CAMS ADVERTISING CODE - APPENDIX (To be decided)

INDEX

1. INTRODUCTION

1.1. The different paradigms of medicine, including that of Western Orthodox Medicine, are based on different belief systems. Each differs with respect to how it views the world and the human being. Each CAMs Paradigm has a philosophical and theoretical framework that stems from the underlying belief system on which the theories, laws, assumptions and values intrinsic to it are based. Many have existed for hundreds and even thousands of years. No Paradigm is superior or inferior to the other.

1.2. All complaints relating to the substantiation of claims made in respect of **"CAMs"** products, services and / or philosophies in an "**advertisement"** shall be exclusively considered in terms of the **"CAMs"** Code.

1.3. Slimming and weight loss CAMs products are excluded from **Appendix D** of the ASA Code dealing with advertising for slimming.

2. DEFINITIONS

DEFINITIONS - TERMS

CAMs

2.1. **"Complementary and Alternative Medicines and/or Substances"** include but are not limited to the medicines and remedies pertaining to all of the **"CAMs Paradigms"**, which include **"African Traditional Medicine"**; **"Anthroposophical Medicine"**; **"Aromatherapy"**; **"Ayurvedic Medicine"**; **"Biochemical Tissue Salts"**; **"Chinese Medicine"**; **"Energy Substances"**; **"Gemmotherapy"**; **"Herbal Medicine"**; **"Homoeopathic Medicine"**; **"Homotoxicological Medicine"**; **"Mineraloids"**; **"Nutraceuticals"**; **"Nutritional Food Substances"; "Orthomolecular Medicine"; "Sowa Rigpa Medicine"** and **"Unani-Tibb Medicine"**, that :

2.1.1. are complementary to the innate healing power of the human being or an animal; and/or

2.1.2. are medicines, substances, or mixtures of substances, including foods containing ingredients, which originate from plants, minerals or animals and include sarcodes, nosodes, allersodes, or isodes; and/or

2.1.3. are 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 illness, abnormal physical or mental state or the "Symptoms" thereof in humans and animals.

"CAM" and **"CAMs"** will have the same corresponding meaning.

2.2. **"African Traditional Medicine"** means the sum total of all knowledge and practices based on the African Tradition, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental, or societal imbalance, and relying exclusively on practical experience and observation handed down from generation to generation, whether

verbally or in writing. **"African Traditional Medicines"** are formulated on the basis of this Tradition and Knowledge.

2.3. **"Anthroposophical Medicine"** means a holistic extension of modern medicine and the art of healing. The Anthroposophical understanding of man and nature is not only based on the physical body, but also on knowledge of different aspects of the human being, namely the life (etheric), soul (astral) and spirit (ego) organisations. The process and functions of the body underlying these four aspects are differentiated into three corresponding and interrelated systems, namely the nerve-sense, rhythmic (circulatory and respiratory) and metabolic movement systems. It is through these systems that the individual, in thinking, feeling and willing, interacts with the world. Anthroposophical medicine treats illness and associated **"Symptoms"** by correcting disturbances within these interrelationships, thereby reinstating a healthy balance. Medicines are formulated in conjunction with the foregoing understanding.

2.4. **"Aromatherapy"** uses volatile oils to bring about "healing". These volatile oils contain odiferous elements of the plant which are produced by several methods. Methods include but are not limited to steam or water distillation of vegetable plant matter, the mechanical pressing of peels or via CO_2 extraction and / or other distillation methods that are used only for their therapeutic purposes. Aromatherapeutic essential oils include but are not limited to all essential oils, attars and absolutes.

2.5. **"Ayurvedic Medicine"** means medicines that are manufactured according to Ayurvedic principles from plant, animal or chemical substances. Both single herbal or combination preparations (formulae) are used. Ayurveda means "the science of life" (*Ayus* – life; *Veda* – science). Ayurveda is an ancient practitioner and health care system that emphasises the prevention of **"Disease"** and the promotion of good health through diet, exercise, daily routines, rejuvenation procedures, food supplements and medicines.

2.6. **"Biochemical Tissue Salts"** means a limited number of mineral compounds, which are present in the human body in their elementary form. They include the 12 biochemical medications designated by Dr Schuessler and twenty-seven other adjunctive biochemical medications as well.

2.7. **"Chinese Medicine"** means practices according to the age old traditional systems of China. It includes medicines that contain herbal, mineral and animal substances in order to maintain health and treat ill health. The substances are usually used in traditional formulations or as single substances together with modalities or techniques such as acupuncture moxa and massage to treat ill health.

