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PART 1 OF 2

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 868 **22 August 2008**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

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

The Minister of Health in consultation with the Medicines Control Council intends, in terms of section 35 of the Medicines and Related Substances Act, 1965, (hereinafter referred to as "the Act") to make the regulation in the Schedule.

Interested persons are invited to submit, within three months from the date of publication of this notice, comments on the proposed regulation to the Director-General: Health (for the attention of the Cluster Manager: Medicines Regulatory Affairs) Private Bag X828, PRETORIA, 0001.

SCHEDULE

Amendment of regulation 25

1. Regulation 25 of the General Regulations Made in Terms of the Medicines and Related Substances Act, 1965, is hereby amended by the addition in subregulation (1) of the following paragraph:

"(d) Category D = Complementary and alternative medicines intended for use in humans or animals whether they require further manipulation or not, and exclude African Traditional Medicines."

DR ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

No. R. 869 22 August 2008

NATIONAL DEPARTMENT OF HEALTH

MEDICINES AND RELATED SUBSTANCES ACT, 1965

REGULATIONS RELATING TO COMPLEMENTARY AND ALTERATIVE MEDICINES

The Minister of Health in consultation with the Medicines Control Council intends, in terms of section 35 of the Medicines and Related Substances Act, 1965, (hereinafter referred to as "the Act") to make the regulations in the Schedule.

Interested persons are invited to submit, within three months from the date of publication of this notice, comments on the proposed regulations to the Director-General: Health (for the attention of the Cluster Manager: Medicines Regulatory Affairs) Private Bag X828, PRETORIA, 0001.

SCHEDULE

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Definitions

1. In these Regulations any word or expression defined in the Act or the General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (GN No. 510 of 10 April 2003) and not defined herein bears the same meaning as in the Act or the said regulations, and unless the context otherwise indicates-

"active ingredients" means that entity, moiety, species, or tincture that is responsible or is co-responsible for the activity of the medicine or substance;

"additional warnings" means any warnings known to an applicant that may not necessarily appear in the Schedules of medicines or substances;

"adverse drug reaction" means a response in human or animal to a medicine or substance which is harmful and unintended, and which occurs at any dosage and can also result from lack of efficacy of a medicine or substance, off-label use of a CAM or a CAM Substance, overdose, misuse or abuse of a CAM or a CAM Substance

"anthroposophical medicines" means any substance or mixture of substances, preparation, compound, product, or thing which:

a. is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with anthroposophical principles, techniques or philosophy;

b. is obtained by method of successive dilution and succession and / or trituration whether achieved manually, mechanically or whatever scale of dilution;
c. includes but is not limited to starting substances; and
d. includes nosodes, allersodes, isodes and sarcodes;

"aromatherapeutic essential oils" means volatile oils containing odiferous elements of the plant produced by methods which include but are not limited to: steam or water distillation of vegetable plant matter, the mechanical pressing of peels, CO_2 extraction and/or other distillation methods;

"ayurvedic medicines" means any substance or mixture of substances, preparation, compound, product, or thing which is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with ayurveda principles, techniques or philosophy;

"biochemic tissue salts" means biochemical cell salts essential to cellular structure and function used according to the principles of Schussler's biochemic therapy, singularly in combination;

"complementary or alternative medicine or substance" means any medicine or substance or mixture of substances which-

(a) originate from plants, minerals or animals and include sarcodes, nosodes, allersodes or isodes; and
(b) are complementary to the innate healing power of a human being or an animal; and
(c) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power in humans to mitigate, modify, alleviate, or prevent illnesses, abnormal physical or mental state or the symptoms thereof in humans or animals;

"raw material" means the primary raw material that has undergone no processing other than milling or drying;

"substance" means a tincture or an extract which is either an intermediate substance which is neither a raw material nor a finished product and it includes starting materials such as tinctures or extracts;

"Chinese medicines" means any substance or mixture of substances, preparation, compound, product, or thing which is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with Chinese Medicine principles, techniques or philosophy;

"contra-indications" means any specific condition or situation in which a medicine or substance or dosage is improper, undesirable or inadvisable to be used;

"first derivative - means an extract made from plants or plant parts that has been modified by deliberate and intended manipulation using non standard extractants, enrichments or separations of individual ingredients;

"flower and gem essences" means substances produced on the principle of vibrational healing prepared using venous techniques to harness suitable energy from naturally occurring plants, minerals or gems;

"gemmotherapeutic substances" means ethanolic glycerine macerates prepared from fresh, embryonic plant or vegetative tissue;

"herbal medicines" means non-pathogenic fungi, algae and lichens or a multi-component material derived from a plant, used for medicinal purposes;

"homoeopathic medicines" means any substance or mixture of substances, preparation, compound, product, or thing which:

a. is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with homotoxicology principles, techniques or philosophy;
b. is obtained by method of successive dilution and succession and / or trituration whether achieved manually, mechanically or whatever scale of dilution; and
c. includes but is not limited to starting substances, nosodes, allersodes, isodes and sarcodes;

