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.

Particulars of Applicant:

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 or relabelling……..……..

(iii) partial manufacture……

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

……
……
……
……

(j) I enclose the fee of

……

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

…….. ……

Name in full *Signature*

Designation……..

Date……..

**Delete the inapplicable.*

Note:

(1). The form of preparation, i.e. capsules, ear drops, emulsions, eye drops, injections, ointments, solutions, suppositories, suspensions, tablets, etc. and the colour thereof must be mentioned here.

(2.) Purpose for which the complementary medicine is to be used.

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 PCM

APPENDIX IV

ADDITIONAL INFORMATION

Name of applicant

……

Name of complementary 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 medicines

……
……

(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:

……

(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……

…….