2.8. **"Energy Substances"** means substances such as magnetised water; flower, gem and other nature essences; mixtures of coloured water and/or oils that facilitate healing, for example, aura soma oils and sprays. These substances operate on the principle of 'vibrational' healing.

2.9. **“Gemmotherapy**” means a therapeutic method which, prompted by principles of homoeopathic drainage uses plant bud extracts or other embryonic vegetal tissue which is freshly harvested from the growing plant. It utilizes substances which include ethanolic / glycerine macerates that are prepared from fresh, embryonic young plant tissue such as young shoots, rootlets, inner bark of roots, stems or and plant sap.

2.10. **“Herbal Medicine**” means any plant material or a multi-component material derived from a plant that is used for medicinal purposes. These plants include lower plants such as non-pathogenic fungi, algae and lichens but not including bacteria or cyanobacteria [blue-green algae]. They include extracts, isolates or derivatives of these substances.

2.11. **"Homoeopathic Medicine"** means any substance or mixture of substances, preparation, compound, product, or thing which:

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

2.11.2. is obtained by a method of successive dilution and succussion and / or trituration whether achieved manually, mechanically or whatever scale of dilution; and

2.11.3. includes but is not limited to starting substances, nosodes, allersodes, isodes and sarcodes.

2.12. **“Homotoxicological Medicine”** means any substance or mixture of substances, preparation, compound, product, or thing which:

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

2.12.2. is obtained by a method of successive dilution and succussion and / or trituration whether achieved manually, mechanically or whatever scale of dilution;

2.12.3. includes but is not limited to starting substances, nosodes, allersodes, isodes and sarcodes.

2.13. **“Mineraloids”** means original biochemic cell salts essential to cellular structure and function in material form, used according to the principles of Fisher’s Mineral therapy, singly or in combination.

2.14. **“Nutraceuticals”** means any natural or nature identical food or food component, extract, salt, derivative or concentrate, thereof. A nutraceutical includes vitamins, minerals, fats, fatty acids, phospholipids and sterols, protein, peptides and amino acids, carbohydrates and fibre (soluble and insoluble), organic alcohols, enzymes, antioxidants, bioflavonoids, animal foods, plant foods, and probiotics, as well as salts and derivatives thereof.

2.15. **“Nutritional Food Supplement”** means a preparation intended to supplement the diet and provide nutrients which include any natural or nature identical food or food component, extract, salt, derivative or concentrate, thereof. A Nutritional Food Supplement includes vitamins, minerals, fats, fatty acids, phospholipids and sterols, protein, peptides and amino acids, carbohydrates and fibre (soluble and insoluble), organic alcohols,

antioxidants, bioflavonoids, animal foods, plant foods, and probiotics, as well where applicable, salts and derivatives thereof.

2.16. **"Symptom"** means any subjective evidence of **"Disease"** or of a patient's **"Condition"**, that is, such evidence as perceived by the patient and / or health practitioner.

2.17. **"Orthomolecular medicine"** means a form of complementary and alternative medicine aimed at maintaining health through nutritional supplementation. It is sometimes referred to as megavitamin therapy as the practice often uses doses of vitamins and minerals many times higher than the recommended Dietary Reference Intake. Orthomolecular practitioners may also incorporate a variety of other treatment modalities into their approaches, including dietary restriction and mega doses of non-vitamin nutrients. The term "orthomolecular" was coined by Linus Pauling to mean "the right molecules in the right amounts with treatments based on patients' individual biochemistries.

2.18. **"Sowa Rigpa Medicine"** conforms to the Traditions of Tibet, and means medicines which are manufactured and/or formulated according to the principles of Sowa Rigpa from substances traditionally used, i.e. plant, animal, mineral or chemical substances, and addresses the state of health and/or **"Disease"** in the human body in order to preserve, maintain or restore health.

2.19. **"Unani-Tibb Medicine"** means a medicine that is manufactured and/or formulated according to the original patho-physiological, diagnostic and therapeutic system of the humoral theory of Greek medicine using plant, animal, mineral or chemical substances in order to preserve, maintain or restore health.

2.20. **"CAMs Paradigm"** means the different paradigms relating to CAMs that are based on different belief systems. Each differs with respect to how it views the world and the human being. Each **"CAMs Paradigm"** has its own philosophical and theoretical framework that stems from the underlying belief system on which the theories, laws, assumptions and values intrinsic to it are based. Many have existed for hundreds and even thousands of years. No **"CAMs Paradigm"** is superior or inferior to the other.

