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GENERAL

IT is hereby notified that the Minister of Health and Child Care has, in terms of section 74 and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act [*Chapter 15:03*], made the following regulations:—

PART I

PRELIMINARY

Title

1. These regulations may be cited as the Medicines and Allied Substances Control (Complementary Medicines) Regulations, 2015.

Interpretation

2. In these regulations—

"applicant" means—

(a) the principal; or

(b) any other person acceptable to the Authority;

"appropriate fee" means the fee prescribed in the First Schedule;

"batch number" means the number or other cipher allocated to a complementary medicine by a manufacturer, by which the origin of all raw materials and the complete process of manufacture of the complementary medicine can be determined;

"business address", in relation to a business, means the full physical address of the premises where that business is carried on or any abbreviated address approved by the Authority;

"Complementary Medicine General Sale" or "CMGS" means a complementary medicine which is listed as such in the Fifth Schedule or approved as such by the Authority;

"complementary medicine" means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use in—

(a) the mitigation or prevention of disease or abnormal physical mental state or the symptoms thereof in human beings or in animals;

(b) restoring, correcting or modifying any physical, mental or organic function in man or in animals;

which originates from a plant, mineral, animal or insect and includes substances generally referred to as Aromatherapeutic Substances, Ayurvedic Medicines, Energy Substances or Medicines, Homeopathic Remedies, Nutritional Substance in pharmaceutical form, Traditional Chinese Medicines, Traditional Dutch Remedies, Unanni Tibb Medicines, Western Herbal Medicines and such other medicines or remedies as may be approved by the Authority;

"country of origin", in relation to a complementary medicine, means the country where the basic research in connection with the manufacture of that medicine was undertaken;

"expiry date", in relation to any batch of a complementary medicine, means the date on which the shelf life of such complementary medicine will expire;

"form" means the appropriate form set out in the Second Schedule;

"housemark" or "logo" means the mark, device, design, letter, word, name or numeral or any combination thereof which is used in or proposed to be used in relation to any complementary medicine for the purpose of indicating a connection with the principal or manufacturer of the medicine and the medicine itself;

"label", in relation to a package of a complementary medicine, means any written, pictorial or other matter marked on or affixed to the primary package;

"package insert" means a pamphlet on which is printed the particulars prescribed in section 8;

"Pharmacy Complementary Medicine" or "PCM" means a complementary medicine which is listed as such in the Fourth Schedule or approved as such by the Authority;

"shelf life", in relation to any batch of a medicine, means the date up to which a medicine in that batch will retain the potency and properties stated on the label as fixed by the Authority.

Exemption

3. These regulations shall not apply to any person who compounds, dispenses or administers a complementary medicine to his or her patient in the practice of his or her profession at his or her premises.

PART II

FORMS

Particulars

4. Any person who is required to make an application shall complete the appropriate form and shall furnish the Director-General, or some other person appointed by him or her, with such further information or particulars as may be required.

Forms to be completed in English

5. All forms shall be completed in the English language.

Illegible or incomplete forms

6. The Director-General may reject any form if any part of such form is illegible or not properly completed or the appropriate fee is not paid.

PART III

CLASSIFICATION AND APPROVAL OF COMPLEMENTARY MEDICINES

Interpretation in Part III

7. In this Part—

"principal" means the person who owns the formula of the complementary medicine.

Categories for approval

8. For the purposes of approval, the Authority shall divide or classify the complementary medicines into categories specified in the Third Schedule.

Application for approval of complementary medicines

9. (1) For the purposes of subsection (6)(b)—

"finished product", in relation to a complementary medicine, means a complementary medicine which is wholly manufactured outside Zimbabwe and is imported into Zimbabwe and is ready for sale without having to be relabelled or repackaged.

(2) Any person who is required to make an application shall complete the appropriate form and shall furnish the Director-General, or some other person appointed by him or her, with such further information or particulars as may be required.

(3) An application for the approval of a complementary medicine may be made by—

(a) the principal; or

(b) any other person acceptable to the Authority.

(4) Every application for the approval of a complementary medicine shall be submitted in Form C.M.1 in duplicate.

(5) In addition to subsection (4), such application shall be accompanied by the following—

(a) a sample of the complementary medicine in the smallest of each of the package forms available for distribution to the public including the identification marks on such complementary medicine where appropriate; or if such package forms are not yet available, a sample in a package, in which the applicant intends to make the complementary medicine available for distribution to the public; and

(b) detailed information of all package inserts which the applicant intends to use; and

(c) such samples of the complementary medicine or the raw materials thereof as the Authority may request for analysis; and

(d) a single copy of any literature in support of the application:

Provided that the Authority may require additional copies of such literature; and

(e) a draft package insert or, where there is no package insert, three labels or copies of the package; and

(f) one copy of all records and batch data relating to a particular batch, where appropriate or possible, which shall include raw material analytical reports, master sheets relating to manufacture and packaging, in-process control records, final product analytical records and authorisation for release, and any other relevant records; and

(g) the appropriate fee, together with such additional fee as may be fixed by the Authority for the purpose of analyzing such complementary medicine.