"homotoxicological medicines" means any substance or mixture of substances, preparation, compound, product, or thing which:

a. is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with homotoxicology principles, techniques or philosophy;
b. is obtained by method of successive dilution and succession and / or trituration whether achieved manually, mechanically or whatever scale of dilution;
c. includes but is not limited to starting substances, nosodes, allersodes, isodes and sarcodes;

"indication" means a symptom that describes the use of a medicine or a particular circumstance or function indicated by the effect that that the medicine is likely to have;

"intermediate complementary medicine or substance" means a medicine or a substance that has undergone processing so that it is no longer in its raw material form and which needs to undergo further processing of any kind, including possibly labelling, in order to be a finished product;

"intern" means a person registered as such in terms of section 19 of the Allied Health Professionals Act, Act 63 of 1982;

"investigators brochure" means the basic document which is required in a clinical trial of a medicine or substance together with the clinical trial protocol, containing both clinical and non-clinical data related to the medicine or substance;

"mineraloid substances" means original biochemic cell salts essential to cellular structure and function in material form, used according to the principles of Schusslers biochemic therapy, single of in combination;

"minimum legibility" means a printing in 6-point Helvetica, typeface in black ink on white cartridge paper or the equivalent thereof;

"mode of action - means the manner which explains the function or way in which a medicine or substance purports to work;

"nutraceutical" means any natural or nature identical food or food component, extract, slat, derivative or concentrate thereof and excludes nutritional food substances;

"nutritional food substance" means any natural or nature identical food or food component, extract, salt, derivative or concentrate thereof;

"reference number" means a number allocated by a person dispensing a medicine to a particular prescription for a particular patient;

"Sowa Rigpa medicines" means any substance or mixture of substances, preparation, compound, product, or thing which is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with Sowa Rigpa principles, techniques or philosophy;

"the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); and

"Unani-Tibb medicines" means any substance or mixture of substances, preparation, compound, product, or thing which is compounded, formulated, manufactured, prepared, manipulated, altered or adjusted in accordance with Unani-Tibb principles, techniques or philosophy.

Application of regulations

2. These regulations are specifically made in terms of section 35(6) of the Act and apply only to complementary and alternative medicines and substances (hereinafter referred to as "CAMS").

Classes

3. CAMS are subdivided into the following classes:

(a) Anthroposophical medicines;
(b) Aromatherapeutic essential oils;
(c) Ayurvedic medicines;
(d) Biochemic tissue salts;
(e) Chinese medicines;
(f) Gemmotherapeutic substances;
(g) Flower and gem essences;
(h) Herbal medicines
(i) Homoeopathic medicines;
(j) Homotoxicological medicines;
(k) Mineraloid substances;
(l) Nutraceuticals;
(m) Nutritional food substances;
(n) Sowa Rigpa medicines;
(o) Unani-Tibb medicines; and
(p) Any combinations of CAMS classes.

Applications for registration

4. (1) Any person residing and doing business in the Republic may make an application for the registration of CAMS.

(2) An application referred to in sub-regulation (1)-

(a) shall be made in at least one official language to the Registrar in a form determined by the Council;
(b) shall include the particulars of the person with appropriate knowledge of all aspects of CAMS who shall be responsible for communication with the Council;
(c) may be made in writing or electronically; and
(d) shall be accompanied by an application fee.

(3) An electronic application for the registration of CAMS may only be used in instances where:

(a) such CAMS is listed in Schedules 0, 1 or 2;
(b) indications or health claims in respect thereof correspond with those ascribed to its active ingredients in the Schedules;

(c) compulsory words and phrases, as contained in the Schedules in respect of such CAMS can and are being used by the applicant;

(d) the dosage form is consistent with the dosage forms permitted for Schedules 0, 1 or 2.

(4) An application for registration must be made in writing in instances where such CAMS:

(a) appears in Schedules 3, 4, 5, 6 or 7;

(b) contains first derivatives not appearing in any of the Schedules; or

(c) cannot, for any reason, be made electronically.

(5) A CAMS in respect of which an application for registration is made must comply with the technical requirements as determined by Council and the Council may request any additional information that it deems necessary.

Particulars to be published in the Gazette

5. The following information with regard to a CAMS in respect of which an application for registration has been approved by the Council shall be published in the *Gazette* –

(a) proprietary name;

(b) registration number;

(c) approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit;

(d) dosage form;

(e) name of the holder of the certificate of registration;

(f) name and address of the manufacturer(s)and manufacturing facilities;

(g) name of the final product release control (FPRC);

(h) name of the final product release responsibility (FPRR);

(i) date of registration; and

(j) conditions of registration, if any.

Information that must appear in the register

6. The information referred to in paragraphs (a) - (j) of regulation 5 must be entered into the register by the Registrar.