DEFINITIONS – DESCRIPTOR WITHOUT CLAIMS AND INDICATIONS

2.21. **"Descriptor without claims and Indications"** means a descriptor that contains no claims, whether direct or indirect, which refer to "symptoms" and as such are neither "Low Risk Level claims and Indications" nor "high risk level claims and Indications". Examples include descriptors such as: "Antioxidants; Multivitamins; Minerals etc."

DEFINITIONS - LOW RISK LEVEL CLAIMS AND INDICATIONS

2.22. **"Low Risk Level claims and Indications" include "health claims and Indications"; "vitamin and / or mineral supplementation claims"; "relief of symptoms claims"; "reduction of risk of a disease claims"; "structure - function claims"; "reduction in frequency of a discrete events claim"; and / or "claims of aiding or assisting in the management of a named symptom" when not attached to a High Risk Indication or Claim and provided that they are, where applicable :**

1. **"Self-diagnosable"; and**
2. **are "Self-limiting in the acute situation"**
3. **and contain the on-pack statement "If symptoms persist consult your healthcare practitioner after a suitable period of time" or words to that effect. The suitable period of time must be explicitly stated.**

"Self-diagnosable" means consumers are able to diagnose the "Condition" themselves.

"Self-limiting in the acute situation" means that if the "Condition" is not treated it will become better with time on its own accord. Sometimes there are exceptions where the 'self-limiting in the acute case' criteria are not applicable. For instance, this can apply to "Conditions" such as corns, where the "Condition" in the acute case is not self-limiting but is also not dangerous, - although it is not self-limiting.

2.23. **"Health Claims and Indications"** means **"Health Maintenance Claims including Nutritional Support claims"** and / or **"Health Enhancement Claims"**.

"Health Maintenance Claims including Nutritional Support claims" means **"Claims"** or **"Indications"** that refer to an effect a product or substance may have in maintaining health (or words to that effect). They may also relate to the normal physiological consequences for good health associated with a product or substance, or to the provision of nutritional support and to the use of the terms, cleansing, detoxification and tonic.

"Health Enhancement Claims" means **"Claims"** or **"Indications"** which relate to health enhancement for normal healthy people, such as "improving", "promoting", "enhancing" or "optimising" (or words to that effect) body organs or systems.

2.24. **"Vitamin and / or Mineral Supplementation claims"** means **"Claims"** or **"Indications"** referring to the supplemental intakes of a vitamin or mineral.

2.25. **"Relief of Symptoms Claims"** means **"Claims"** or **"Indications"** relating to the relief from **"Symptoms"** but are not related to a named **"Disease"**/ **"Disorder"** or **"Condition"**. They relate specifically to the temporary relief of a particular **"Symptom"**.

2.26. **"Reduction of risk of a Disease claim"** means **"Claims"** or **"Indications"** relating the reduction of risk of a particular **"Disease"**, **"Disorder"**, **"Condition"**, **"Symptom"** or ailment.

2.27. **"Structure - Function Claims"** means **"Claims"** or **"Indications"** that focus on maintaining or supporting particular body structures or functions, such as supporting bone cartilage integrity, or maintaining healthy intestinal flora. They do not focus on **"Disease"**.

2.28. **"Reduction in frequency of a Discrete Events claim"** means **"Claims"** or **"Indications"** referring to the ability of a product or substance to reduce the frequency of a discrete event such as a migraine, which has an observable beginning and end.

2.29. **"Claims of Aiding or Assisting in the Management of a Named Symptom"** means **"Claims"** or **"Indications"** which relate to aiding or assisting with the treatment or prevention of named **"Symptoms"** and are **"Low Risk Level Claims and Indications".**

Claims which relate to Aiding or Assisting with pre-diagnosed conditions will be considered to be Low Level Risk Claims when used together with the statement, "Aids and assists in the treatment of ['pre-diagnosed' condition]".

"Claims of Aiding or Assisting in the management of a named disease"; "Claims of Aiding or Assisting in the management of a named "Disorder"; "Claims of Aiding or Assisting in the management of a named condition" have the same corresponding meaning.

DEFINITIONS - TRADITIONAL USE:

2.30. **"Traditional use"** means use of the designated active ingredient/s that:

2.30.1. Is/are well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over a period of time; and

2.30.2. accords with well-established traditional procedures of preparation, application and dosage.

