative or is the service provider some other appropriately qualified person, such as a sponsored registered nurse? If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then medical representatives must not be involved, unless with the express permission of patient and healthcare professional. Medical representatives may provide administrative support in relation to the provision of a screening service, but must not be present*

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during the actual screening and must not discuss or help interpret individual clinical findings.

5. *Neither the company nor its medical representatives may be given access to data/records that could identify, or could be linked to, particular patients. This does not apply to clinical researchers whose activities are controlled under the Clinical Trial Guidelines issued by DOH (last update 2000).*

6. *Sponsored healthcare professionals should not be coerced to participate in the promotion of specific products. All healthcare professionals are required to comply with their respective Codes of Professional Conduct. These codes require, inter alia, that the healthcare professional's registration status is not used in the promotion of commercial products or services.*

7. *Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.*

8. *Service providers must operate according to detailed written instructions provided by the company. It is recommended that these should be similar to the briefing material for medical representatives as referred to in Clause 13.9 of the Code. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions must not advocate, either directly or indirectly, any course of action that would be likely to lead to a breach of the Code.*

9. *Service providers must abide by the principle set out in Clause 13.5 of the Code that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the company they represent.*

10. *A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed to. The identity of the sponsoring company, organisation or individual must be given. For example, a*

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general practitioner allowing a sponsored registered nurse access to patient records should be informed in writing of any data to be extracted and the use to which those data will be put.

11. Any printed material designed for use in relation to the provision of medical and educational goods and services must be non-promotional. It is not acceptable for such materials to promote the prescription, supply, sale or administration of the sponsoring company's medicines. Nor is it acceptable for materials to criticise competitor products as this might be seen as promotional. All printed materials must identify the sponsoring pharmaceutical company.

12. Materials relating to the provision of medical and educational goods and services, such as internal instructions, external instructions, the written protocol for recipients and printed material etc, must be examined by the Code signatories within companies to ensure that the requirements of the Code are met as recommended in the supplementary information to Clause 12.1 of the Code. A copy of the materials must be made available to the Authority on request.

13. Companies are advised to inform relevant parties such as health authorities, medical aid schemes, health insurance companies and health care organisations, of their activities where appropriate. This is particularly recommended where companies propose to provide medical and educational goods and services that would have budgetary implications for the parties involved. For example, the provision of a screening service for a limited period might mean that funds would have to be found in the future when company sponsorship stopped. Another example might be the provision of diagnostic or laboratory services and the like, which the health authority, medical aid scheme, health insurance company or health care organisation would normally be expected to provide.

Clause 16.1 Note 2: Statutory Professional Councils

All healthcare professionals are referred to the Good Practice Guidelines of their respective

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Professional Bodies.
Healthcare professionals should not ask for or accept any material rewards, except those of insignificant value, from companies, organisations or individuals that sell or market drugs or appliances.

Clause 16.1 Note 3: Terms of Trade

Schemes that enable healthcare professionals to obtain personal benefits, for example gift vouchers, in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to financial discounts.

Clause 16.1 Note 4: Package Deals

Clause 16.1 does not prevent the offer of package deals wherein the purchaser of particular medicines receives with them other associated benefits, such as apparatus for administration, provided that the transaction as a whole is fair and reasonable and the associated benefits are relevant to the medicines involved.

Clause 16.1 Note 5: Donations to Charities

Donations to charities made by companies in return for healthcare professionals' attendance at company stands at meetings or offered as rewards for completing and returning quiz cards in mailings and such like are not necessarily unacceptable under this clause, provided that the level of donation for each individual is modest, the money is for a reputable charity and any action required of the healthcare professional is not inappropriate. Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. For example, it would not be acceptable for a representative to pay into a practice equipment fund set up as a charity as this would be a financial inducement prohibited under Clause 16.1.
Donations to charities in return for medical representatives gaining interviews are also prohibited under Clause 13.3 of the Code. Any offer by a company of a donation to a charity, which is conditional upon some action by a healthcare professional, must not place undue pressure on the healthcare professional to fulfil that condition. At all times, the integrity of the industry and the provisions of Clause 7.1 must be kept in mind.

16.2 Gifts in the form of promotional aids and prizes, whether related to a particular product or of general utility, may be distributed to members of the health professions and to appropriate administrative staff, provided that the gift or prize is inexpensive and relevant to

Clause 16.2 Note 1: Gifts

Items provided on long term or permanent loan to a doctor or a practice are regarded as gifts and are subject to the requirements of this clause. Gifts must be inexpensive and relevant to the recipients'

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the practice of their profession or employment.

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work. An 'inexpensive' gift means one which has cost the donor company no more than R200, including VAT.

Items of general utility which have been held to be acceptable gifts to doctors as being inexpensive and of relevance to their work include but are not limited to pens, pads, diaries, nail brushes, surgical gloves, desk trays, calendars, a peak flow whistle and desk clocks. Names of medicines should not be used on promotional aids when it would be inappropriate to do so, for example, when it might mislead as to the nature of the item.

Clause 16.2 Note 2: Competitions and Quizzes

The use of competitions, quizzes and suchlike for the purposes of sales promotion is not necessarily an unacceptable form of promotion. Any competition must, however, be in good taste and must not involve any subject matter that is inappropriate for the promotion of a medicine as required under Clause 7.1. A competition is more likely to be considered acceptable if its subject matter is clearly related to the practice of medicine and pharmacy. Any competition used for promotional purposes must be a bona fide test of skill and must recognise the professional standing of the recipients.

The provisions of Clause 16.2 apply to the provision of competition prizes. Prizes of a higher value than would ordinarily be acceptable for a promotional aid are acceptable where the competition is a serious one and the prizes are few in number, relevant to the potential recipient's work and not out of proportion to the skill required in the competition. The maximum acceptable cost to the donor of a prize in a promotional competition is R1000, including VAT.