Registration certificate

7. A certificate of registration shall be issued by the Registrar in the form determined by the Council after the Council has approved of the registration of a CAMS.

Application for amendment of the application or register

8. (1) A holder of a certificate of registration may submit to the Registrar an application on a form determined by the Council to amend an application previously made or an entry made in the Register with regard to a particular CAMS.

(2) The application referred to in sub-regulation (1) shall be accompanied by an application fee and must contain the following information –

(a) the name of the applicant;
(b) registration number;
(c) business address of the applicant;
(d) declaration by the applicant that the information furnished is complete and accurate;
(e) the details of the amendment applied for; and
(f) any other information as may be determined by the Council.

Labelling

9. (1) The immediate container of every CAMS that is sold must have a label on which the particulars in sub-regulation (3) appear.

(2) The label shall be in clearly legible and indelible letters in English and at least one other official language.

(3) The following particulars in respect of a CAMS must appear on the label:

(a) class;
(b) the scheduling status preceded by the letters **"S"** surrounded by a square border immediately preceding the proprietary name;
(c) the proprietary name;
(d) the registration or application number;
(e) the dosage form;
(f) the approved name of each active ingredient and the quantity and / or potency thereof where applicable contained in a dosage unit, or per suitable mass or volume or unit, where applicable;
(g) the name and percentage of any preservative, if applicable;
(h) the quantity of ethyl alcohol in those intended for oral or parenteral administration, expressed as a percentage of the total volume of the complementary medicine or substance, if such quantity exceeds two percent of the volume;
(i) the total content of the package expressed in the appropriate unit or volume;

(j) the indications, health claims and/or the class related indications for the use together with the compulsory wording and phrases as well as all warnings and time warnings, where applicable;

(k) the recommended dosage, where practical and applicable;

(l) the instruction "Shake the bottle before use" where applicable;

(m) the particular route of administration must be indicated by means of suitable words or appropriate abbreviations;

(n) the lot number;

(o) the expiry date;

(p) the name and address of the holder of the certificate of registration or application for registration;

(q) the requirements regarding the manner in which it shall be stored with specific reference to the applicable storage temperature and such other precautions required for preservation;

(r) the statement: "For external use only", where applicable;

(s) the warning: "Keep out of reach of children";

(t) the warning: "Do not use more than 30 days after opening", in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability has not been approved by Council;

(u) any specified warning required to be stated on the label as a condition of registration;

(v) contra-indications, additional warnings, side-effects and special precautions, known symptoms of overdose and particulars of treatment shall be stated on the label where practical and applicable.

(4) In an instance where the package bears both an immediate container label and an outer label or carton, the above requirements in sub-regulation (1) shall apply to the outer label or carton as well (unless the inner label is clearly and fully visible through the outer carton); provided that it shall be sufficient to state on the immediate container label-

(a) of a CAMS intended for administration by injection and having a total volume not exceeding 5 ml, the details provided for in sub-regulation 10 (3) (c), (f) (m), (n), (o) and (p);

(b) in the case of an ointment, cream, gel, or powder having a net mass not exceeding 10 grams, the details provided in subregulation 10 (3) (c), (d), (f), (g), (n), (o), (p), and (u);

(c) in the case of a liquid, solution or suspension having a total volume more than 1 ml but not exceeding 15 ml, the details provided in subregulation 10 (3) (c), (d), (e), (f), (n), (o), (p), (t) and (u);

(d) in the case of a liquid, solution or suspension excluding those intended for administration by injection having a total volume not exceeding 1 ml, the details provided in subregulation 10 (3) (c) and (n);

(e) in the case of those packed in blister, inner flexible packaging or any similar packaging, the details provided for in subregulation 10 (3) (c), (n), (o) and (p);

(5) The Council may, on application by an applicant, authorise the inclusion on the label any specified information not required by these regulations to be so included;

(6) The labelling requirements shall not apply to any CAMS sold –

(a) in accordance with the provisions of section 14 (4) of the Act;

(b) by a practitioner or intern, or by a pharmacist, on the prescription of a practitioner for the treatment of a particular patient; or

(c) in a hospital or clinic on a prescription issued by a practitioner for the treatment of a particular patient;

(7) a proprietary CAMS that is dispensed by a practitioner or intern, or by a pharmacist, on the prescription of a practitioner for the treatment of a particular patient shall be dispensed in a package to which a label is attached containing the following information:

(a) the proprietary name;

(b) the name of the person for whose treatment it is sold, or in the case of a veterinary one, the name of the person to whom it is supplied and the description as accurate as possible of the animal for which the treatment is intended;

(c) the directions with regard to the manner in which it should be used;

(d) the name and business address of the practitioner or pharmacy selling it;

(e) the date of dispensing;

(f) a reference number allocated to such prescription by the dispenser; and

(g) any additional information regarding storage conditions, warnings or safety precautions, as may be required.