(6) Every applicant shall, without delay, inform the Authority either before or after the approval of a complementary medicine—

(a) of any alteration from the information or particulars furnished by him or her in applying for approval in terms of subsections (4) and (5); and

(b) whether the complementary medicine is to be imported as a finished product into, or relabelled or repackaged or dealt with in any other manner in Zimbabwe.

(7) Before an application for approval of a complementary medicine is considered, the Authority may require confirmation that the manufacturer of the complementary medicine conforms to current Good Manufacturing Practices as determined by the Authority.

(8) The Authority may conduct an inspection of any premises that manufacture complementary medicines for which approval is sought or otherwise, on payment by the applicant of a fee.

(9) Any person who contravenes subsection (6) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Labelling and marking of complementary medicines

10. (1) Every complementary medicine shall, unless otherwise directed by the Authority, bear or incorporate a label on the package

in which such complementary medicine is sold, on which is printed in clear and indelible letters in the English language and any other language as may be directed or approved by the Authority, in addition to the approval number, the following particulars which relate to that complementary medicine only—

(a) the name and address of the principal;
(b) the name and address of the manufacturer;
(c) the approved name of the complementary medicine, if any;
(d) the housemark, if any, of the principal or manufacturer of the complementary medicine;
(e) the quantity and strength of the active ingredient of the complementary medicine, where applicable;
(f) the name and percentage of any agent which is added to the complementary medicine as a preservative;
(g) the date of manufacture and the expiry date of the complementary medicine;
(h) the batch number of the complementary medicine;
(i) the quantity of the complementary medicine in the package;
(j) the strength of the complementary medicine, where applicable;
(k) the requirements for the method of storage or other necessary precautions for the preservation of the complementary medicine;
(l) the category for distribution of the complementary medicine which may be represented by words or symbols as set out in the Third Schedule;
(m) the dosage of the complementary medicine and the directions for use;
(n) any warning notices which shall be in a colour other than the colour of the particulars referred to in paragraphs (a) to (m);
(o) any other particulars as may be directed by the Authority:

Provided that in the case of a package containing a complementary medicine of a quantity of five millilitres or less, it shall be adequate to record the information required by paragraphs (a), (b), (c), (d), (e), (f), (g), (h), (l) and (o) on the outer label.

(2) Notwithstanding subsection (1), the Authority may, if it deems it expedient, direct that the name and address of the manufacturer of a particular complementary medicine shall not appear on the package.

(3) Every complementary medicine shall, where possible, be marked with the housemark of the principal or manufacturer of the complementary medicine, as the case may be, and such other distinguishing mark for the purpose of identifying such medicine.

(4) Every complementary medicine approved in terms of these regulations shall bear the words "NO APPROVED THERAPEUTIC CLAIMS" on the label, unless otherwise exempted by the Authority from complying with this requirement.

Package inserts

11. Every package of a complementary medicine shall, unless otherwise directed by the Authority, contain a package insert on which is printed in clear and indelible letters in the English language and any other language as may be directed or approved by the Authority, the following particulars which relate to that complementary medicine only—

(a) the information which is required to be included on a label in terms of section 36 of the Act;

(b) the name and address of the manufacturer;

(c) the approved name of the active ingredients or the botanical name of the complementary medicine, if any;

(d) the housemark, if any, of the principal or manufacturer of the complementary medicine;

(e) the quantity and strength of the active ingredient of the complementary medicine, where applicable;

(f) the name and percentage of any agent which is added to the complementary medicine as a preservative;

(g) the strength of the complementary medicine where applicable;

(h) the requirements for the method of storage or other necessary precautions for the preservation of the complementary medicine;

(i) the category for distribution of the complementary medicine which may be represented by words or symbols as set out in the Third Schedule;

(j) the dosage of the complementary medicine and the directions for use;

(k) the description of the pharmacological action of the complementary medicine where applicable;

(l) approved indications of the complementary medicine;

(m) contra-indications of the complementary medicine;

(n) warnings relating to the use of the complementary medicine and such warning shall be printed in a colour as approved by the Authority;

(o) the side-effects and special precautions of the complementary medicine;

(p) known symptoms of over-dosage and particulars of its treatment;

(q) the identification of the complementary medicine;

(r) the form in which the complementary medicine is presented, whether tablet, capsule, liquid, etc., and the colour thereof;

(s) the date of publication of the package insert;

(t) any necessary warning concerning the administration or use of the complementary medicine by children, old people, pregnant women or patients suffering from certain diseases, or the use of the medicine in conjunction with the consumption of alcohol or any particular food or any other medicine;

(u) a summary of relevant information concerning the purpose and the beneficial, detrimental, injurious or other effects of the complementary medicine, and the

possible dangers that may arise from the prolonged use of the medicine;

(v) relevant information, including particulars in regard to a specific medicine as an antidote (if known), concerning the treatment of a patient in cases where an overdose of the complementary medicine has been administered or where a patient reacts adversely to the medicine;

(w) any other particulars or warning notices as may be directed by the Authority.