Clause 16.2 Note 3: Gifts to or for use by Patients

Some items distributed as promotional aids are intended for use by patients and these are acceptable provided that they meet the requirements of Clause 16.2; for example, puzzles and toys for a young child to play with during a visit to the doctor.

Other items that may be made available to patients, for example by completing a request card enclosed with a medicine, should meet the relevant principles set out in Clause 16.2, that is they should be inexpensive and related to either the condition under treatment or general health. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 18.

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No gift or promotional aid for use by patients must be given for the purpose of encouraging patients to request a particular medicine.

16.3 The prescribing information for a medicine as required under Clause 2 does not have to be included on a promotional aid if the promotional aid includes no more than the following about the medicine:

- The name of the medicine
- An indication that the name of the medicine is a trade mark
- The name of the company responsible for marketing the product.

Clause 16.3 Note 1: Promotional Aids – Name of the Medicine

The name of the medicine means the proprietary name or the approved name. Both names may be included but it is not obligatory to include both. A promotional aid may bear the names of more than one medicine.

Clause 16.3 Note 2: Prescribing Information on Note Pads and Calendars

If a promotional aid consists of a note pad or calendar in which the individual pages bear advertising material, there is no need for the individual pages to comply with Clause 2, provided that the information required by that clause is given elsewhere; for example, on the cover.

17. Hospitality and Meetings

17.1 Companies, organisations or individuals are permitted to provide appropriate hospitality to members of the health professions and appropriate administrative staff in association with scientific and promotional meetings, scientific congresses and other such meetings. Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must be appropriate and not out of proportion to the occasion and the costs involved must not exceed that level that the recipients would normally adopt when paying for themselves. It must not extend beyond members of the health professions or appropriate administrative staff.

Clause 17.1 Note 1: Hospitality and Meetings, including CPD Events

Companies, organisations or individuals must take cognisance of the provisions of the Policy Statement pertaining to Perverse Incentives and Related Matters as published by the Health Professions Council.

The provision of hospitality may, in certain circumstances, include the payment of reasonable, actual travel costs for delegates to attend meetings within the Republic of South Africa. Such payments may only be made to Professional Associations organising the event.

The payment of travel expenses and the like for persons accompanying the delegate is not permitted.

The payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel, for speakers, is permissible. Pharmaceutical companies, other organisations or individuals may appropriately sponsor a wide range of meetings. These range from small lunchtime audio-visual presentations in a group practice, hospital meetings and meetings at postgraduate education centres, launch meetings for new products, management training courses, meetings of clinical trialists, patient support group meetings, satellite symposia through to large international meetings organised by

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independent bodies with sponsorship from pharmaceutical companies, other organisations or individuals.

With any meeting, certain basic principles apply:

- *the meeting must have a clear educational content;*
- *the hospitality associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion, and*
- *any hospitality provided must not extend to spouses and other persons unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right.*
- *spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.*

Administrative staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter related to practice administration.

The provisions of this and all other relevant clauses in the Code apply equally to meetings and courses organised or sponsored by pharmaceutical companies, organisations or individuals which are continuing professional development (CPD) approved.

The fact that a meeting or course has CPD approval does not mean that the arrangements are automatically acceptable under the Code. The relevant provisions of the Code and, in particular, those relating to hospitality, must be observed.
A useful criterion in determining whether the arrangements for any meeting are acceptable is to apply the question 'would you and your company be willing to have these arrangements generally known?' The impression that is created by the arrangements for any meeting must always be kept in mind.

Meetings organised for groups of doctors, other healthcare professionals and/or for administrative staff that are wholly or mainly of a social or sporting nature are unacceptable.

Meetings organised by pharmaceutical companies, other organisations or individuals, that involve South African healthcare professionals at venues outside South Africa are not necessarily unacceptable.

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There have, however, to be valid and cogent reasons for holding meetings at such venues. As with meetings held in South Africa, in determining whether such a meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like. As with any meeting, it should be the programme that attracts delegates and not the associated hospitality or venue.

Clause 17.1 Note 2: Certification of Meetings

Companies, organisations or individuals must ensure that all planned meetings are checked to see that they comply with the Code. Companies, organisations or individuals, must have a written document that sets out their policies on meetings and hospitality and the associated allowable expenditure. In addition, meetings that involve travel outside South Africa must be formally certified as set out in Clause 12.2 of the Code.

17.2 Payments may not be made to doctors or groups of doctors, either directly or indirectly, for rental for rooms to be used for meetings.

Clause 17.2 Payment of Room Rental

This provision does not preclude the payment of room rental to postgraduate medical centres and the like. Payment of room rental to doctors or groups of doctors is not permissible even if such payment is made to equipment funds or patients' comforts funds and the like or to charities or companies.

17.3 When meetings are sponsored by pharmaceutical companies, other organisations or by individuals, that fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

Clause 17.3 Sponsorship and Reports of Meetings

Attention is drawn to Clause 7.9, which requires that all material relating to medicines and their uses that is sponsored by a pharmaceutical company, other organisations or individuals must clearly indicate that it has been sponsored by that company. It should be noted that where companies are involved in the sponsorship and/or distribution of reports on meetings or symposia etc these reports may constitute promotional material and thus be fully subject to the requirements of the Code.

18. Relations with the General Public and the Media

18.1 Medicines must not be advertised to the general public if they are prescription only medicines or are medicines, which, though not prescription only, may not legally be advertised to the general public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by the Department of Health and/or MCC.

Clause 18.1 Advertising of Medicines to the General Public

The advertising of prescription only medicines to the general public is prohibited by regulations under the Medicines Act 1965.
The promotion of medicines to the general public for self-medication purposes is covered by Part I B of this Code.