DEFINITIONS - HIGH RISK CLAIMS AND INDICATIONS:

2.31. **"High risk level Claims and Indications"** means reference to serious **"Diseases"** or **"Disorders"** and which relate to the:

2.31.1. Treatment, cure or management of a serious **"Disease"**/ **"Disorder"** or **"Condition"**; or

2.31.2. **"Claims"** to be able to prevent a serious **"Disease"**/ **"Disorder"** or **"Condition"**.

2.32. **"High Risk Level Claims and Indications"** means **"Claims and Indications"** that exceed the Low Risk Level Criteria of Self Diagnosable, Self-Limiting together with the appropriate consumer warnings to consult a health practitioner if the condition persists.

DEFINITIONS – GENERAL

2.33. **"Advertisement"** is defined in terms of clause 4.1 of Section I of the ASA code, save that an "advertisement" primarily aimed at a medical doctor, homeopath, chiropractor, phytotherapist, Unani-Tibb practitioner, Ayurvedic practitioner and/or Chinese Medicine practitioner shall be excluded; and information contained on a label or packaging pursuant to a statutory or regulatory requirement (including but not limited to the trade name, Indications, scheduling status and ingredients listing) shall be excluded.

2.34. **"CAMs Monographs"** means authoritative descriptions of **"CAMs"** substances or preparations.

2.35. **"CAMs Pharmacopoeia"** means an authoritative book containing lists of **"CAMs"** with their uses, preparation, dosages, formulae and uses which are specifically related to a particular "**CAMs Paradigm"**.

2.36. **"Case-control study"** means a study that starts with identification of people with the **"Disease"**, **"Disorder"** or **"Condition"** of interest (the cases) and a suitable control group without the **"Disease"** or outcome (the controls). The relationship of an attribute (medicine, treatment, exposure or risk factor) to the outcome of interest is examined by comparing the frequency or level of the attribute in the cases and in the controls. For example, to determine whether thalidomide caused birth defects, a group of children with birth defects (cases) could be compared to a group of children without birth defects (controls). The groups would then be compared with respect to the proportion exposed to thalidomide through their mothers taking the tablets. **"Case-control studies"** are sometimes described as being retrospective as they are always performed looking back in time.

2.37. **"Claim"** in relation to a **"CAM"** means the specific therapeutic purpose or use indicated for the product.

"Indication" has the same corresponding meaning.

2.38. **"Cohort Study"** means an observational study in which a defined group of people (the cohort) is followed over time. The outcomes in subsets of the cohort are compared, for example to examine people who were exposed or not exposed, or exposed at different levels, to a particular intervention or other factor of interest. A cohort can be assembled in the present and followed into the future (this would be a prospective study or a 'concurrent cohort study'), or the cohort could be identified from past records and followed from the time of those records to the present (this would be a retrospective study or a 'historical cohort study'). Because random allocation is not used, matching or

statistical adjustment at the analysis stage must be used to minimise the influence of possible confounders.

"Follow-up study", "Incidence study", "Longitudinal study" and "Prospective study" have the same corresponding meaning.

2.39. **"Condition"** means a simplified description for a **"Disorder"**, which is a derangement or abnormality of function.

2.40. **"Crossover trial"** means a research design in which participants receive a number of treatments in sequence. Generally, this means that all participants have an equal chance during the trial of experiencing both treatment and placebo dosages without direct knowledge, instead of either placebo or the treatment. Participants may be transferred directly from one treatment to another or may have a washout period in between test treatments. This type of trial can be randomised so that all participants do not get the alternative treatments in the same order.

2.41. **"Disease"** means any deviation or interruption of the normal structure or function of any part, organ or system (or combination thereof) of the body that is manifested by a characteristic set of **"Symptoms"** and signs and whose aetiology, pathology and prognosis may be known or unknown.

2.42. **"Disorder"** means a derangement or abnormality of function.

2.43. **"Double blind"** means that neither the participants in a trial nor the investigators (outcome assessors) are aware of which intervention the participants are given during the course of the trial.

2.44. **"Drug Symptom Picture"** means Homeopathic remedies chosen according to a detailed list of **"Symptoms"**. These lists are developed through Homoeopathic Provings.

2.45. **"Efficacy"** means a relative concept referring to the ability of a medicine or treatment to achieve a beneficial clinical effect. This may be measured or evaluated using objective or subjective parameters.