(8) In respect of CAMS sold the following shall be stated on the label:

(a) the name of the raw material;

(b) the scheduling status, where applicable;
(c) the composition where applicable;
(d) the class to which the raw material belongs, where applicable;
(e) storage instructions;
(f) the name of the supplier;
(g) the expiry date;
(h) the batch lot number;
(i) the alcohol concentration, where applicable;
(j) the total volume or quantity supplied.

Package inserts

10. (1) Each package of a CAMS 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 at least one official language and in type having a minimum legibility under the headings and in the format specified in this regulation and which shall contain the following particulars –

(a) the scheduling status;
(b) the proprietary name;
(c) the dosage form;
(d) the composition, potency or concentration of all substances in the formulation contained in a dosage unit, or per suitable mass or volume or unit, where applicable;
(e) the class;
(f) the indications, health claims and/or the sub-category related indications for use together with the compulsory wording and phrases as well as all warnings and time warnings, where applicable;
(g) the information required by Council to be on the package insert, where applicable;
(h) the mode of action, where applicable;
(i) contra-indications, where applicable;
(j) warnings and time warnings, where applicable;
(k) interactions;
(l) pregnancy and lactation;
(m) the dosage and directions for use;
(n) side effects and special precautions;
(o) known symptoms of overdosage and particulars of its treatment;
(p) identification;
(q) presentation;
(r) storage instructions that are practically formulated and which includes storage temperatures;
(s) the registration number, alternatively the application number;

(t) the name and business address of the holder or proposed holder of the certificate of registration;

(u) the date of publication of the package insert.

(v) In an instance where the application was made electronically, only the indications that are stated in the applicable lists may be used in a package insert.

(2) The requirements in subregulation (1) shall not apply to CAMS-

(a) sold in accordance with the provisions of section 14 (4) of the Act;

(b) sold by a practitioner, or intern or by a pharmacist, on the prescription of a practitioner for the treatment of a particular patient, or

(c) sold in a hospital or clinic on a prescription issued by a practitioner for the treatment of a particular patient, unless the dispensed prescribed one is a proprietary product, in which case only the requirements pertaining to labelling under regulation 10 (7) shall apply;

(d) where the information is contained on the immediate container label.

Patient information leaflets

11. (1) Where required, Schedule 3 and higher CAMS may contain a patient information leaflet instead of the package insert, provided that the package insert is supplied or can immediately be supplied to a practitioner on demand.

(2) The patient information leaflet shall contain the following information in at least one official language-

(a) scheduling status;

(b) class;

(c) the proprietary name and dosage form;

(d) the composition, potency or concentration of all substances in the formulation contained in a dosage unit, or per suitable mass or volume or unit, where applicable;

(e) the indications, health claims and/or the sub-category-related indications;

(f) information required by the Council to be on the patient information leaflet;

(g) instructions before taking the medicine, which include where applicable-

i) contra-indications;

ii) precautions;

iii) warnings e.g. concerning sedative properties or risks involved with sudden withdrawal;

iv) interactions;

v) the following general statements:

(aa) "If you are taking the medicine on a regular basis, using the medicine at the same time with another medicine or medicine may cause undesirable interactions. Please consult your health care professional for advice."

(bb) "As sometimes different medicines taken together may cause undesirable effects, make sure you have disclosed all your current medicines and medications to your health care professional. If you start taking any new additional medicines while taking this one, consult your health care professional.";

(cc) "If you are pregnant or breast feeding your baby while taking this medicine please consult your health care professional for advice.";

(h) Instructions on how to take the medicine, including the following statements:

i) "Do not share medicines prescribed for you with any other person without discussing this thoroughly with your health care professional .";

ii) "In the event of overdosage, consult your health care professional or contact the nearest hospital / clinic";

(i) Side-effects, including the following general statement:

i) "Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your health care professional for advice.";

ii) "If you experience any untoward effects, please consult your health care professional.";

(j) Storage and disposal information, including the following general statement: "Store all medicines out of reach of children.";

(k) Presentation, which includes the number, volume or mass per package unit and a description of the packaging material, e.g. bottle, blister pack;

(l) identification, i.e. the description of its physical appearance as tablet, capsule, etc.;

(m) registration or application number;

(n) the name, business address and telephone number of the holder or proposed holder of the certificate of registration;

(o) the date of publication of the patient information leaflet.

(3) The Council may authorise a deviation from sub-regulation (1).

(4) A person dispensing or administering a proprietary CAMS must ensure that a patient information leaflet is made available at the point of such dispensing or administration.

Marketing

12. A marketing Code of Practice prescribed by the Minister in terms of section 18C of the Act applies to CAMS.

Advertisements

13. (1) The under mentioned requirements shall apply to any advertisement of a CAMS.