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Methods of sale of medicines through pharmacies are also covered by the SAPC Good Pharmacy Practice guidelines.

18.2 Information about medicines that is made available to the general public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine.

Clause 18.2 Note 1 Information to the General Public

This clause allows for the provision of non-promotional information about prescription medicines to the general public either in response to a direct inquiry from an individual, including inquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like. It also includes information provided by means of posters distributed for display in surgery waiting rooms etc.

Any information so provided must observe the principles set out in this clause, that is, it should be factual, balanced and must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine. It must not constitute the advertising of medicines to the general public prohibited under Clause 18.1. The provisions of Clause 18.3 must be observed if an inquiry is from an individual member of the public.

Particular care must be taken in responding to approaches from the media to ensure that the provisions of this clause are upheld.

In the event of a complaint which relates to the provisions of this clause, companies will be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfils the requirements of this clause. Assessment reports and package inserts may be provided to members of the public on request.

Companies may provide members of the health professions with inserts concerning a medicine with a view to their provision to patients to whom the medicine has already been prescribed, provided that such an insert is factual and non-promotional in nature. Companies may conduct disease awareness and public health campaigns provided that the purpose of these is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine.

Clause 18.2 Note 2 Financial Information

Information made available in order to inform

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shareholders, the Johannesburg Stock Exchange and the like by way of annual reports and announcements etc. may relate to both existing medicines and those not yet marketed. Such information must be factual and presented in a balanced way.

Clause 18.2 Note 3 Approval of Information

Information on medicines made available under this clause should be examined by the nominated signatories to ensure that it does not contravene the Code or the relevant statutory requirements.

18.3 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer recommended to consult his or her own healthcare professional.

Clause 18.3 Note 1 Replies Intended for Use in Response to Individual Enquiries

Replies intended for use in response to enquiries that are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not have the appearance of promotional material.

Clause 18.3 Note 2 Requests for Information or Advice on Personal Medical Matters

This clause prohibits the provision of information or advice on personal medical matters to individual members of the general public requesting it. The intention behind this prohibition is to ensure that companies, organisations or individuals do not intervene in the patient/doctor relationship by offering advice or information that properly should be in the domain of the doctor. However, information may be given, including information on medicines prescribed for the enquirer, provided that it complies with the requirements of Clauses 18.1 and 18.2 and does not impinge on the principle behind this Clause. For example, answering requests by members of the public as to whether a particular medicine contains sucrose or some other inactive ingredient, or whether there would be problems associated with drinking alcohol whilst taking the medicine or whether the medicine should be taken before or after a meal, is acceptable. The situation with enquiries relating to side effects, the indications for a medicine and such like is not as clear cut and particular caution is required in dealing with them.

All requests from members of the general public need to be handled with great care and a decision taken as to whether the company, organisation or individual can responsibly answer the inquiry.

Requests from patients for information may in some

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	instances best be handled by passing the information to the patients' doctors for discussion with them rather than providing the information directly to the patients concerned.
18.4 Companies are responsible for information about their products that is issued by their public relations agencies.	
19. The Internet	
19.1 Access to promotional material directed to an South African audience provided on the Internet in relation to prescription only medicines, or medicines which, though not prescription only, may not legally be advertised to the general public, must be limited through a password protection scheme, and be accessible to healthcare professionals and appropriate administrative staff only.	***Clause 19.1 Good Website Practices*** *This may include the use of a "quality seal" or accreditation by a national or international organisation.*
19.2 Information or promotional material about medicines covered by Clause 19.1 above which is placed on the Internet outside South Africa will be regarded as coming within the scope of the Code if it was placed there by a South African company, organisation or individual or an affiliate of a South African company, organisation or individual or at the instigation or with the authority of such a company, organisation or individual, and it makes specific reference to the availability or use of the medicine in South Africa.	
19.3 Information about medicines covered by Clauses 19.1 and 19.2 above which is provided on the Internet and which can be accessed by members of the public must comply with Clause 18.2 of the Code.	
19.4 Notwithstanding the provisions of Clauses 19.1 and 19.3 above, a medicine covered by Clause 19.1 may be advertised in a relevant independently produced electronic journal intended for healthcare professionals or appropriate administrative staff which can be accessed by members of the public.	***Clause 19.4 Advertisements in Electronic Journals*** *It should be noted that the MCC's guidance notes on advertising and promotion state that each page of an advertisement for a prescription only medicine should be clearly labelled as intended for healthcare professionals.*
19.5 Assessment reports and package inserts for medicines covered by Clause 19.1 above may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.	

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19.6 It should be made clear when a user is leaving any of the company's sites, or sites sponsored by the company, or is being directed to a site, which is not that of the company.	***Clause 19.6 Sites linked via Company Sites*** *Sites linked via company sites are not necessarily covered by the Code and users should therefore be warned when leaving a site covered by the Code for one which is not.*

20. Compliance with Undertakings

20.1 When an undertaking has been given in relation to a ruling under the Code, the company, organisation or individual concerned, must ensure that it complies with that undertaking.

PART 1B THE MARKETING AND PROMOTION OF MEDICINES DIRECT TO THE CONSUMER.

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Advertising and promotional material that are subject to the Code include:

- Advertorials
- Aerial promotions such as on hot air balloons
- Booklets
- Cinema commercials
- Consumer leaflets
- Direct mail materials
- Internet materials, including press releases intended for internet publication
- On-pack statements
- Outdoor advertising
- Point of sale materials
- Posters
- Print advertisements
- Promotional aids including those used for direct selling activities
- Sales promotions
- Telephone help lines
- Television and radio commercials
- Sports, art and other sponsorships

Advertising does not include factual, accurate, informative announcements and reference material concerning registered medicine or health products and relating, for example, to adverse reaction warnings, trade catalogues and price lists provided they include no product claims, measures or trade practices relating to prices, margins or discounts.