2.46. **"Evidence-based Reference Texts"** means books and Texts where the information contained in them is largely derived from reliable scientific evidence e.g. Commission E monographs from Germany or the Natural Medicines Comprehensive Database.

2.47. **"Expert"** means a person who has a comprehensive and authoritative knowledge or skill in a particular **"CAMs paradigm"** or **"CAMs paradigms"**. This knowledge or skill may have been attained or be based on experience, traditional experience, training, education and traditional education. The skill or knowledge may relate to all or to some areas of a particular paradigm e.g. a person may be skilled in a clinical application of a medicine within a paradigm but not be skilled in the technical issues relating to that particular

paradigm, while another **"Expert"** may be skilled in both the clinical and the technical aspects of the **"CAMs Paradigm"**. Some **"Experts"** may be skilled in both the clinical and the technical aspects and will be knowledgeable across more than one **"CAMs Paradigm"**. The skill should include practical experience relating to the relevant aspect of the **"CAMs Paradigm"**.

2.48. **"HPA"** means the Health Products Association of Southern Africa.

2.49. **"Institute"** means a University or Training College that provides recognised training to **"CAMs"** Practitioners.

2.50. **"Materia Medica"** means an Homeopathic Materia Medica which is a collection of **"Drug Symptom Pictures"**, organised alphabetically by remedy, to describe the **"Symptom"** patterns associated with a specific remedy.

2.51. **"Monographs"** means authoritative descriptions of preparations, substances or medicines.

2.52. **"Nutritional Food Supplements"** and **"Dietary Supplements"** or **"Food Supplements" or "Nutritional Supplements"** will have the same corresponding meaning.

2.53. **"Peer review"** means the review and appraisal of an item of evidence by an independent **"Expert"** in a relevant field.

2.54. **"Pharmacopoeia"** means an authoritative book containing a list of medicinal drugs with their uses, preparation, dosages and formulae. It is a book containing directions for the identification of samples and the preparation of compound medicines. It is often published by the authority of a government, a medical or pharmaceutical society or a specific professional recognised interest group. In a broader sense it is a reference work for medicine specifications

2.55. **"Randomisation"** means the process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

2.56. **"Randomised controlled trial"** means an experiment in which investigators randomly allocate eligible people into intervention groups to receive or not to receive one or more interventions that are being compared. The results are assessed by comparing outcomes in the treatment and control groups.

"RCT" has the same corresponding meaning.

2.56. **"Reduction of risk of a "Disorder" claims"** and **"Reduction of risk of a Condition claims"** have the same corresponding meaning.

2.57. **"Serious disease"** means one for which there is a substantial body of medical opinion that the **"Disease"** (**"Disorder"** or **"Condition"**) cannot or should not be diagnosed or treated except under the supervision of a Health Care Practitioner.

"Serious "Disorder" and **"Serious condition"** have the same corresponding meaning.

2.58 **"Systematic review"** means an analysis of a large number of clinical trials (sometimes known as a 'meta-analysis') aimed at looking for an overall pattern in the trial results. Cochrane Reviews are examples of such **"Systematic reviews"**. In a systematic analysis, only those trials that meet a number of pre-set conditions in relation to research design (e.g. sample size, **"Randomisation"**) are included in the final meta-analysis.

2.59. **"Trade secret"** means information relating to an advertiser's proprietary ideas, patentable ideas, copyrights and/or trade secrets, existing and/or contemplated products and services, research and development, production, and / or processes and which was so created is not in the public domain.

3. CONFIDENTIALITY

3.1. Where an advertiser, or its representative(s), expended skill and effort in order to create a **"trade secret"**, it will constitute a confidential trade secret of the advertiser within the meaning of Clause 5.1.1 of Section I of the ASA Code.

3.2. Clause 3.1 above should not, however, be interpreted as narrowing the meaning of Clause 5 of Section II of the ASA Code.

4. TRUTHFULNESS

4.1. All **"Claims"** or **"Indications"** must be factual, valid and not misleading.

4.2. All **"Claims"** or **"Indications"** should not lead to inappropriate use of the product.

4.3. Evidence must relate to the whole product or to the same active constituent(s) with similar dosage regimen, dose form and route of administration to the product/ingredient for which a **"Claim"** or **"Indication"** is being made.