(2)(a) CAMS which do not contain a scheduled substance and those which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and

(b) CAMS which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6, may be advertised only for the information of medical practitioners, dentists, veterinarians, pharmacist, practitioners and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein;

(c) Paragraph (b) shall not be so construed as to prohibit informing the public of the prices, names, pack sizes and strengths of CAMS which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6.

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

(4) A written advertisement for a CAMS shall contain-

(a) the proprietary name of such CAMS;

(b) the approved name of quantity of each active ingredient of such CAMS in lettering having minimum legibility: Provided that, in the case of a CAMS containing only one active ingredient, such letting shall be not less than one half the size of the largest letting used for the said proprietary name; and

(c) in the case -

(i) of a registered CAMS, the registration number allocated to it;

(ii) of a CAMS in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by Registrar, followed by the words 'Act 101/1965';

(iii) 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 advertisement;

(iv) of a veterinary medicine, an indication that the CAMS is for veterinary use; and

(v) an indication that the medicine must be used in accordance with applicable CAMS principles.

(5) in the case of an advertisement for a CAMS which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredients unless a reference of this nature has been approved by the Council for inclusion in the package insert of such medicine.

Importation

14 (1) No person shall import any finished CAMS which has not been issued with a Registration Number or an Application Number into the Republic except through one of the following ports of entry-

(a) Cape Town Airport or harbour;
(b) Port Elizabeth Airport or harbour;
(c) Durban Airport or harbour; or
(d) OR Tambo International Airport.

(2) A person may only import a CAMS if such person is licensed in terms of the Act to import such medicines or products;

(3) The Council may authorise the importation of unregistered CAMS which do not have a registration number or an application number in the Republic.

(4) No person shall order, receive or be supplied with any unregistered CAMS from outside of the Republic for personal use unless the Council has authorized the said person in terms of Section 21 of the Act to import during a specified period a specified quantity of the particular medicine.

Importation of intermediate substances or raw materials

15. (1) No person shall import into the Republic any intermediate substances unless the substance can be shown to be an ingredient in a finished product which has been issued with a registration number or an application number, or which can be shown to be a substance that is supplied to a person authorised to compound and dispense under Section 22 (C) (1) of the Act, and such importation must only be through one of the following ports of entry—

(a) Cape Town Airport or harbour;
(b) Port Elizabeth Airport or harbour;
(c) Durban Airport or harbour; and
(d) OR Tambo International Airport.

(2) No person shall import any raw material into the Republic except through one of the following ports of entry—

(a) Cape Town Airport or harbour;
(b) Port Elizabeth Airport or harbour;
(c) Durban Airport or harbour; and
(d) OR Tambo International Airport.

(3) Raw materials grown and harvested in Africa from the following countries may be imported through the following border crossings:

Namibia: Nakop and Vioolsdrift;
Lesotho: Maseru Bridge and Ficksburg Bridge;
Mozambique: Komatipoort (Lebomba);
Swaziland: Oshoek and Golela;
Botswana: Tlokweng; or
Zimbabwe: Beitbridge.

Exportation

16. A person may only export a CAMS if such person is licensed in terms of the Act to export such CAMS and a registration number or an application number in the Republic has been allocated in respect thereof.

Possession for personal medical use by persons entering or departing from the Republic

17. (1) Any person entering or departing from the Republic may be in possession of a CAMS for personal medicinal use, which does not exceed the quantity required for use for a period of three months.

(2) A person referred to in sub-regulation (1) must in respect of Schedule 3 and above CAMS-

(a) have a valid prescription or proof of purchase from a legal supplier; and
(b) upon entering the Republic, have his or her particulars of residence in the Republic, recorded at the port of entry.

Prescription book

18. (1) A prescription book or other permanent record in respect of Schedule 2 and higher shall be kept on all premises where such CAMS are dispensed and shall contain the following details:

(a) the name of a CAMS;
(b) the date on which the prescription was dispensed;
(c) the dosage form and quantity;
(d) the name and address of the patient, or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the complementary medicine or substance was sold;
(e) the name of the practitioner, medical practitioner, dentist, veterinarian, or any other authorised person who issued the prescription; and
(f) a prescription reference number.

(2) The record in sub-regulation (1) shall be retained at the business address of the dispensing practitioner for a period of at least five years after the date of the last entry made therein.

Record keeping by manufacturer, distributor or wholesaler

19. (1) A manufacturer or wholesaler of CAMS shall keep a record in respect thereof in the form of an invoice that shall reflect:

(a) the date and transaction of every sale;
(b) the name of the complementary medicine or substance;
(c) the name and contact details, including the address of every purchaser;
(d) the quantities sold; and

(e) the price at which it was sold.

(2) a record referred to in sub-regulation (1) shall be kept for a period of five years from the date of sale.

Adverse drug reaction

20. (1) The applicant or holder of a certificate of registration in respect of a CAMS shall inform the Council, in the manner and within the time frame as determined by the Council, of suspected adverse reactions reported to him or her, as a result of the use of such CAMS.