Labeling requirements and package inserts are subject to the Act and the regulations.

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1. Registration

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A medicine must not be promoted prior to the product being registered by the MCC which permits its sale, supply and use in South Africa.

A complementary medicine should not be advertised or promoted for use as a self-medication product in South Africa unless it has been submitted to the MCC for registration and must have either received a Registration Number or else a valid Reference Number, authorising the sale of such a product.

No medicine may be promoted prior to the receipt of a Reference Number or Registration Number from the MCC.

The promotion of a self-medication medicine must be in accordance with the terms of its registration and must not be inconsistent with the particulars listed in the package insert or approved text.

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Clause 1 Registration

The legitimate exchange of medical and scientific information during the development of a medicine or health product, including un-sponsored editorial in the public media, is not prohibited provided that any such information or activity does not constitute promotion, which is prohibited under this or any other clause.

The promotion of "off-label" indications, unregistered in South Africa, is prohibited. This does not preclude discussing the merits of such unregistered, "off label" indications in proper scientific discussions.

2. Advertising

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Advertising shall be balanced, true and shall not mislead or contain any exaggerated claims, either direct or implied. All advertising must be consistent with the requirements of the Medicine Act.	
2.1 *Advertising shall not cause consumers unwarranted anxiety that they are suffering from any ailment. Nor should it imply that suffering may arise if a consumer fails to respond to the advertisement's claim. Language which brings fear or distress should not be used.*	
2.2 *Advertising shall not suggest that normal good health could be improved by using a product. Nor should it suggest that normal good health could be affected by not taking a product.*	
2.3 *Advertising shall not be aimed principally or exclusively at children except the medicines listed in Appendix 3. Advertising shall not show children using, or within reach of, medicine or health products without adult supervision.*	For the purpose of the Code a child is someone under 16. The way in which children perceive and react to marketing communications is influenced by their age, experience and context in which the message is delivered; marketing communications that are acceptable for young teenagers will not necessarily be acceptable to young children. These factors must be taken into account. Marketing communications addressed to or targeted at or featuring children should not exploit their credulity, loyalty, vulnerability or lack of experience. Promotions addressed to or targeted at children should not encourage excessive purchases.
2.4 *Advertising shall not contain material which could either by detailed description or case*	

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history, lead to consumers making an erroneous self-diagnosis.

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2.5	*Advertising shall not offer to diagnose, advise, prescribe or treat personally by correspondence.*	
2.6	*Advertising shall not claim, or imply, that a product's effects are guaranteed.*	
2.7	*Advertising can refer to the prevention of symptoms and use of a product in chronic conditions, if in line with the registered indication. However, as with all advertising for self-medication products, care should be taken not to encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any medicine or health product.*	
2.8	*Advertising shall use language that can be understood by the consumer.*	
2.9	*The use of medical terminology is acceptable. Care must be taken that this does not confuse or mislead the consumer.*	
2.10	*Advertising shall be clearly distinguished from editorial matter.*	
2.11	*Advertising shall not suggest that a medical consultation or surgical operation is unnecessary nor shall it discourage consumers from seeking medical or pharmaceutical advice.*	
2.12	*Advertising shall not be misleading as to the nature of the product, its ingredients or indication.*	**Clause 2.12 Misleading Advertising**

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Examples of misleading advertising would include the following:

- Suggestion that the product is a foodstuff, cosmetic or other non-medicinal product.

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	• Suggestion that a product is side effect free. It is however acceptable to highlight the absence of a specific side effect, e.g. 'no drowsiness'. • Although it is acceptable to indicate that a self-medication product is palatable, advertising shall make it clear that it is a medicine or health product. • Advertising shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than permitted by the MCC. • Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.
2.13 *Advertising shall not contain improper, alarming or misleading claims of a recovery.*	
2.14 *No advertisement for any incentive scheme for a self- medication product is permissible.*	
2.15 *Advertising shall not contain recommendation of a product by scientists or health professionals unless substantiated.*	*It is acceptable to state that a product's active ingredients, formulations or preparations have been used or prescribed by a health professional/s, provided there is evidence that this is the case and that it does not contravene the product's condition of registration.*
2.16 *Advertising shall not include a recommendation by a person who, because of their celebrity, may encourage consumers to take a medicine or health product.*	

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3. Information in advertising

All advertising must be consistent with the provisions of the Medicine Control Act of 1965.

Clause 3 Information in Advertising

Promotional items such as pens that feature only the brand name and no other promotional copy are acceptable provided that such advertising conforms with the spirit of the Code and that no claims are made for the product.

Advertisements must comply with the relevant regulations of the Medicine Control Act of 1965 i.e. all advertising must give the information necessary for the correct use of a product.

As such there are four mandatory items of information which must be present in all written advertising.

A written advertisement for a medicine or health product shall contain the following elements:

3.1 *The proprietary name of such a medicine or health product.*

3.2 *The approved name and quantity of each active ingredient of such medicine or health product in lettering having a minimum legibility as defined in regulation 1 (vi) of the regulations, provided that, in the case of a medicine or health product containing only one active ingredient, such lettering shall not be less than one half the size of the largest lettering used for the said proprietary name.*

3.3 The registration number or application number allocated to the medicine by the

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Medicine Control Council.

3.4 A medicine in respect of which an application for registration has been submitted in accordance with the provision of section 14, the reference number allocated to such application by the Registrar, followed by the words '(Act 101/1965).