5. SUBSTANTIATION

SUBSTANTIATION – GENERAL

5.1. Advertisers shall when called upon to substantiate an advertising **"Claim"**, furnish acceptable evidence, either documentary or verbal, as provided for in the **"CAMs"** Code in respect of the **"Claims"**.

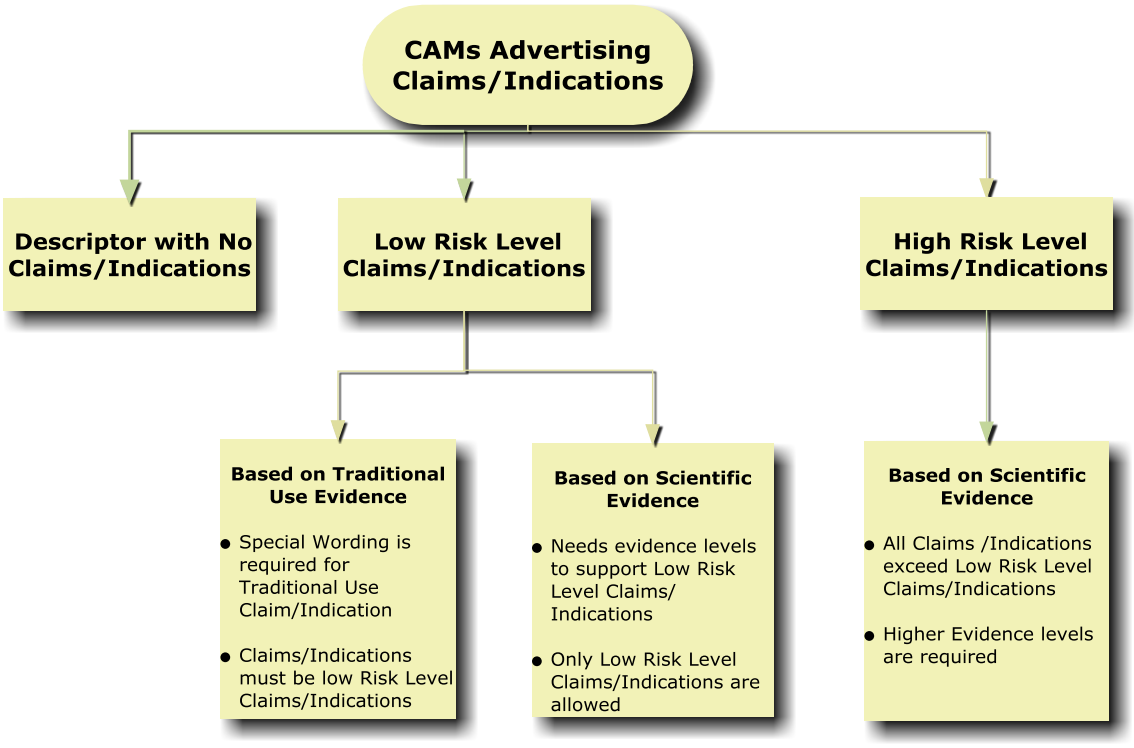
5.2. Evidence for the substantiation of any **"Claim"** or **"Indication"** must be relevant to the **"Claim"** or **"Indication"** the species, the dose, the concentration or the identity of ingredients.

5.3. It is possible for **"CAMs"** products to have **"Claims"** or **"Indications"** that are based on **"Traditional use"** in addition to **"Claims"** or **"Indications"** where the evidence is based on science. Where this is the case, each aspect of the substantiation of evidence must relate respectively to that part of the **"Claim"/"Indication"**/s that relates either to **"Traditional use"** or to science.

5.4. Constituents of **"CAMs"** products may belong to a particular **"CAMs Paradigm"** or they may belong to combinations of different **"CAMs Paradigms"**. Evidence to substantiate a **"Claim"** or **"Indication"** shall in each case be taken from the applicable **"CAMs Paradigm"** and shall fulfill the requirements relating to that **"CAMs Paradigm"**.

5.5. CAMs products may contain single or multiple ingredients. Acceptable evidence, either documentary or verbal, as provided for in this **"CAMs"** code in respect of the **"Claims"** shall be provided for each active ingredient of a **"CAMs"** product with regard to the action of how that specific ingredient relates to a particular **"claim"** or **"indication"**. Active ingredients should not be interpreted to include inactive or excipient ingredients, or the mere reference to the inclusion of an ingredient.