(2) Sub-regulation (1) also applies in the case of unregistered CAMS used in terms of sections 14 (4), 15C and 21 of the Act.

(3) The holder of the certificate or the applicant referred to in sub-regulation (1), or the practitioner as the case may be, shall –

(a) within the time frame determined by the Council after receipt of the report referred to in sub-regulation (1) inform the Council of the steps to be taken to address the adverse reactions;

(b) whenever requested by the Council, conduct a concise critical analysis of the safety and efficacy profile of the CAMS concerned and submit the results thereof to the Council within a specified time frame; and

(c) in an instance where, after receipt of the results referred to in paragraph (b), the Council determines that the CAMS may not be safe to use, submit, if required to do so to the Council –

(i) case reports of all suspected adverse reactions in respect of the CAMS; and

(ii) other pharmacovigilance data such as drug usage figures, periodic safety update reports, pharmacovigilance studies, or any other information as determined by Council etc;

(d) keep and maintain or have access to records of all adverse reaction data in respect of his, her or its CAMS.

(4) Nothing in this regulation shall prohibit any person from reporting any adverse drug reaction to the Council.

Repacking

21. A CAMS may only be repacked by a manufacturer.

Destruction

22. (1) CAMS shall be destroyed in the case of Schedule 1 and higher, by a pharmacist or an authorised person in charge of a place where they are kept and such pharmacist or authorised person shall certify such destruction.

(2) No CAMS may be disposed of into municipal sewerage systems.

(3) The destruction or disposal of CAMS must be done in such a manner that they are not retrievable.

Conduct of clinical trials

23. (1) Any person desiring to initiate or conduct a clinical trial in respect of an unregistered CAMS, a new indication or new dosage regimen of a registered one, shall apply to the Council for authority to conduct such a clinical trial on a form determined by the Council.

(2) An application referred to in sub-regulation (1) shall be accompanied by an application fee, and shall contain at least the following information:

(a) trial protocol;

(b) investigator's brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human pharmacological and clinical data with the substance concerned;

(c) Curriculum Vitae of all investigators;

(d) signed declaration by the applicant and all investigators that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by the Council in the conduct of the trial; and

(e) informed consent document and endorsement by any ethics committee recognised by the Council; and

(f) proof of trial insurance to cover participants and trialists.

(3) The clinical trial protocol referred to in sub-regulation (2)(a) shall contain at least the following information:

(a) number of human subjects to be involved in the trial;

(b) the name of an investigator who shall be an appropriately qualified and competent person approved by the Council, resident in the Republic;

(c) the name of the person responsible for the trial at each site; and

(d) any other information as determined by the Council.

(4) Clinical trials must be conducted in accordance with guidelines for good clinical practice as determined by the Council.

(5) No person shall conduct clinical trials referred to in sub-regulation (1) without the authorisation of the Council.

(6) The person conducting the clinical trial must submit progress reports to the Council after every six months from the date when the clinical trial was started and 30 days after the completion or termination of the clinical trial.

(7) The Council may request additional information, inspect a clinical trial or withdraw the authorisation to conduct a clinical trial if the Council is of the opinion that the safety of the subjects of the trial is compromised, or that the scientific reasons for conducting the trial have changed.

Licence compound or dispense

24. (1) As contemplated in section 22C(1) of the Act, a practitioner desiring to dispense or compound or dispense or both compound and dispense CAMS shall apply to the Director-General for a licence to compound or dispense CAMS.

(2) An application referred to in sub-regulation (1) shall be accompanied by an application fee as determined by the Director-General.

(3) The application shall contain at least the following information:

(a) the name and both residential and business addresses (both physical and postal) of the applicant;
(b) the exact location of the premises where compounding or dispensing will be carried out;
(c) proof of completion of a supplementary course contemplated in section 22C(2) of the Act;
(d) telephone and fax numbers of the applicant, where available;
(e) proof of registration with the relevant statutory council;
(f) any other information that the Director-General may require; and
(g) proof of ability to supply a patient information leaflet or package insert where appropriate.

(4) A person referred to in sub-regulation (1) who has been issued with a licence shall:

(a) keep sales records either in hard copy or electronically relating to CAMS compounded or dispensed for a period of 5 years from the date of sale;

(b) ensure that the dispensary and any premises where CAMS are kept are suitable for compounding and dispensing in accordance with good dispensing practice;

(c) keep the CAMS under the manufacturer's recommended storage conditions as specified on the label and or package insert;

(d) not pre-pack CAMS at the premises unless authorised to do so by the Director-General in terms of section 29 (4) of the Pharmacy Act, 1974;

(e) label CAMS properly with the name of the patient and a reference number linking the patient to a patient record;

(f) not compound or dispense CAMS to patients unless the sale is preceded by a diagnosis and a prescription for a particular patient;

(g) not keep expired complementary medicines or substances on the premises other than in a demarcated area in a sealed container clearly marked: "EXPIRED MEDICINES" and such expired medicines shall be destroyed in terms of regulation 22;

(h) secure the premises where the compounding and dispensing is carried out whenever he or she is not physically present at those premises;

(i) withdraw the CAMS in the event of a recall;

(j) conspicuously display the licence in the premises referred to in paragraph (b); and

(k) comply with the conditions of his or her licence.