3.5 *In any case where a name other than the proprietary name is also used, such other name in lettering one half the size of the largest type size in which the proprietary name appears in such advertisements.*

All these elements must be clear, legible and clearly communicated. Failure to comply is a breach of the law.

4. Information, Claims and Comparisons

4.1 Upon reasonable request, companies, organisations or individuals must promptly provide members of the health professions and appropriate administrative staff with accurate and relevant information about the medicine that the company, organisation or individual markets.

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Clause 4.1 General Information, Claims and Comparisons

The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, inter alia, information or claims relating to pricing and market share.

Thus, for example, any claim relating to the market share of a product must be substantiated without delay upon request as required under Clause 4.5.

Clause 4.1 Misleading Information, Claims and Comparisons

- *Claims for superior potency in relation to weight are generally meaningless and best avoided unless they can be linked with some practical advantage, for example, reduction in side-effects or cost of effective dosage;*
- *Use of data derived from in-vitro studies, studies*

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in healthy volunteers and in animals. Care must be taken with the use of such data so as not to mislead as to its significance.

The extrapolation of such data to the clinical situation should only be made where there is data to show that it is of direct relevance and significance;

- *Economic evaluation of medicine. Care must be taken that any claim involving the economic evaluation of a medicine is borne out by the available evidence and does not exaggerate its significance.*

  To be acceptable as the basis of promotional claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the product registration.

- *Emerging clinical or scientific opinion. Where a clinical or scientific issue exists that has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a balanced manner in promotional material.*

  A systematic review of the debate must be available upon request;

- *Hanging comparisons whereby a medicine is described as being better or stronger or suchlike without stating with which the medicine is compared, must not be made;*

- *Price comparisons. Price comparisons, as with any comparison, must be accurate, fair and must not mislead.*

  A valid comparison can only be made where a price comparison is made on the basis of the therapeutically equivalent dosage requirement for the same indications.

  For example, to compare the cost per ml for topical preparations is likely to mislead unless it can be shown that their usage rates are similar, or, where this is not possible, for the comparison to be qualified in such a way as to indicate that usage rates may vary;

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- *Statistical information. Care must be taken to ensure that there is a sound statistical basis for all information, claims and comparisons in promotional material.*

  Differences that do not reach statistical significance must not be presented in such a way as to mislead.

  Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect.

  Accordingly, before statistical information is included in promotional material it must have been subjected to statistical appraisal.

  Care should also be taken if there is statistical significance but no obvious clinical significance.

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4.2 Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication.

4.3 A comparison is only permitted in advertising or promotional material if:

- It is not misleading;
- Medicine or services for the same needs or intended for the same purpose are compared;
- one or more material, relevant, substantiable and representative features are compared;
- no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, proprietary names, other distinguishing marks and those of a competitor;
- the trademarks, proprietary names, other distinguishing marks, medicine, services, activities or circumstances of a competitor are not discredited or denigrated. Trade marks/proprietary name of a competitor may only be mentioned with a written permission from the competitor;
- no unfair advantage is taken of the reputation of a trade mark, proprietary name or other distinguishing marks of a competitor;
- medicine or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.

4.4 Any information, claim or comparison must be capable of substantiation.

4.5 Substantiation for any information, claim or comparison must be provided without delay at the request of the Authority. It need not be provided, however, in relation to the validity of indications approved in the product registration.

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4.6 When promotional material refers to published studies, clear and complete references must be given.

4.7 When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay at the request of the Authority, and a stamp with the text "unpublished data" must be placed on each page of the data.

4.8 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code.

Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made

4.9 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, toxic hazards or risks of addiction. The word 'safe' must not be used without qualification.

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Clause 4.8 Artwork, Illustrations, Graphs and Tables

Care must be taken to ensure that artwork does not mislead as to the nature of a medicine or any claim or comparison and that it does not detract from any warnings or contra-indications For example, anatomical drawings used to show results from a study must not exaggerate those results Depictions of children should not be used in relation to products not authorised for use in children

Particular care should be taken with graphs and tables to ensure that they do not mislead, for example by their incompleteness or by the use of suppressed zeros or unusual scales.

Differences that do not reach statistical significance must not be presented in such a way as to mislead

Graphs and tables must be adequately labelled so that the information presented can be readily understood. If a graph, table or suchlike is taken from a published paper but has not been reproduced in its entirety, the graph must clearly be labelled as having been adapted from the paper in question (See also Clause 4 5).

Any such adaptation must not distort or mislead as to the significance of that graph, table etc. It should also be noted that if a table, graph etc in a paper is unacceptable in terms of the requirements of the Code, because, for example, it gives a visually misleading impression as to the data shown, then it must not be used or reproduced in promotional material.

Clause 4.9 Use of the word 'safe'

The restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this Clause.

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4.10 Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

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Clause 4.10 Note 1: Superlatives

Superlatives are those grammatical expressions that denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was 'the best' treatment for a particular condition, for example, could not be substantiated as there are too many variables to enable such a sweeping claim to be proven.

The use of a superlative which could be substantiated is a simple statement of fact that can be very clearly demonstrated, such as that a particular medicine or health product is the most widely prescribed in South Africa for a certain condition, if this is not presented in a way that misleads as to its significance.

Clause 4.10 Note 2: Use of the Words 'The' and 'Unique'

In certain circumstances the use of the word 'the' can imply a special merit, quality or property for a medicine that is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is 'The analgesic' implies that it is in effect the best, and might not be acceptable under this clause.

Similarly, great care needs to be taken with the use of the word 'unique'. Although in some circumstances the word unique may be used to describe some clearly defined special feature of a medicine in many instances it may simply imply a general superiority. In such instances it is not possible to substantiate the claim, as the claim itself is so ill defined.

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4.11 The word 'new' must not be used to describe any product or presentation, which has been generally available, or any therapeutic indication, which has been available for more than twelve months in South Africa.