5.6. Evidence for the Substantiation of Claims for the different CAMs Paradigms is handled according to the following scheme:



5.7. The substantiation of **“Indications”** and **“Claims”** for **“CAMs”** products may require either Traditional or Scientific substantiation for **“Claims”** or **“Indications”**, depending on whether the particular aspect of the **“Claims”** and / or **“Indications”** relate to Traditional or Scientific evidence, as set out below.

SUBSTANTIATION – DESCRIPTORS WITHOUT CLAIMS AND INDICATIONS

5.8. As **"Descriptors without claims and Indications"** show general use of the product, they do not infer **"Efficacy" and "Efficacy"** data is not required.

5.9. The ingredients and the concentration of the ingredients of **"CAMs"** products using **"Descriptors without claims and Indications"** should demonstrate that they can be used for that "Descriptor".

SUBSTANTIATION - LOW RISK LEVEL CLAIMS AND INDICATIONS BASED ON TRADITIONAL USE

5.10. **"Low Risk Level claims and Indications"** based on **"Traditional use"** shall infer that the product has been used within the tradition or **"CAMs Paradigm"** for the particular **"Claim"**/**"Indication"** or **"Condition"**. It shall not infer the **"Efficacy"** of a product using a **"Traditional use" "Claim"** or **"Indication"**.

All **"Indications"** / **"Claims"** that are based on evidence of **"Traditional use"** for **""Low Risk Level Claims and Indications"** must be worded to the effect that: *"This (tradition/paradigm) medicine has been/is traditionally used for (**"Claims"** / **"Indications"**)".* **"Traditional use" "Claims"** or **"Indications"** may only refer to the **use** of a **"CAMs"** product or substance for a specific **"Claim"** or **"Indication"**.

5.10.1. As **"Traditional use"** data does not infer **"Efficacy"**, **"Efficacy"** data is not required.

5.10.2. Higher risk level **"Indications"** and **"Claims"** for **"Traditional use"**, exceeding those described above, cannot be based on evidence of **"Traditional use"**, but they may be used if suitable scientific evidence is available for the use of the **"Claim"** or **"Indication"**.

5.10.3. **"CAMs"** products using **"Traditional use" "Claims"** or **"Indications"** should be manufactured according to traditional or **"CAMs Paradigm"** related methods.

5.10.4. Acceptable evidence of **"Traditional use"** may be obtained from the following types of information:

5.10.4.1. **"Pharmacopoeia"**

5.10.4.2. Orthodox **"Pharmacopoeia"** that describe **"CAMs"** substances with **"Claims"** (e.g. Martindale – The Complete Drug Reference).

5.10.4.3. Traditional **"Pharmacopoeia"** (e.g. The Ayurvedic Pharmacopoeia).

5.10.4.4. Specific **"CAMs Monographs"** (e.g. ESCOP or WHO **"Monographs"**).

5.10.4.5. Independent histories of **"Traditional use"** e.g. specific books that record relevant information for a specific **"CAMs Paradigm"** including suitable **"Claims"** or **"Indications"**.

5.10.4.6. Proof showing the product or substance to be available through any country's government public dispensaries for the **"Claim"** or **"Indication"** claimed.

5.10.4.7. **"Drug Symptom Pictures"** from recognised **"Materia Medica"**.

5.10.4.8. Evidence of use described by 3 independent traditional **"Experts"** from a particular **"CAMs Paradigm"**.

For the substantiation of a **"Traditional use" "claim"** at least 2 separate references, whether from the same or different types of information, as set out above in clause 5.11.4, will be required, or where the sole body of evidence available is verbal within a particular Paradigm, two independent experts shall verify the accuracy of the claims and / or Indications within a CAMs Paradigm.

Acceptable references for **"Traditional use"** shall:

- Be written by an author who can be shown to be an **"Expert"** in a particular **"CAMs Paradigm"**; or
- Be used by an educational institution in the **"CAMs Paradigm"** as a reference text; or
- Be published by an official government agency or international agency dealing with the relevant **"CAMs Paradigm"**/s; or
- Be an official **"Pharmacopoeia"** or a traditional **"Pharmacopoeia"**; or
- Be deemed to be a relevant reference by at least 2 independent **"Experts"** within a **"CAMs Paradigm"**.

5.10.5. The following shall be required for an Expert Report Relating to **"Traditional use"** evidence:

Section	**Information required**
"Expert" details	CV Justification of **"Expert"** status
Recommendation	Proposed **"Claims"** / **"Indications"** Ingredient details
Identification of evidence	Sources searched: **"CAMs Pharmacopoeia"**, national formularies, **"Monographs"**, textbooks, historical references etc.
Relevance of evidence	Assessment of relevance of retrieved results to proposed **"Claim"** / **"Indication"**, proposed formulation, target population and context of use

SUBSTANTIATION - LOW RISK LEVEL CLAIMS AND INDICATIONS BASED ON SCIENTIFIC EVIDENCE

5.11. **"Low Risk Level claims and Indications"** based on scientific evidence may be obtained from any the following types of information:

5.11.1. Orthodox **"Pharmacopoeia"** that describe **"CAMs"** substances with **"Claims"** (e.g. Martindale – The Complete Drug Reference).

5.11.2. Specific **"CAMs Monographs"** (e.g. ESCOP or WHO **"Monographs"**).

5.11.3. Evidence obtained from well-designed controlled trials without **"Randomisation"**.

5.11.4. Evidence obtained from well-designed analytical studies preferably from more than one centre or research group, including epidemiological cohort and **"case-control studies".**

5.11.5. Peer-reviewed published papers.

5.11.6. **"Evidence-based Reference Texts"**.

5.11.7. Recognised Websites evaluating peer-reviewed published evidence (e.g. the Natural Medicines Comprehensive Database; or the Natural Standard Professional Database).

Evidence relating to a specific ingredient of a scientific evidence based product must show that the exact same identity ingredient is used at or above the concentration that was used in the types of scientific evidence, as set out above in clause 5.11 referred to above.

Where **"Peer reviewed"** published papers are not available due to the requirement of Intellectual Property relating to the product or the active ingredient, 2 independent **"Institutes"** or **"Experts"** that can show that they are authorities on the subject matter at hand and who can verify evidence of substantiation, will be suitable.

Where an item of evidence has been published, but has not been not been published in a **"Peer reviewed"** journal, it should have been assessed by an **"Expert"**.

SUBSTANTIATION - HIGH RISK LEVEL CLAIMS AND INDICATIONS

5.12. **"High risk level Claims and Indications"** require scientific evidence obtained from:

5.12.1. A **"Systematic review"** of all relevant randomised, controlled trials without significant variations in the directions and degrees of results; or

5.12.2. At least one properly designed, randomised controlled (preferably multi-centre) **"Double blind"** trial.

It is preferable to have data from at least two trials independent of each other, but in some cases, one large well-conducted trial may suffice.

Evidence relating to a specific ingredient of a scientific evidence based product must show that the exact same identity ingredient is used at or above the concentration that was used in the type of scientific evidence, as set out above in clause 5.12 referred to above.

Where **"Peer reviewed"** published papers are not available due to the requirement of Intellectual Property relating to the product or the active ingredient, 2 independent opinions emanating either from **"Institutes" and** / or **"Experts"** (which should not be construed as both opinions emanating from the same or similar source), that can show that they are authorities on the subject matter at hand and who can verify evidence of substantiation, will be suitable.

5.13. The following shall be required for an Expert Report relating to scientific evidence:

Section	**Information Required**
"Expert" details	CV Justification of **"Expert"** status
Recommendation	Proposed **"Claims"** / **"Indications"** Ingredient details
Identification of evidence	Literature search results Any additional non-published studies/information
Relevance of evidence	Assessment of the relevance of retrieved results to proposed **"Indication"**, proposed formulation and context of use
Study quality	Level of evidence Participant inclusion/exclusion criteria Study method including **"Randomisation"** and control of confounders Sample size determination Statistical analysis of results
"Efficacy"	Assessment of statistical and clinical significance Consistency of findings
Balance of Evidence	Final Recommendation

AMENDMENT OF CLAUSE 11 OF THE PROCEDURAL GUIDE

11. Expert assistance in discrimination complaints and CAMs complaints.

11.1 Where an allegation of discrimination forms part of a complaint lodged with the ASA, or where a complaint relates to the substantiation of "Claims" for a CAMs product, the Directorate or the Committee or Tribunal hearing such complaint shall be obliged to co-opt at least one expert in the field to which the complaint relates to assist the Directorate, the Committee or Tribunal, as the case may be, in reaching a ruling.

11.2 The primary responsibility for identifying appropriate experts in a number of fields, and for procuring their agreement to sit as permanent members of a panel from which experts may be drawn to assist the Directorate, Committees and Tribunal in the manner provided for in the previous sub-section, shall rest with the Directorate.