Categories for distribution

12. (1) Where the Authority approves for sale a complementary medicine, it shall fix as a condition of approval the appropriate category for distribution of that complementary medicine, prescribed in the Third Schedule.

(2) The same categories for distribution of a complementary medicine shall apply to veterinary medicines and shall be identified by the suffix (VET):

Provided that the veterinary complementary medicines approved for sale in a General Dealer's premises or category shall be identified by the suffix (C.M.V.G.D).

Register of approved complementary medicines

13. The Director-General shall enter in the register of Complementary Medicines in respect of each complementary medicine approved by the Authority—

(a) the date of the application for approval of the complementary medicine; and

(b) the number allocated to the application for approval; and

(c) the proprietary name (trade mark) of the complementary medicine, if any; and

(d) the approved name of the complementary medicine; and

(e) the form in which the complementary medicine is presented, whether tablet, capsule, liquid, etc. and the colour thereof; and

(f) the strength of the complementary medicine; and

(g) the qualitative and quantitative details of every ingredient in each dosage unit of the complementary medicine; and

(h) the name and address of the principal; and

(i) the name and address of the manufacturer; and

(j) the country of origin of the complementary medicine; and

(k) the name and address of the applicant; and

(l) the date of approval of the complementary medicine; and

(m) the approval number of the complementary medicine; and

(n) the shelf life of the complementary medicine; and

(o) the category for distribution of the complementary medicine fixed in terms of section 12 and any other conditions of approval; and

(p) the date and particulars of any variation in the conditions of approval of the complementary medicine; and

(q) where applicable, the date of the cancellation of the approval of the complementary medicine.

Certificate of approval

14. After approving a complementary medicine, the Director-General shall issue a certificate of approval in Form C.M.2 to the applicant or principal, as the case may be.

Production and return of approval certificates

15. (1) Whenever the Authority—

(a) cancels any approval certificate; or

(b) varies or amends the conditions of any approval certificate; or

(c) imposes new conditions on the renewal of any approval certificate;

the Director-General shall request the holder of the certificate to produce such certificate within such period as he or she may specify and the holder thereof shall produce such certificate within the specified period.

(2) Whenever the Authority varies, amends or imposes any new conditions on any approval certificate, the Authority shall return such certificate duly endorsed to the holder thereof within a reasonable time.

(3) Where a certificate is lost or destroyed, the holder of the certificate may apply to the Authority in Form C.M.5, together with the prescribed fee, for a replacement certificate:

Provided that if the holder of the certificate finds the lost certificate he or she shall forthwith surrender it to the Authority.

(4) Any person who fails to comply with a request made in terms of subsection (1) shall be guilty of an offence and liable to a fine not exceeding level three or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

PART IV

GENERAL CONDITIONS OF SALE

Complementary medicines to be sold from licensed or authorised premises

16. No person shall sell any complementary medicine unless the sale is effected on premises—

(a) licensed in terms of Part VI of the Act or from premises authorised by the Authority; or

(b) authorised by a general dealer's licence issued in terms of the Shop Licences Act [*Chapter 14:17*].

Sale of expired complementary medicines prohibited

17. (1) No person shall sell any complementary medicine on a date later than the expiry date which appears on the package of such complementary medicine.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Conditions of sale

18. (1) No person shall sell any complementary medicine unless he or she is authorised to do so by the Authority.

(2) No person shall sell any complementary medicine to any person apparently under the age of 16 years in the case of a complementary medicine general sale or a complementary medicine listed in the Fourth Schedule, except upon production of a written order signed by the parent or guardian of the child known to such person.

(3) Any person who contravenes subsections (1) or (2) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Record-keeping of complementary medicines by wholesalers

19. (1) This section shall not apply to a wholesale dealer who holds a wholesale dealer's permit issued in terms of the Medicines and Allied Substances Control (General) Regulations, 1991, published in Statutory Instrument 150 of 1991, or who is otherwise authorised in terms of the Act to sell medicines by wholesale.

(2) Every person who is engaged in the wholesale dealing of complementary medicines shall keep a record of—

(a) every quantity of a complementary medicine—
  (i) acquired by him or her;
  (ii) supplied by him or her;

(b) in respect of each acquisition and disposal of a complementary medicine—
  (i) details of the quantity;
  (ii) the date of the transaction;
  (iii) the name and address of the supplier;
  (iv) the name and address of the person to whom the complementary medicine is supplied;
  (v) the batch number of such complementary medicine;
  (vi) the expiry date of the complementary medicine.