4.12 Advertising of a self-medication medicine shall not suggest that a product is a foodstuff, cosmetic or other non-medicinal product.

4.13 Although it is acceptable to indicate that a self-medication medicine is palatable, advertising shall make clear that it is a medicine.

4.14 Advertising shall not suggest, directly or indirectly, that a product contains an unknown active ingredient.

4.15 A product, or any of its attributes, shall not claim to be unique unless substantiated.

4.16 Advertising shall not mislead about the novelty of a preparation.

4.17 Advertising claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported by evidence and if in line with the product's registration dossier.

However, such evidence may not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims.

4.18 Advertising shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the MCC.

4.19 Advertising shall not suggest that the safety or efficacy of a product is due to the fact that it is natural unless this has been clinically proven to accepted industry standards.

4.20 Advertising shall not claim that a product is 'natural' unless all of its components are naturally occurring. 'Natural' can be used to describe those elements that are naturally occurring e.g. 'natural ingredient'.

4.21 Advertising shall not suggest that a product is herbal, unless all the active ingredients are plants or extracts of plants.

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4.22 Advertising shall not suggest that a product is side effect free. It is acceptable to highlight the absence of a specific side effect, e.g. 'no drowsiness'.

4.23 All comparisons shall be balanced and fair. All descriptions, claims and comparisons to be used, must be based on fact as has been approved by the MCC.

4.24 Advertising shall; not unfairly denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment.

4.25 Advertising shall not suggest that a product's effects are better than or equal to another identifiable product or treatment.

4.26 Brand names of products of other companies shall not be used without permission of the owner.

4.27 **Superiority claims shall not be used, unless supported by direct comparative tests or other demonstrations as approved by the MCC**

5. Disparaging References

5.1 **The medicine and activities of other pharmaceutical or healthcare companies, organisations or individuals, must not be disparaged.**

5.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

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Clause 5.1 Disparaging References

Much medicinal advertising contains comparisons with other products and, by the nature of advertising, such comparisons are usually made to show an advantage of the advertised product over its competitor. Provided that such critical references to another company's, organisation's or individual's products are accurate, balanced, fair etc., and can be substantiated, they are acceptable under the Code. Unjustified knocking copy, in which the products or activities of a competitor are unfairly denigrated, is prohibited under this clause. Attention is drawn to the requirements for comparisons set out in Clauses 4.2 to 4.5.

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6. Suitability and Taste

6.1 All material and activities must recognise the special nature of medicine and must not be likely to cause offence. High standards must be maintained at all times.

Clause 6 Suitability and Taste

The special nature of medicine requires that the standards set for the promotion of medicine are higher than those that might be acceptable for general commodity advertising. It follows therefore that certain types, styles and methods of promotion, even where they might be acceptable for the promotion of products other than medicine, are unacceptable. These include the use of sexual imagery for the purpose of attracting attention to the material.

6.2 The name or photograph of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.

6.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies, organisations or individuals, in a way that is likely to mislead or confuse.

6.4 Promotional material must not include any reference to the MCC unless this is specifically required by the MCC.

6.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

6.6 All material relating to medicine and their uses, which is sponsored by a pharmaceutical or complementary medicine company, organisation or individual, must clearly indicate that it has been sponsored by that company, organisation or individual.

The only exception to this is market research material, which need not reveal the name of the company, organisation or individual involved but must state that it is sponsored by a company, organisation or individual.

Clause 6 Declaration of Sponsorship

The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset

7. Disguised Promotion

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7.1 Promotional material and activities must not be disguised.

7.2 Market research activities, post-marketing surveillance studies, clinical assessments and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products.

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Clause 7.2 Note 1: Guidelines for Clinical Trials in South Africa

The "Guidelines for good practice in the conduct of clinical trials in human participants in South Africa" (DOH 2000 or later versions) shall be adhered to. Clinical trials or safety studies should not be undertaken solely for the purposes of promotion.

Clause 7.2 Note 2: Market Research

Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional.

The two phases must be kept distinct. Market research material should be examined before publication or use to ensure that it does not contravene the Code.

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7.3 Advertisements in published media must not resemble editorial matter. Care must also be taken with company-sponsored reports on meetings and the like to ensure that they are not disguised promotion. Sponsorship must be declared in accordance with Clause 6.

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Clause 7.3 Trademarks considered misleading by MCC

MCC may not accept a trademark and/or related artwork if it considers it misleading in any way in terms of the Medicines Act

8. Provision of Reprints and the Use of Quotations

8.1 Advertising should be clearly distinguished from editorial matter.

8.2 Reprints of articles in journals must not be provided unsolicited unless the articles have been refereed. If a non-refereed article is requested by a consumer, a copy may be provided on written request, provided that each page is stamped with the text "non-refereed article".

Clause 8.2 Provision of Reprints

The provision of an unsolicited reprint of an article about a medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed. Particular attention must be paid to the requirements of Clause 1.

When providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information.

8.3 Quotations from medical and scientific literature must accurately reflect the meaning of the author(s). If unpublished "personal communications" shall not be used unless the company is able to supply a written substantiation upon request.

Clause 8.3 Quotations

Any quotation chosen by a company for use in promotional material must comply with the requirements of the Code itself.

For example, to quote from a paper that stated that a certain medicine was 'safe and effective' would not be acceptable even if it were an accurate reflection of the meaning of the author of the paper, as it is prohibited under Clause 4.9 of the Code to state without qualification in promotional material that a medicine is safe.

Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance.

(See Clause 4 which prohibits misleading information, claims etc in promotional material).

Attention is drawn to the provisions of Clause 4.6, which requires that when promotional material refers to published studies, clear references must be given to where they can be found

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All personal communication statements should also be peer reviewed for scientific validity.