(5) For the purposes of this regulation, "compounding or dispensing" does not refer to a CAMS requiring preparation for a once-off administration to a patient during a consultation.

Licence to manufacture, distribute, act as a wholesaler, import or export

25. (1) A person wanting to manufacture, import, export, or act as wholesaler or distributor of CAMS must-

(a) prior to commencing business-

(i) apply to the Council for a licence to manufacture, import, export, act as wholesaler or distribute such medicines or substances;

(ii) appoint, and designate as such a responsible person who will control the manufacturing, importing, exporting, wholesaling or distribution;

(iii) appoint and designate a natural person who resides in the Republic, who shall be responsible to Council for compliance with the Act;

(b) submit to the Registrar an application, on a form determined by the Council, for a licence as contemplated in sub-regulation (1) (a) (i);

(c) submit acceptable documentary proof as part of the application relating to—

(i) the particulars of the owner of the business;

(ii) the qualifications and experience of the responsible person contemplated in sub-regulation1 (a) (ii);

(iii) the qualifications of the staff involved with manufacturing, importing, exporting or distributing in terms of the Act;

(iv) the ability to comply with Good Manufacturing or Distribution Practices as determined by Council, which shall include—

(aa) a copy of a local area map of the location of the manufacturing or distribution premises indicating all adjacent properties and the nature of the business being carried on, on such properties;

(bb) a floor plan of the building in which the business premises are situated;

(cc) layout of the actual manufacturing or distribution premises;

(dd) an inventory all of equipment to be used conducting the business;

(ee) a manual of practices and procedures to be implemented to ensure the safety and quality, and where applicable, efficacy of the medicine to be manufactured or distributed and sold;

(2) must specify the CAMS to be manufactured, imported, exported, warehoused, distributed and sold;

(3) must pay the application and inspection fees as determined by the Council.

(4) The Registrar may give the person referred to in sub-regulation (1) written notice to furnish the Council with such additional documentation or information as the Council may require, within a reasonable time, specified in the written notice.

(5) The Council must inspect the business premises specified in the application.

(6) If the Council is satisfied that—

(a) the person referred to in sub-regulation (1) complies with the prescribed requirements;

(b) the application for a licence to manufacture, act as wholesaler, or distribute CAMS complies with the prescribed requirements; and

(c) the applicant is able to comply with good manufacturing or distribution practices'

the Council must approve, with or without conditions, the application and issue such a person with a licence.

(7) The Registrar must—

(a) keep a separate register for each of the type of licensees referred to in sub-regulation (1) (a) (i); and
(b) enter the licence number, the name of the licensee and his or her physical and postal addresses, in such register.

(8) Notwithstanding the period of validity of the licence the licensee shall pay the annual fee for continued registration as determined by the Council.

(9) A licensee must notify the Registrar in writing of any change to any of the particulars furnished in the application or entered in the register, which occurs after the issue of the licence.

(10) Any entry into the register which is proved to the satisfaction of the Council to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.

(11) A person in respect of whose entry and removal as contemplated in sub-regulation (10) has been made must be notified of such removal and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

(12) The Council may direct the Registrar to remove from the register the name of the licensee—

(a) who does not comply with the Act or the conditions of a licence;
(b) if the responsible person fails to control the manufacturing, importing, exporting, wholesaling or distribution; and
(c) if 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, 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.

Period of validity and renewal of a licence

26. (1) A licence issued in terms of regulation 24 shall be valid for a period of three years whereas a licence issued in terms of regulation 25 shall be valid for a period of five years from the date of issue.

(2) A licence referred to in sub-regulation (1) which has expired may be renewed upon application to the Director-General or the Council, as the case may be.

(3) An application referred to in sub-regulation (2) shall—

(a) contain at least the information or documentation referred to in regulations 24 (3) and 25 (1) (c), as the case may be;
(b) be accompanied by a prescribed fee; and
(c) be made at least 90 days before the expiry of the existing licence.

Particulars that must appear on a prescription book

27. (1) Every prescription for a CAMS must be written in legible print, typewritten or computer generated and signed in person by a practitioner or intern, medical practitioner, dentist, veterinarian or authorised prescriber and must at least state the following:

(a) the name, qualification, practice number and address of the prescriber;
(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 medicine is delivered in the case of a prescription issued by a veterinarian;
(c) the date of issue of the prescription;
(d) the approved name or the proprietary name of the medicine;
(e) the dosage form;
(f) the strength of the dosage form and the quantity of the medicine to be supplied;
(g) instructions for the administration of the dosage, frequency of administration and the withdrawal period in the case of veterinary medicine for food producing animals;
(h) the age and sex of the patient and in the case of veterinary medicines, the animal species; and
(i) the number of times the prescription may be repeated.

(2) In the case of a faxed, e-mailed, telephone or electronic transmission by other means of a prescription, the pharmacist or authorised dispenser must verify the authenticity of the prescription.

Taking of samples

28. (1) An inspector may take a sample or any quantity of samples of a medicine or substance for purposes of testing, examination or analysis in terms of the Act, or for any other investigational purposes, by a designated person.

(2) The sample or samples contemplated in sub-regulation (1) must—

(a) be taken in the presence of the person who is in charge of such medicine or substance, or in the absence of such person, in the presence of any witness present;

(b) be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;

(c) be packed and sealed and suitably labelled or marked in such a manner as its nature may permit and must be transmitted by any suitable means to the designated person together with the certificate signed by the inspector, a copy of which must be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.

(3) A sample or samples contemplated in sub-regulation (1) must as soon as possible be tested, examined or analysed and a report of the results thereof be submitted to the Registrar.

(4) An inspector referred to in sub-regulation (1) may take a sample during a routine inspection from a manufacturer, a wholesaler, practitioner, therapist or retailer for testing, examination or analysis in terms of these regulations.

(5) Notwithstanding sub-regulation (1), the Council may require any applicant or holder of a certificate of registration for a medicine or substance or substance to supply the Council with a sample of a particular medicine or substance, or documentation relating to the medicine or substance, in order to test, examine or analyse such sample.

(6) Certificates or reports issued in terms of this regulation must be submitted to the Registrar within seven days from the date of issue.

Seizure of CAMS

29. (1) A CAMS may be seized if it—

(a) is unregistered or does not have an allocated application number and is being sold in contravention of the Act;

(b) is suspected counterfeit;
(c) is misbranded;
(d) has expired;
(e) is suspected stolen;
(f) is scheduled and is possessed by an unauthorised person or by an authorised person but in unauthorised quantities;
(g) has been declared undesirable in terms of the Act;
(h) belongs to the State and is found in possession of an unauthorised person; or
(i) is used in an unauthorised clinical trial.

(2) An inspector seizing any item shall as soon as possible, and at the scene of seizure, make a written inventory of all items seized and the inventory shall include—

(a) the date, place and time of seizure;
(b) the name and personal details of the person from whom the items were seized;
(c) the name and quantity of every item seized; and
(d) the name of the inspector conducting the seizure.

(3) An seized item may be used as evidence in any criminal proceedings in terms of the Act.

Offences and penalties

30. (1) Any person who fails to comply with, or contravenes the provisions of or wilfully furnishes incorrect information in respect of

(a) Regulation 10 with regard to labelling;
(b) Regulation 11 with regard to package inserts;
(c) Regulation 12 with regard to the patient information leaflet;
(d) Regulation 13 with regard to the marketing;
(e) Regulation 14 with regard to advertising;
(f) Regulations 15 and 16 with regard to importation;
(g) Regulation 16 with regard to exportation;
(h) Regulation 17 with regard to possession;
(i) Regulation 18 with regard to the prescription book;
(j) Regulation 22 with regard to the destruction of medicines;
(k) Regulation 23 with regard to the conduct of trials;
(l) Regulation 24 with regard to the licence to compound or dispense;
(m) Regulation 25 with regard to the licence to manufacture, act as a wholesaler or a distributor,

shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

(2) Generally any person who fails to comply with, or contravenes the provisions of, or wilfully furnishes incorrect information in respect of these regulations, or sells adulterated, counterfeit, unregistered, expired medicines or substances without an application number allocated to him, shall be guilty of an offence and upon conviction be liable to a fine or to imprisonment for a period not exceeding 10 years.

Guidelines

31. (1) The Council shall determine the guidelines for the evaluation of the safety, efficacy and quality of CAMS and shall publish such guidelines in the *Gazette*.

Commencement

32. These regulations shall come into operation twelve months from the date of publication.

ME TSHABALALA-MSIMANG
MINISTER OF HEALTH

No. R. 870 22 August 2008

MEDICINES AND RELATED SUBSTANCES ACT, 1965

SCHEDULES ON COMPLEMENTARY AND ALTERNATIVE MEDICINES MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

The Minister of Health, on the recommendation of the Medicines Control Council intends, in terms of section 22A(2) of the Medicines and Related Substances Act, 1965, (hereinafter referred to as "the Act") to make the Schedules in the Schedule.

Interested persons are invited to submit, within three months from the date of publication of this notice, comments on the proposed Schedules to the Director-General: Health (for the attention of the Cluster Manager: Medicines Regulatory Affairs) Private Bag X828, PRETORIA, 0001.