(3) Every person who keeps a record in terms of subsection (2) shall make every entry required to be made in terms of subsection (2) on the day on which the complementary medicine is received, or on which the transaction with respect to the supply of the complementary medicine takes place, or if that is not reasonably practicable, on the next day following that day.

(4) Any person who contravenes subsection (2) or (3) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Disclosure of composition of complementary medicines: labels

20. (1) No person shall sell any complementary medicine unless the medicine is labelled in accordance with the requirements of section 10.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Restriction on advertising complementary medicines

21. (1) No person, shall advertise any complementary medicine without the approval of the Authority in writing.

(2) No person shall advertise any complementary medicine to members of the public in terms calculated to lead to its use for the treatment of human beings for any of the conditions or indications set out in the Sixth Schedule:

Provided that this subsection shall not apply to advertisements published by any local authority, or by the Minister or with the consent of the Minister.

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

(4) Any person who contravenes subsection (1), (2) or (3) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Undesirable medicines or substances

22. (1) No person shall sell, supply or deliver any substances specified in the Seventh Schedule intended for use as a complementary medicine to any person for any reason whatsoever.

(2) No person shall include any of the substances specified in the Seventh Schedule as an ingredient in any preparation or in any complementary medicine:

Provided that this section shall not apply to homeopathic remedies.

(3) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Persons who may sell pharmacy complementary medicines

23. No person shall sell a pharmacy medicine other than—

(a) a pharmacist, or person acting under his continuous personal supervision, from premises licensed in terms of Part VI of the Act; or

(b) a wholesale dealer.

24. (1) Any person may, subject to any other law relating to the sale of goods, sell any complementary medicine general sale:

Provided that such complementary medicine general sale is—

(a) labelled in accordance with section 10; and

(b) sold in original unbroken packs.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

PART V

GENERAL

Sampling and testing of complementary medicines

25. (1) When taking a sample of any complementary medicine in terms of section 66(3) of the Act, an inspector, customs officer or police officer above the rank of sergeant shall issue a certificate in Form C.M.3, to the analyst and shall hand or transmit a copy of such certificate to the owner, or seller of the complementary medicine or to his or her agent.

(2) After analyzing, testing or examining a sample of any complementary medicine in terms of section 65(4) of the Act, the analyst shall issue a certificate in Form C.M.4.

(3) The Authority may require the owner, principal or agent of any complementary medicine or any other person to supply free of charge, within a period stipulated by the Authority, such number of samples of any complementary medicine and the working standards of the active ingredients and excipients of such complementary medicine, as it considers necessary for the purposes of testing, examining or analysing such complementary medicine.

Adulteration of complementary medicines prohibited

26. (1) No person shall adulterate any complementary medicine.

(2) No person shall add any allopathic medicine or active pharmaceutical ingredient which is used in the manufacture of any allopathic medicine to any complementary medicine so as to adulterate such complementary medicine.

(3) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Counterfeit, falsified and substandard complementary medicines

27. (1) No person shall sell any complementary medicine, which is a counterfeit, falsified or substandard complementary medicine.

(2) For the purposes of subsection (1) counterfeit complementary medicine means any complementary medicine which—

(a) is fraudulently mislabelled with respect to the identity or source of such medicine;

(b) may include the correct ingredients, wrong ingredients or without active ingredients, with the incorrect quality of active ingredients, with the incorrect quantity of active ingredient or with fake packaging.

(3) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

Withdrawal of complementary medicines

28. (1) Where the Authority is of the opinion that the withdrawal of any complementary medicine is necessary for the protection of the public, the Authority may require any person to withdraw such complementary medicine in accordance with the procedure for the withdrawal of any medicine as determined by the Authority from time to time.

(2) Every person who is in possession of a complementary medicine required to be withdrawn in terms of subsection (1) shall comply with the procedure for the withdrawal of any complementary medicine as determined by the Authority from time to time.

(3) Where necessary, the Authority may order the destruction of a complementary medicine withdrawn in terms of subsection (1).

Liability of carrier

29. No provision of these regulations relating to the possession of any complementary medicine, shall apply to a carrier, his agent or employee who is in possession of a complementary medicine in the ordinary course of the carrier's business.

Disposal of existing stocks

30. (1) If at any time any complementary medicine becomes a prohibited or specially restricted medicine in terms of the Medicines and Allied Substances Control (General) Regulations, 1991, published in Statutory Instrument 150 of 1991, or Chapter VII of the Criminal Law (Codification and Reform) Act [*Chapter 9:23*] or the Dangerous

Drugs Regulations, 1975, published in Rhodesia Government Notice 1111 of 1975, any person other than a person to whom a complementary medicine is lawfully sold who is in possession of such complementary medicine at the time, shall inform the Authority of his or her possession and shall dispose of such complementary medicine in such manner as the Authority may direct.

(2) Any person who contravenes the provisions of subsection (1) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and imprisonment.

Transitional provisions

31. (1) Any person who was authorised to sell any complementary medicine by the Authority and who intends to continue selling such medicine shall submit an application for its approval within six months from the date of commencement of these regulations in terms of section 6 and such person may continue to sell such medicine until the application is either approved or refused by the Authority.

(2) Any person who fails to submit an application in terms of subsection (1) whose product was previously authorised by the Authority such authorisation shall be deemed invalid.

(3) Any person who fails to submit an application in terms of subsection (1) and continues to sell any complementary medicine shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and imprisonment.

Fees

32. (1) For the purposes of subsection (2)(b)—

"finished product", in relation to a complementary medicine, means a complementary medicine which is wholly manufactured outside Zimbabwe and is imported into Zimbabwe and is ready for sale without having to be relabelled or repackaged.

(2) The fees payable in terms of these regulations shall be the appropriate fees opposite the appropriate item specified in the first column of the First Schedule and shall—

(a) in the case of an applicant whose complementary medicine is wholly manufactured in Zimbabwe or is relabelled or repackaged in Zimbabwe, be paid and shall be the amount specified in the second column of the First Schedule;

(b) in the case of an applicant whose complementary medicine is imported into Zimbabwe as a finished product, be paid and shall be the amount specified in the third column of the First Schedule.

(3) The fee payable for the retention of the right to sell an approved complementary medicine shall be the appropriate fee prescribed in the First Schedule which shall be payable on or before the 1st July annually.

(4) The fees specified in terms of this section shall not be payable by any person or institution that has been exempted, in writing, by the Authority.

FIRST SCHEDULE (*Section 2*)

FEES

		Fee US$
1.	Application for the approval of a complementary medicine—	
	(a) in the case of a complementary medicine imported into Zimbabwe as a finished product. . .	600,00
	(b) in the case of a medicine imported into Zimbabwe and which is re-labelled and repackaged before being sold	500,00
	(c) in any other case	400,00
2.	Retention of the right to sell an approved complementary medicine, annually—	
	(a) in the case of a medicine imported into Zimbabwe as a finished product	150,00
	(b) in the case of a medicine imported into Zimbabwe and which is re-labelled and repackaged before being sold	120,00
	(c) in any other case	100,00

		Fee US$
3.	Any amendment to the original application for the approval of a complementary medicine	100.00
4.	Application for a replacement or copy of a certificate of approval	50.00

SECOND SCHEDULE (*Section 2*)

FORMS

Form CM 1

MEDICINES AND ALLIED SUBSTANCES CONTROL
(COMPLEMENTARY MEDICINES) REGULATIONS, 2015

APPLICATION FOR THE APPROVAL OF A COMPLEMENTARY MEDICINE

(To be submitted in duplicate)

To be sent to the Director – General, Medicines Control Authority of Zimbabwe, P.O. Box 10559, Harare, or to be lodged at the offices of the Director – General, Medicines Control Authority of Zimbabwe, 106, Baines Avenue, Harare.

Samples and printed matter to be forwarded by post or by other means and carriage, customs duty and clearance to be paid and effected by the applicant in all instances.

1. Name:.....
.....
2. Business address:.....
.....
3. Postal address:.....
.....
4. Telephone and fax number:.....
.....
5. Email address:.....
.....
6. Particulars of complementary medicine:
   (a) Name of complementary medicine:.....
.....

(b) The form in which the complementary medicine is presented, and the colour thereof (1): .....
.....
.....

(c) Name and address of principal: .....

(d) Name and address of manufacturer: .....
.....

(e) Country of manufacture: .....
.....

(f) The strength of the complementary medicine if applicable: .....
.....

(g) Indications (2): .....
.....

(h) Which of these processes will be carried out in Zimbabwe:

(i) packaging or repackaging.....

(ii) labelling and relabelling: .....

(ii) partial manufacture: .....

(i) State who will carry out the above processes: .....

(j) I enclose a fee of: .....

I, the undersigned declare that the information provided in this Form is true and correct.

....

Name in full *Signature*

Designation .....

Date .....

APPENDIX I

Part A

DETAILS OF CONSTITUENTS IN PRODUCT

Name of applicant: .....

Name of complementary medicine: .....

The form in which the medicine is presented and the colour thereof: .....
.....
.....

The following is a Schedule of the—

(a) active ingredient(s), giving their approved names and quantity in a dosage unit of the medicine;
(b) inactive ingredients giving specifications and quantity and reason for inclusion, e.g., preservative, antioxidant;
(c) specification of any raw materials used in the manufacturing process and not present in the finished medicine; and
(d) specification of packaging material in immediate contact with the medicine.

Constituents	Approved name	Quantity per dosage unit	Active or non-active	Specifications *(1)*	Reason for inclusion of ingredient

Specifications of additional raw material (if any) (2) used in the manufacturing process and not in the final product: .....
.....
.....
.....
.....

***Delete the inapplicable**

Note:

(1) According to WHO recommendations.

(2) Where no specifications for raw materials and packaging materials exist this must be mentioned.

Part B

DETAILS CONCERNING PLANTS (APPLICABLE FOR HERBAL PRODUCTS ONLY)

Name of applicant: .....

Name of complementary medicine: .....
.....

The form in which the complementary medicine is presented and the colour thereof the botanical name of the plant(s) used according to the binomial system (genus, species, variety and, if appropriate, the reference to the originator of the classification, e.g. Linnaeus):....
.....
.....
.....
.....

A description of the plant material based on visual (macroscopic) and/or microscopic examination:.....
.....
.....
.....

Suitable identification tests including, where appropriate, identification tests for known active ingredients or markers are attached:.....
.....
.....
.....

State the name of the botanist, expert, authority or institution that provided the botanical identification / authentication of the plant: .....
.....
.....
.....

Whether the whole plant or only a part is used (specify): .....
.....
.....
.....

When dried plant is used, the drying system should be specified:.....
.....
.....
.....
.....

Details of the source of the plant are attached:- country of origin of raw materials, whether it was cultivated or collected from natural sources, and where applicable, method of cultivation, time period and condition of harvesting (e.g. extreme

weather), collection procedures, collection area, quantity and date of pesticide used: .....
.....
.....
.....
.....

APPENDIX II

SAFETY AND QUALITY ASSURANCE

Name of applicant: .....

Name of complementary medicine: .....
.....
.....

The form in which the complementary medicine is presented and the colour thereof: .....
.....
.....

Detailed manufacturing procedure: .....
.....
.....

Analytical control procedures performed on raw materials including:

(a) determination of fungal and/or microbiological contamination: .....
.....
.....

(b) determination of ash (total ash and ash insoluble in hydrochloric acid):
.....
.....
.....

(c) determination of extractable matter: .....
.....
.....

(d) determination of water or volatile solvent(s): .....
.....

(e) determination of possible pesticide contamination: .....
.....
.....
.....

Analytical control procedures performed during the manufacturing process:....
.....
.....

Analytical control procedures used to determine compliance with specifications including:

(a) determination of arsenic, mercury and lead.....
.....
.....
.....

(b) determination of fungal and/or microbiological contamination: .....
.....
.....
.....

(c) determination of likely contaminants: .....
.....
.....
.....

(d) determination of residual solvents:.....
.....
.....

Data and reasoning on which the stability of the complementary medicine is predicted (minimum of two batches is required): .....
.....
.....

The shelf life claim: .....
.....
.....

Please state any known side effects and other safety issues on the: .....
.....
.....
.....

APPENDIX III

Name of applicant: .....
.....
.....

Name of complementary medicine: .....
.....

The form in which the complementary medicine is presented and the colour thereof: .....
.....
.....

Details concerning whether this complementary medicine has been approved or ..... registered in the country of origin? YES/NO*

[If YES a valid certificate of approval or registration in respect of such complementary medicine issued by the appropriate authority established for the approval or registration of complementary medicines in the country of origin must accompany this application]:.....
.....
.....

Details concerning whether an application for the approval or registration of the complementary medicine been made in any other country? YES/NO*

If YES, state details :.....
.....
.....

Has the approval or registration of the complementary medicine been rejected, refused, deferred or cancelled in any country? YES/NO*

If YES, state full details: .....
.....
.....

Do you intend to advertise the complementary medicine? YES/NO*.....
.....
.....

Under what category do you envisage distributing the complementary medicine(1): .....
.....
.....

****Delete the inapplicable.***

Note: (1) Category CMGS or CMPP.

APPENDIX IV

ADDITIONAL INFORMATION

Name of applicant: .....

Name of medicine: .....

The form in which the complementary medicine is presented and the colour thereof: .....
.....

The following are references to literature about the medicine: .....
.....
.....

The attached are relevant documents concerning the medicine: .....
.....
.....

Copies of the package inserts or draft package inserts are attached: .....
.....
.....
.....

Copies of labels or copies of package inserts are attached: .....
.....
.....
.....

All proposed advertising and promotional material is attached: *(1)*.....
.....
.....

Note:

All advertisements require prior approval.

APPENDIX V

Name of applicant: .....

Name of complementary medicine: .....
.....

The form in which the complementary medicine is presented and the colour thereof: .....
.....
.....

(a) The following particulars refer to the toxicological trials undertaken: ..
.....
.....;

(b) The following particulars refer to therapeutic effects of the medicine: ..
.....;

(c) The following particulars refer to the tests which have been performed on animals regarding the efficacy of the medicine and the purposes for which it will be promoted, with special reference to the dosage and method of administration (pharmacological trials): .....
.....
.....;

(d) the following particulars refer to the tests, which have been performed as in (c) above on humans: .....
.....
.....

(e) The following are particulars of the purpose, mode of action, side effects, contra-indications of the medicine: .....
.....
.....;

(f) the following data relating to the pharmacokinetics and the bioavailability of the medicine in humans and animals is attached: .....
.....
.....;

(g) state details of medicine residue in species intended for human consumption: .....
.....

(h) state details of withdrawal periods for species intended for human consumption: .....
.....

Form CM 2

MEDICINES AND ALLIED SUBSTANCES CONTROL (COMPLEMENTARY MEDICINES) REGULATIONS, 2015

CERTIFICATE OF APPROVAL OF COMPLEMENTARY MEDICINE

Number: .....

It is hereby notified that a Complementary Medicine has been approved as follows:

1. Approved name of Complementary Medicine: .....
2. Trade mark of Complementary Medicine: .....
3. The form in which the Complementary Medicine is presented and the colour thereof: .....
   .....
   .....
4. Active ingredient(s) and strength: .....
   .....
5. Approval number of Complementary Medicine: .....
6. Shelf life of Complementary Medicine in months: .....
7. Category for distribution of Complementary Medicine:
8. Name and address of manufacturer(s): .....
   .....
9. Name and address of principal: .....
   .....
   .....
   .....
10. Name and address of applicant: .....
    .....
    .....
11. Address at which certificate will be kept: .....
    .....
    .....
    .....

12. Date of original approval: .....
13. The Complementary Medicine will be ..... in Zimbabwe.
14. Conditions of approval imposed by the Authority .....
15. Date of issue of certificate .....

Issued at Harare this ..... day of ..... 20.....

.....
Director-General
Medicines Control Authority of Zimbabwe

Form CM 3

MEDICINES AND ALLIED SUBSTANCES CONTROL
(COMPLEMENTARY MEDICINES) REGULATIONS. 2015

CERTIFICATE OF INSPECTOR, CUSTOMS OFFICER OR POLICE OFFICER TAKING

A SAMPLE OF A COMPLEMENTARY MEDICINE

I hereby certify that the accompanying is/ are a sample(s) of a Complementary Medicine taken on .....
at (1) .....
.....
in the presence of (2) .....

being the owner/ seller/ person in charge of the Complementary Medicine.

PARTICULARS IN CONNECTION WITH THE SAMPLE (S)

1. Name of Complementary Medicine: .....
2. Name and business address of manufacturer of sample: .....
   .....
   .....
3. Name and business address of owner or seller of sample: .....
   .....
   .....
4. Estimated quantity of sample: .....
   .....
   .....

5. Batch number appearing on label of sample: .....
.....
.....
6. Expiry date appearing on label of sample: .....
.....
.....
7. Other particulars appearing on label of sample: .....
.....
.....
8. Sample marked or labelled as follows: .....
.....
.....
9. Type of seal used .....
10. Any other appropriate particulars (e.g. package insert) .....

I, ..., being the owner/ seller/ person in charge/ witness, of the Complementary Medicine confirm that the particulars contained herein are correct and that the sample was divided into three samples and sealed in accordance with the provisions of subsection (3) of section 66 of the Act.

.....

Owner/ Seller/ Person in charge/ Witness* (3)

Date: .....

Delete the inapplicable.

Note: (1), (2) and (3):

1. Full address.
2. Name and full address of owner/seller/person in charge/witness.
3. This form is not an admission of guilt.

A copy of this certificate together with a part of the sample shall be handed or forwarded by registered post to the owner or seller of the Complementary Medicine, or to his agent.

Form CM 4

MEDICINES AND ALLIED SUBSTANCES CONTROL
(COMPLEMENTARY MEDICINES) REGULATIONS, 2015

CERTIFICATE BY ANALYST OF RESULT OF TEST OR EXAMINATION OR ANALYSIS OF A COMPLEMENTARY MEDICINE

I, (full name) .....
.....
.....
a duly appointed analyst in terms of paragraph (b) of subsection of section 65 of the Medicines and Allied Substances Control Act (*Chapter 15:03*), hereby declare that, on (date).....
.....
I received a sample of (1).....
.....
.....
quantity; (2).....
.....
.....
from (3) .....
.....
.....
for (4) test, examination, analysis; that sample was marked as follows (5) .....
.....
.....;
and sealed as follows (6).....;
that I have (4) tested, examined and/ or analysed the sample and found the results which are annexed hereto.
Summary of results: .....
.....
.....
.....
.....
Date ....
Analyst

Note: (1), (2), (3), (4), (5) and (6).

1. Name of contents as described on the label.
2. Quantity.
3. Name of person from whom sample was received.
4. Delete whichever is not applicable.
5. Name of manufacturer, batch number and any other particulars on the label.
6. Manner of seal.

Form CM 5

APPLICATION FOR REPLACEMENT CERTIFICATE

ISSUED IN ACCORDANCE WITH THE MEDICINES AND ALLIED SUBSTANCES CONTROL (COMPLEMENTARY MEDICINES) REGULATIONS, 2015

1. Name of person making this application: .....
   .....
2. I hereby apply for a replacement of my certificate that was issued on..... being certificate number .....
   .....
   .....
3. I declare that to the best of my knowledge and belief that certificate has been lost/destroyed (*delete inapplicable*).

   N.B If the certificate was lost and is subsequently found the ***applicant*** *must immediately return a copy of that certificate to the licensing authority. Failure to do so is a criminal offence.*

4. Date: .....
5. Signature of applicant: .....

FOR OFFICIAL USE OF LICENSING AUTHORITY ONLY

Name of Officer: .....

Designation .....

Signature:.....

Date &Stamp

THIRD SCHEDULE (*Sections 8 and 12*)

CATEGORIES FOR THE DISTRIBUTION OF COMPLEMENTARY MEDICINES

Pharmacy Complementary Medicines are complementary medicines controlled in terms of Part IV.

Complementary Medicines General Sale are complementary medicines controlled in terms of Part IV.

FOURTH SCHEDULE (*Sections 2 and 18(2)*)

PHARMACY COMPLEMENTARY MEDICINES

Agnus castus (*Vitex agnus castus*)

Asafoetida (*ferula asafetida L.*)

Ashwagandha (*Withania somnifera*)

Bearberry (*Arctostaphylos uva-ursi*)

Bee pollen (*Apis mellifera L*)

Bogbean (*Menyanthes trifoliate L.*)

Chinese Goldthread (*Coptis chinensis*)

Cone Flower *(Echinacea species)*

Cynara scolymus L. (*Asteraceae*)

Flaxseed *(Linum Usitatissimum)*

Glucosamine *((3R,4R 5S)-3-Amino-6-(hydroxymethyl)oxane-2,4,5-triol)*

Stickle wort (*Agrimonia eupatoria*)

Any other medicines declared by the Authority from time to time

FIFTH SCHEDULE (*Sections 2 and 18(2)*)

COMPLEMENTARY MEDICINES GENERAL SALE

Alfalfa (*Medicago saliva L.*)
Aloe vera (*Aloe barbadensis*)
Aniseed (*Pimpinella anisum L.*)
Avens (*Geum urbanum L.*)

Balm of Gilead (*Commiphora gileadensis) formaly ((Commiphora opobalsamum)*
Bayberry (*Myrica cerifera L.*)
Betacarotene
Bilberry (*vaccinium myrtillus L.*)
Bistort (*Polygonium bistorta L.*)
Lactobacillus acidophilus
Bloodroot (*Sanguinaria Canadensis L.*)
Boldo (*Peumus boldus*)
Calendula (*calendula officinalis L.*)
Capsicum species (*Solanaceae*)
Chamomile (*Matricaria recutita L.*)
Elder (*Sambucus nigra L.*)
Elecampane (*Inula helenium L.*)
Flavonoids
Frangula (*Rhamnus frangula L.*)
Garlic (*Allium sativum L.*)
Ginger (*Zingiber officinale*)
Ginkgo (*Ginkgo biloba*)
Ginseng (*Panax ginseng*)
Thyme-leafed gratiola or water hyssop *(Bacopa monnieri)*
Any other medicines declared by the Authority from time to time

SIXTH SCHEDULE (*Section 21(2)*)

CONDITIONS OR INDICATIONS FOR WHICH ADVERTISING IS PROHIBITED

Alcoholism
Appendicitis
Arteriosclerosis
Cardiovascular disease
Cataract
Diabetes
Epilepsy
Erectile dysfunction
Gallstones
Gangrene
Glaucoma
Hernia

HIV-AIDS
Hypertension
Hypotension
Infertility
Infantile diarrhoea
Kidney stone
Libido enhancement
Locomotor or any other ataxia
Malignant disease
Meningitis (all types)
Multiple sclerosis
Nephritis
Osteoarthritis
Parkinson's disease
Plague
Pleurisy
Pneumonia
Pneumoconiosis
Poliomyelitis
Prostrate gland disorders
Rheumatic fever
Rheumatoid arthritis
Sexually transmitted infection
Thrombosis
Tuberculosis
Any other conditions declared by the Authority from time to time

SEVENTH SCHEDULE (*Section 22*)

UNDESIRABLE SUBSTANCES

Arsenic
Calamus (*Acorus calamus L.*)
Cardinium
Cyanide
Chloroform (in liquid oral complementary medicines or preparations)
Lead and lead salts
Mercury and its salts
Ponceaux Fx
Tartrazine (in complementary medicines intended for oral use)