8.4 Quotations relating to medicine taken from public broadcasts, for example radio, television or Internet, and from private occasions, such as medical conferences or symposia, must not be used without the written permission of the speaker.

8.5 Testimonials should be less than 3 years old and be the genuine views of the user.

8.6 Promotional material should not include a recommendation by a person who, because of their celebrity status, may encourage consumers to take a medicine. A healthcare professional or celebrity should not be identified as the writer of a testimonial.

8.7 The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

Clause 8.7 Current Views of Authors

If there is any doubt as to the current view of an author, companies, organisations and individuals should check with the author prior to its use in promotional material.

9. Scientific Information Service

All companies, organisations or individuals must compile and collate all information about the medicine that they market, and must be able to provide such information to authorities, members of health care professions or the general public, where appropriate. This may include information about adverse drug reactions.

Comparisons made should be balanced and fair. All descriptions, claims and comparisons to be used, must be based on fact as have been approved by the Medicine Control Council. Superiority claims should not be used, unless supported by direct comparative tests or other demonstrations as approved by a recognised and competent Authority.

10. Certification of Promotional Material

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10.1 Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by the individual or by two persons on behalf of the company, or organisation in the manner provided by this clause.

Each company, organisation or individual should have a Standard Operating Procedure for this process, which must be available for audit by the MCC or the Authority.

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Clause 10.1 Certification

An acceptable way to comply with Clause 10.1 is for the final proof to be certified but this is not obligatory, provided that that which is certified is in its final form to which no subsequent amendments will be made.

All promotional material must be certified in this way including promotional aids, audio-visual material, promotional material on databases, Internet Websites and medical representatives' technical briefing materials.

Other material issued by companies, organisations or individuals that relates to medicine, but which is not intended as promotional material for those medicine per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange and the like, and educational material for patients etc, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

Cognisance should be taken of the fact that a non-promotional item can be used for a promotional purpose and might therefore come within the scope of the Code.

In certifying audio, audio-visual material and material used on interactive data systems or Internet, all companies, organisations or individuals must ensure that a written transcript of the material is certified including reproductions of any graphs, tables and the like that appear in the recording. In the event of a complaint, a copy of the written transcript of the material will be requested.

The guidelines on company, organisation or individual procedures relating to the Code give further information on certification.

See also the supplementary information to Clause 1 on promotion at international conferences regarding the certification of such material.

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10.2 One of the two persons in a company, or the individual, must be a registered healthcare practitioner or a responsible pharmacist or, in the case of a product for dental use only, a registered medical practitioner, a responsible pharmacist or a dentist.

The other must be an appropriate senior official of the company or organisation.

10.3 The names of those nominated as authorised signatories in 10.1, together with their qualifications, shall be submitted in advance to the Advertising Unit of the MCC or the Authority. Changes in the names of nominees must be notified within 30 days.

10.4 The certificate must state that the signatories have examined the final form of the material and that, in their opinion, it is in accordance with the requirements of the relevant advertising regulations and this Code, is not inconsistent with the product registration and

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Clause 10.2 Joint Ventures and Co-Promotion

In a joint venture in which a third party provides a service on behalf of a number of pharmaceutical and complementary medicine companies, organisations or individuals, the pharmaceutical and complementary medicine companies, organisations or individuals involved are responsible for any activity carried out by that third party on their behalf.

It follows therefore that the pharmaceutical and complementary medicine companies, organisations or individuals involved should be aware of all aspects of the service carried out on their behalf and take this into account when certifying the material or activity involved.

Similarly if two or more pharmaceutical and complementary medicine companies, organisations or individuals organise a joint meeting, each entity should ensure that the arrangements for the meeting are acceptable.

Under co-promotion arrangements whereby companies, organisations or individuals jointly promote the same medicine and the promotional material bears the names of two or more entities, each company, organisation or individual should certify the involved promotional material, as they will be held jointly responsible for it under the Code.

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the package insert, and is a fair and truthful presentation of the facts about the medicine.

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Material that is still in use must be re-certified at intervals of no more than two years to ensure that it continues to conform to the relevant advertising regulations and the Code.

10.5 Companies, organisations or individuals shall preserve all certificates. In relation to certificates for promotional material, the material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved.

Companies, organisations or individuals shall preserve certificates and the relevant accompanying information for not less than three years after the final use of the promotional material or the date of the meeting, and shall produce them on request from MCC or the Authority.

11. Relations with the General Public and the Media

11.1 Medicine must not be advertised to the general public if they are medicine which, though not prescription only, may not legally be advertised to the general public. This prohibition does not apply to vaccination campaigns carried out by companies, organisations or individuals and approved by the Department of Health and/or MCC.

11.2 Information about medicine that is made available to the general public either directly or indirectly must be factual and presented in a balanced way.

It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Clause 11.2 Financial Information

Information made available in order to inform shareholders, the Johannesburg Stock Exchange and the like by way of annual reports and announcements etc., may relate to both existing medicine and those not yet marketed. Such information must be factual and presented in a balanced way.

11.3 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer advised to consult his or her own health professional.

Clause 11.3 Requests for Information or Advice on Personal Medical Matters

This clause prohibits the provision of information or advice on personal medical matters to individual members of the general public requesting it.

The intention behind this prohibition is to ensure that companies, organisations or individuals do not intervene in the patient/healthcare relationship by

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offering advice or information that properly should be in the domain of the doctor, pharmacist or other health care professional.

All requests from members of the general public need to be handled with great care and a decision taken as to whether the company, organisation or individual can responsibly answer the enquiry.

Requests from patients for information may in some instances best be handled by passing the information to the patients' doctors, pharmacists or healthcare professionals for discussion with them rather than providing the information directly to the patients concerned.

11.4 Companies, organisations or individuals are responsible for information about their products that is issued by their public relations agencies.

Clause 11.4 Approval of Information

Information on medicine made available under this clause should be examined by the nominated signatories to ensure that it does not contravene the Code or the relevant statutory requirements.

12. Product Training

12.1 A suitably trained person gives all product training.

Product training with respect to over the counter medicines and complementary medicines may be offered to healthcare professionals, pharmacy assistants, health shop personnel and members of the public provided that :

12.2 The product training respects the spirit of the Code and in particular complies with Clauses 2, 3, 4, 5 and 6 of the Code.

12.3 Any training material including slides and handouts complies with the requirements of Clause 10.

12.4 Product training must be consistent with the package insert of a complementary medicine.

12.5 All background information that is given is consistent with the contents and requirements of a particular category of complementary medicine.

13. Product Information

13.1 It should be made clear when a user is leaving any of the company's sites, or sites sponsored by the company, or is being directed to a site, which is not that of the company.

Suitably trained persons may give information pertaining to complementary medicine products to health professionals, pharmacy and health shop staff, administrative staff and members of the public. In this regard all information shall Be:
given by suitably trained persons;

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	consistent with the package insert and all other information that may be required; I n keeping with the Code.
13.2 The responsible person mentioned in Clause 10 must periodically check that information that is given out is in keeping with the Code.	

14. Compliance with Undertakings

When an undertaking has been given in relation to a ruling under the Code, the company, organisation or individual, concerned must ensure compliance with that undertaking.

15. Prohibitions or Restricted Representations

15.1 An advertisement for a self-medication medicine must not contain, expressly or by implication a representation specified in Part 1 of Appendix 1.

15.2 An advertisement for a self-medication medicine must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in Part 2 of Appendix unless prior approval is given under the Medicines Act.

"Serious" in the context of this clause will mean forms of those diseases, conditions, ailments or defects which are:

Generally accepted not to be appropriate to be diagnosed and or treated without consulting a suitably qualified healthcare professional, and/or
Generally not accepted to be beyond the ability of the average consumer o evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

Public interest criteria:

The following should be taken into account:
Consumers or groups of consumers' vulnerability when faced with disease, condition, ailment or defect
Whether the reference would be likely to result in consumers not seeking professional advice where appropriate (such as where timely professional advice is important to prevent negative health consequences or irrevocable deterioration or progression of disease)
Whether the reference would be likely to have a negative impact on public health (or to have an effect on persons other than those to whom the advertisement is directed)

The World Health Organisation notes that responsible self-medication can:
Help prevent and treat symptoms and ailments that do not require medical consultation;
Reduce the increasing burden on medical services for the relief of minor ailments, especially when financial and human resources are limited;
Increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult; and
Enable patients to control their own conditions.

***Additional note**: If this were to apply to products that require prescribing following initial diagnosis, the Code would apply to the advertising of such products.*

16. Specific Categories

16.1 Vitamins

An advertisement for vitamins should not imply that vitamin supplements:

(a) are a substitute for good nutrition or a balanced diet

(b) are in any way superior to or more beneficial than dietary nutrients or that normal health may be affected by not taking vitamin supplements

16.2 Weight management

Claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, can only be made in conjunction with reference to sensible lifestyle factors including a diet and exercise

A weight reduction regime in which the intake of energy is lower than its output is the most common self-treatment for achieving weight reduction. Any claims made for the effectiveness of a weight reduction method or product should be backed if appropriate by trials on people; testimonials that are not supported by trials do not constitute substantiation.

Marketers must show that weight reduction is achieved by loss of body fat before claims are made for a weight reduction aid or regimen. Combining a diet with an unproven weight reduction method does not justify making weight reduction claims for that that method.

A statement to the effect of "Only effective when used in conjunction with a kilojoule controlled balanced diet " should be included on the label and in the advertisement for a product intended for weight loss/management.

16.3 Fat burning, fat and starch blocking, which include direct or implied claims, imply efficacy. All references should be linked, by means of an asterisk, to a clear disclaimer stating "this product has not been proven to burn fat/block fat/block starch"

Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance.

(See Clause 4 which prohibits misleading information, claims etc in promotional material).

Attention is drawn to the provisions of Clause 4.6, which requires that when promotional material refers to published studies, clear references must be given to where they can be found All personal communication statements should also be peer reviewed for scientific validity.

Evidence for slimming claims might consist of one or more categories: Experimental human studies (referred to as placebo-controlled trials) Observational human studies in which a group or groups of people are

studied in their environment (epidemiological studies)
An appropriate expert's extrapolation of relevant findings from seemingly irrelevant human studies (e.g. where a product's proven effect on ill people provides the basis of proving the proposed effect on those healthy people that marketers wish to target) Before and after studies with little or no control
Self-assessment studies(to support objective statements that can be ascertained only by consumer observation)
Published and unpublished literature (perhaps supporting the rationale behind a claim) Anecdotal evidence such as testimonials and endorsements.
If studies have not been published in reputable, peer-reviewed journals, an objective review should be carried by a suitably qualified person possessing relevant expertise

16.4 Claims based on traditional use: Indications can be based on evidence of traditional use of a substance or product, and/or on scientific evidence. Indications/claims are categorised depending on the level of claim being made.

All indications must be true, valid and not misleading, and should not lead to unsafe or inappropriate use of the product. Evidence must relate to the whole product or the same active ingredient(s) with similar dosage regimen, dose form and route of administration to the product/ingredient for which the claim is being made. Evidence must be available before claiming an intended use or indication for a product.
Claims and the levels and kinds of support must be in accordance with the Guidelines for Complementary Medicines.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH