IN THE HIGH COURT OF SOUTH AFRICA (WESTERN CAPE HIGH COURT, CAPE TOWN)

CASE NO: 2714/2010

In the matter between:

WINGS HERBAL SYNERGY CC

Applicant / Appellant

And

COMMISSIONER, SOUTH AFRICAN **REVENUE SERVICES**

Respondent

FILING NOTICE

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AFFIDAVIT:

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(1)

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APPELLANT / APPLICANT'S ATTORNEYS

IN THE HIGH COURT OF SOUTH AFRICA (WESTERN CAPE HIGH COURT, CAPE TOWN)

Case number: 2714/2010 In the matter between: Applicant/Appellant WINGS HERBAL SYNERGY CC and COMMISSIONER, SOUTH AFRICAN REVENUE Respondent **SERVICES AFFIDAVIT** I the undersigned, MARC BLOCKMAN do hereby make oath and say: 1.

1.1. I am a specialist clinical pharmacologist and a professor in the clinical

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pharmacology division of the Department of Internal Medicine, Faculty of Health Sciences at the University of Cape Town.

1.2. Annexed hereto as annexure "MB1" is a copy of my curriculum vitae which sets out in detail my academic qualifications and relevant practical experience. I submit that by virtue of my qualifications and experience I am duly qualified to give the evidence and express the opinions set out in this affidavit.

A. BRIEF

- 2. I have been requested by the South African Revenue Service ("SARS") to express an opinion on the therapeutic and prophylactic properties of the following products:
 - 2.1. FEN+;
 - 2.2. LIVOCLEAR;
 - 2.3. OA/RA;

2.5.	MEGA EGCG;
2.6.	TRAN-QWILL;
2.7.	AFFECT D;
2.8.	FREE MOVEMENT (STUCK FREE);
2.9.	HELICO X;
2.10.	COOL BLUE;
2.11.	GUT BUG;
2.12.	A1 GRANULE;
2.13.	THYROCAPS (SPECIAL T);

2.14. PRO CREATION D;

2.4. AV/AT;

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- 2.15. AFFECT D;
- 2.16. PS CALM;
- 2.17. CURCUMINE & QUERCETIN.
- 3. In order to fulfill my brief I was furnished with the following documents:
 - 3.1. A full set of the founding papers in this matter. This had, as annexure "FA12" thereto, ten expert reports purportedly prepared by Dr G L Muntingh ("Dr Muntingh");
 - 3.2. Two affidavits deposed to by Dr Muntingh and relied on by SARS in two earlier customs tariff appeal cases concerning the classification of products alleged to be medication ("Dr Muntingh's earlier affidavits").
- 4. Having perused and considered Dr Muntingh's affidavits I confirm that I am in agreement with his sentiments expressed therein as to how products claimed to be medicaments should be reviewed and reported on in order to conclude that they actually have therapeutic and/or prophylactic properties. Having regard to the aforesaid and the fact that he has been consulted by the Applicant in this matter. I



have thought it prudent to use as much of his evidence as possible in this affidavit¹.

B. <u>DISCUSSION</u>

5. The proper point of departure is the ordinary meaning of the terms "therapeutic" and "prophylactic".

6. "Therapeutic"

- 6.1 According to the Shorter Oxford English Dictionary, (Vol I 3rd ed) the term is defined as "to treat medically"; "of pertaining to the healing of disease". The Oxford English Dictionary (Vol X1), defines the term "therapeutics" as "that branch of medicine which is concerned with the remedial treatment of disease"; and "of or pertaining to the healing of disease".
- 6.2 **Butterworth's Medical Dictionary** defines the term "therapeutics" as "that branch of medicines which is concerned with the treatment of disease,

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¹ In fact, the content of most of my evidence herein is verbatim the evidence of Dr Munting in his earlier affidavits.

palliative or curative; in common usage this refers mainly to the use of drugs, physiotherapy etc.".

- 6.3 According to **Medicinet.com** (<u>www.medterms.com</u>. the term "therapeutics" in medicine, relates to that part of medicine concerned specifically with the treatment of disease. The therapeutic dose of a drug is the amount needed to treat a disease. In pharmacology, therapeutics accordingly refers to the use of drugs and the method of their administration in the treatment of disease.
- 6.4 According to The American Heritage Stedman's Medical Dictionary

 (Houghton Mifflin Company, 2002), Answers.com

 www.answers.com/topic/therapeutic) the term "therapeutic" refers to

 "Medical treatment of disease; the art or science of healing".
- When stating that a medication, or medicinal substance / preparation is therapeutic, it is also important to realize that this by implication means that the reasons for employing it outweighs any untoward effects that this substance or preparation may exhibit, i.e. it must be demonstrated that it is safe to use.

7 "Prophylactic"

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- 7.1 The Shorter Oxford Dictionary (Vol II 3rd Ed), defines the term "prophylactic" as, "that defends from or tends to prevent disease". The Oxford English Dictionary (Vol III) defines "prophylactic" as "that defends from or tends to prevent disease"; and "a medicine or measure used to prevent or as a precautions against disease".
- According to **Butterworth's Medical Dictionary**, the term "prophylactic" is defined as "Pertaining to the prevention of the development of disease" and/or "A preventative agent or remedy used to ward off an infection".
- 7.3 According to the American Heritage Stedman's Medical Dictionary

 (Houghton Mifflin Company, 2002. Answers.com

 http://www.answers.com/topic/prophylactic) the term "prophylactic" is

 defined as:
 - "Adj.: Acting to defend against or prevent something, especially disease; protective.
 - n.: A prophylactic agent device, or measure, such as a vaccine or drug."

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- 7.4 According to Thomson & Gale Glossary, also quoted by Answers.com

 (www.answers.com/topic/prophylactic. the definition of "prophylactic" is

 "Treatment given to protect against or ward off disease. Many doctors give

 antibiotics to patients who have been bitten by ticks as a prophylactic

 measure against Lyme disease."
- 7.5 Medicinet.com (www.medterms.com, refers to the term "prophylactic" as "A preventive measure. The word comes from the Greek for 'an advance guard' an apt term for a measure taken to fend off a disease or another unwanted consequence. A prophylactic is a medication or treatment designed and used to prevent a disease from occurring. For example, prophylactic antibiotics may be used after a bout of rheumatic fever to prevent the subsequent development of Sydenham's chorea".
- 8. When considering the various definitions in terms of "therapeutic" and "prophylactic", as given above, it is clear that the following terms are mentioned often and are common to the respective definitions:
 - 8.1 Treatment or prevention of *disease*;
 - 8.2 *Medication* to treat or prevent disease.

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9. To further elucidate the terms "therapeutics" and "prophylactic", it is thus necessary to consider, in the ordinary sense, the terms "disease" and "medication".

10. "Disease"

departure from the normal state of health. More specifically, a disease is the sum total of the reactions, physical and mental, made by a person to noxious agent entering his body from without or arising within (such as a micro-organism or poison), an injury, a congenital or hereditary defect, a metabolic disorder, a food deficiency or degenerative process. These cause pathological changes in organs or tissue which are revealed by characteristic signs and symptoms. Since a particular agent tends to produce a pathological and clinical picture peculiar to itself, although modified by individual variations in different patients, a mental concept of the average reactions or a composite picture can be formed which, for the convenience of description is called a particular disease or clinical entity. But a disease has no separate existence apart from a patient and the only entity is the patient."



10.2 According to the American Heritage Stedman's Medical Dictionary

(Houghton Mifflin Company, 2002. Answers.com

http://www.answers.com/topic/disease) the term "disease" is defined as:

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- 1. "A pathological condition of a part, organ, or system of an organism resulting from various causes, such as infection, genetic defect, or environmental stress, and characterised by an identifiable group of signs or symptoms."
- 2. "A condition or tendency, as of society, regarded as abnormal and harmful."
- In the Science and Technology Encyclopaedia (McGraw-Hill Encyclopaedia of Science and Technology. Copyright © 2005 by the McGraw-Hill Companies, Inc, http://www.mcgraw-hill.com/). disease is defined as "A deleterious set of responses which occurs at the subcellular level, stimulated by some injury, and which is often manifested in altered structure or functioning of the affected organism. With advances in understanding and the development of sensitive probes, it has become clear that the fundamental causes of diseases are based on biochemical and

biophysical responses within the cell. These responses are now being categorised and, slowly, the mechanisms are being understood."

11. "Medication"

- The Oxford English Dictionary defines "medicament" as follows: "A substance used in curative treatment". The same dictionary states further that the meaning of the word "medicament" should also be seen in the context of the word "medicinal", which is "Having the nature of a medicament, medicinal. In the same dictionary, the word "medicinal" is defined as "Having healing or curative properties or attributes; adapted to medicinal use".
- 11.2 Wordnet 1.7.1 of Princeton University, 2001 (Answers.com http://www.answers.com/topic/medicament) defines "medication" as "something that treats or prevents or alleviates the symptoms of disease".
- 11.3 Medication, according to Roget's II: The New Thesaurus (Third Edition by the Editors of the American Heritage® Dictionary Copyright © 1995 by Houghton Mifflin Company (published by Houghton Mifflin Company) is defined as "A substance used in the treatment of disease".

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11.4 The American Heritage Stedman's Medical Dictionary (Houghton Mifflin Company, 2002. Answers.com

http://www.answers.com/topic/medicament) states a medicament as:

- n.: "An agent that promotes recovery from injury or ailment; a medicine".
- 12. If the above is considered and read in context, it is clear that the terms "therapeutic", "prophylactic", "disease" and "medicine" are interlinked. When an agent is used therapeutically, it in essence is used to treat a disease; when an agent is used as a prophylactic, in essence it is used to prevent a disease from developing. Looking at this in another context, it could also mean the removal of the cause of a disease e.g. prevention of malaria. If the average definition of a medication is considered i.e. a substance that has healing and/or curative properties, it is clear that a medication has the intrinsic ability to be used therapeutically i.e. to treat a disease or prophylactically i.e. to prevent a disease. Furthermore, it is plausible to say that a medication could have the ability to both treat and prevent the same disease. Therefore, when considering whether a substance is intrinsically a medicine, it must be shown that this substance or agent is therapeutic or prophylactic. By this it is meant that clinical evidence exists that the medication or substance on its own



has the ability to treat a disease or prevent such a disease. Furthermore, where the agent is a combination of substances, this combination per se should demonstrate the ability to treat or prevent disease.

- 13. In order for a medicament to be effective in treating a disease, certain aspects of the disease and the medicament must be known.
 - 13.1 The following must be known with reference to the disease: The etiology of the disease, i.e. what is the cause and the natural progression of the disease.

 This will determine how often, in what quantities and for how long should a medicament be administered to enable cure.
 - 13.2 The following is important with reference to the medicament:
 - 13.2.1 For a drug to be delivered to the correct site of action, at adequate concentrations for an adequate amount of time, correct drug formulation is essential;
 - 13.2.2 The route of administration is determined by the site of action;

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- 13.2.3 The dosage form is in most cases determined by the route of administration; and
- 13.2.4 This is turn will be determined by the chemical and physical properties of the active ingredient.
- 14. In other words, the pharmaceutical characteristics of the medicament must be known and well researched. The vehicle, into which the active ingredient (that part of the preparation that affords the therapeutic intervention) is incorporated, must be inert, i.e. must not react with the active ingredient.
- 15. Also, the vehicle must demonstrate that it can make the active ingredient bioavailable, i.e. release the active ingredient at the site where treatment is required in sufficient quantities for a long enough period. Furthermore, should more than one active ingredient be incorporated into the vehicle, it must be shown that these ingredients are inert with respect to each other. It is possible that one active ingredient may have a chemical interaction with the other(s) and by that, negatively influence the efficacy of the preparation, i.e. pharmacological synergism may be compromised by chemical interaction between the active ingredients.



- 16. The ability of a preparation to treat or prevent a disease can only be proved *in vivo* (by means of human clinical trials), and not *in vitro* (in the laboratory). In other words, a specific formulation containing the active ingredient(s) must demonstrate efficacy by means of clinical trials in a specific disease. The reason for this is that it is very difficult to simulate the condition(s) to be treated in a human patient, in the laboratory.
- In practical terms the aforesaid means that sufficient quantities of the active ingredient should be made available from the vehicle; The active ingredient must then demonstrate that it will stay at the point of disease long enough to have a therapeutic intervention: certain human pathogens must be exposed to a certain minimum concentration before it is demised whilst for other time spent above minimum-inhibitory concentration (MIC) by the active ingredient is important. Each pathogen or infection has a specific dosing regimen.
- Also, the physiological state of the areas of disease may influence the efficacy of an active ingredient, e.g. the pH of the environment where the infection may occur; dilution of the active ingredient once released, rate of removal of the active ingredient from the area of disease. All are factors that can influence the efficacy of a preparation.



- 19. The above factors cannot be properly simulated in a laboratory environment and therefore only clinical trials can demonstrate whether a particular preparation is therapeutic or not. In view of what has been explained above, it would be wrong to conclude from the fact that a preparation contains one or more ingredients which may have a medicinal action, that the preparation itself is a medicament. What has to be shown is that the preparation itself has therapeutic and/or prophylactic effect. It does not necessarily follow from the fact that the constituent parts of a product have significant medicinal products, that the product itself has a therapeutic and/or prophylactic effect.
- 20. In order to evaluate *in vivo* aspects of a medicine, it is standard practice to subject it to Evidence-Based Medicine (EBM). Evidence-based medicine applies the scientific method to medical practice. According to the Centre for Evidence-Based Medicine, "(E)vidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Glossary of terms in Evidence-Based Medicine. Centre for Evidence-Based Medicine. Retrieved on 09/11/2006). Furthermore, evidence-based medicine has demoted ex cathedra statements of the "medical expert" to the least valid form of evidence. All "experts" are now expected to reference their pronouncements to scientific studies.



- 21. Evidence-based medicine categorizes different types of clinical evidence and ranks them according to the strength of their freedom from the various biases that beset medical research. For example, the strongest evidence for therapeutic interventions is provided by randomized, double-blind, placebo-controlled trials involving a homogeneous patient population and medical condition. In contrast, patient testimonials, case reports, and even expert opinion have little value as proof because of the placebo effect, the biases inherent in observation and reporting of cases, difficulties in ascertaining who is an expert, and more.
- 22. For the sake of clarity the emboldened words in the previous paragraph, are defined as follows:
 - 22.1 "Placebo": the inert carrier substance is administered without any active ingredients.
 - 22.2 "Double-blind": this signifies that the subject of the trial as well as the investigator are "blind" as to whether the treatment received by the subject is placebo or contains any active ingredients.



- 22.3 "Randomized": the subjects are randomized in the sense that those subjects receiving placebo and those receiving active ingredients are selected at random.
- 22.4 "Placebo controlled": one half of the subjects receive placebo and the other half receive active ingredients.
- 23. As stated above, double-blind randomised controlled trials are the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome. They have several important features:
 - 23.1 Random allocation to intervention groups. This means that every participant is assigned a treatment in a random manner. This is often by a random number generator or by computer allocation. As there is no human intervention, any biased assignment of treatment is eliminated.
 - 23.2 Both patients and trialists should remain unaware of which treatment was given until the study is complete;
 - 23.3 All intervention groups are treated identically except for the experiment treatment.



- Patients are normally analysed within the group to which they were allocated, irrespective of whether they experienced the intended intervention (intention to treat analysis):
- 23.5 The analysis is focused on estimating the size of the difference in predefined outcomes between intervention groups.
- Other study designs, including non-randomised controlled trials, can detect associations between an intervention and an outcome. However, they cannot rule out the possibility that the association was caused by a third factor linked to both intervention and outcome. Random allocation ensures no systematic differences between intervention groups in factors, known and unknown, that may affect outcome. Double blinding ensures that the preconceived views of subjects and clinicians cannot systematically bias the assessment of outcomes. Intention to treat analysis maintains the advantages of random allocation, which may be lost if subjects are excluded from analysis through, for example, withdrawal or failure to comply. Meta-analysis of controlled trials shows that failure to conceal random allocation and the absence of double blinding yield exaggerated estimates of treatment effects.
- 25. Failure to perform randomized double-blind controlled trials may result in harmful treatments being used. For example, neonates were widely treated with high

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concentrations of oxygen until randomised trials identified oxygen as a risk factor for retinopathy (severe retinal damage) of prematurity.

- 26. It therefore remains an ideal that all healthcare interventions should be evaluated through randomized controlled trials. Given that poor design may lead to biased outcomes, trialists should strive for methodological rigor and report their work in enough detail for others to assess its quality.
- 27. Practicing evidence-based medicine implies not only clinical expertise, but expertise in retrieving, interpreting, and applying the results of scientific studies, and in communicating the risks and benefit of different courses of action to patients.
- 28. Systems to stratify evidence by quality have been developed, such as this one by the U.S. Preventive Services Task Force (U.S. Preventive Services Task Force (USPSTF), Agency for Health Care Research and Quality, www.ahra.gov/clinic/uspstfix.htm. It comprises the following:
 - 28.1 Level I: Evidence obtained from at least one properly designed randomized controlled trial.



- 28.2 Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- 28.3 Level III-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- 28.4 Level IV-3: Evidence obtained from multiple time series with or without the intervention of the drug in question. Dramatic results, (i.e. results which, relative to the study design, are greater or worse than expected), in uncontrolled trials might also be regarded as this type of evidence.
- 28.5 Level V: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
- Accordingly, Natural Standards The Authority on Integrative Medicine (www.naturalstandard.com) has developed a methodology to enable standards for substance monographs on complementary and alternative therapies. This methodology is described as Systematic Aggregation, Analysis, and Review of

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the Literature and entails the following:

29.1 Search Strategy

To prepare each Natural Standard monograph, electronic searches are conducted in nine databases, including AMED, CANCERLIT, CINAHL, CISCOM, the Cochrane Library, EMBASE, HerbMed, International Pharmaceutical Abstracts, Medicine, and NAPRALERT. Search terms include the common name(s), scientific name(s), and all listed synonyms for each topic. Hand searches are conducted of 20 additional journals (not indexed in common databases), and of bibliographies from 50 selected secondary references. No restrictions are placed on language or quality of publications. Researchers in the field of complementary and alternative medicine (CAM) are consulted for access to additional references or ongoing research.

29.2 Selection Criteria

All literature is collected pertaining to efficacy in humans (regardless of study design, quality or language), dosing, precautions, adverse effects, use in pregnancy/lactation, interactions, alteration of laboratory assays (i.e.

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methodology of an assessment), and mechanism in action (*in vitro*, animal research, human data). Standardized inclusion / exclusion criteria are utilized for selection.

29.3 Data Analysis

Data extraction and analysis are performed by health care professionals conducting clinical work and/or research at academic centres, using standardized instruments that pertain to each monograph section (defining inclusion/exclusion criteria and analytic techniques, including validated measures of study quality). Data are verified by a second reviewer.

29.4 Review Process

Blinded review (i.e. the reviewer does not know who the author(s) are) of monographs is conducted by multidisciplinary research-clinical faculty at major academic centres with expertise in epidemiology and biostatistics, pharmacology, toxicology, complementary and alternative medicine (CAM) research, and clinical practice. In cases of editorial disagreement, a three-member panel of the Editorial Board addresses conflicts, and consults experts when applicable. Authors of studies are contacted when



clarification is required.

29.5 Update Process

NaturalStandard.com regularly monitors scientific literature and industry warnings. When clinically relevant new data emerge, best efforts are made to update content immediately. In addition, regular updates with renewed searches occur every 3-18 months, variable by topic.

The Natural Standards have adopted an evidenced based validated grading rational to assess the rigor of the evidence for a particular product. According to the information on their website (http://naturalstandard.com/grading.asp) their standard is the following:

"Natural Standard evidence-based validated grading rationale $^{\mathrm{TM}}$

- Grades reflect the level of available scientific evidence in support of the efficacy of a given therapy for a specific indication.
- Expert opinion and folkloric precedent are not included in this assessment, and are reflected in a separate section of each monograph ("Strength of Expert Opinion and Historic / Folkloric Precedent")
- Evidence of harm is considered separately; the below grades apply only to evidence of benefit.

Level of Evidence Grade

A (Strong Scientific Evidence)

B (Good Scientific Evidence)

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- C (Unclear or Conflicting Scientific Evidence)
- D (Fair Negative Scientific Evidence)
- F (Strong Negative Scientific Evidence)

Lack of Evidence

Criteria

- A: Statistically significant evidence of benefit from >2 properly randomized trials (RCTs), OR evidence from one properly conducted RCT AND one properly conducted meta-analysis, OR evidence from multiple RCTs with a clear majority of the properly conducted trials showing statistically significant evidence of benefit AND with supporting evidence in basic science, animal studies, or theory.
- B: Statistically significant evidence of benefit from 1-2 properly randomized trials, OR evidence of benefit from >1 properly conducted meta-analysis OR evidence of benefit from >1 cohort/case-control/non-randomized trials AND with supporting evidence in basic science, animal studies, or theory. This grade applies to situations in which a well designed randomized controlled trial reports negative results but stands in contrast to the positive efficacy results of multiple other less well designed trials or a well designed meta-analysis, while awaiting confirmatory evidence from an additional well designed randomized controlled trial.
- C: Evidence of benefit from >1 small RCT(s) without adequate size, power, statistical significance, or quality of design by objective criteria,* OR conflicting evidence from multiple RCTs without a clear majority of the properly conducted trials showing evidence of benefit or ineffectiveness, OR evidence of benefit from >1 cohort/case-control/non-randomized trials AND without supporting evidence in basic science, animal studies, or theory. OR evidence of efficacy only from basic science animal studies, or theory.
- D: Statistically significant negative evidence (i.e., lack of evidence of benefit) from cohort/case-control/non-randomized trials, AND evidence in basic science, animal studies, or theory suggesting a lack of benefit. This grade also applies to situations in which >1 well designed randomized controlled trial reports negative results, notwithstanding the existence of positive efficacy results reported from other less well



designed trials or a meta-analysis. (Note: if there is >1 negative randomized controlled trials that are well designed and highly compelling, this will result in a grade of "F" notwithstanding positive results from other less well designed studies.)

F: Statistically significant negative evidence (i.e., lack of evidence of benefit) from >1 properly randomized adequately powered trial(s) of high-quality design by objective criteria.*

Lack of Evidence: Unable to evaluate efficacy due to lack of adequate available human data.

* Objective criteria are derived from validated instruments for evaluating study quality, including the 5-point scale developed by Jadad et al., in which a score below 4 is considered to indicate lesser quality methodologically (Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McOuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Controlled Clinical Trials 1996; 17[1]:1-12).

† Listed separately in monographs in the "Historical or Theoretical Uses which Lack Sufficient Evidence" section."

C. FINDING, CONCLUSION & OPINION

- 31. I have searched the published literature for clinical evidence reflecting robust published peer-reviewed clinical evidence and safety regarding the clinical efficacy of the (final) products (- not one or more of their constituents) in issue, but could not find any.
- 32. As far as the possible therapeutic or prophylactic properties of individual constituents of the various products are concerned, I reiterate my earlier evidence:



- 32.1 It does not necessarily follow from the fact that the constituent parts for products have significant medicinal properties, that the product itself has any therapeutic and/or prophylactic effect;
- What accordingly has to be shown is that the products themselves have therapeutic or prophylactic efficacy;
- 32.3 In view of the fact that there were no robust, published peer-reviewed clinical trials (as per the considerations provided above) available for the products themselves, it cannot be concluded that they have any therapeutic and/or prophylactic efficacy.

DEPONENT

Signed and sworn before me at Oscillatory on this the H day of Marcon 2011 the deponent having acknowledged that the knows and understands the contents of this declaration and that the has no objection to the taking of the prescribed oath and that the considers it binding on her conscience. I certify further that the provisions of Regulation R.1258 of 21 July 1972 have been complied with.

Bonn.

COMMISSIONER OF OATHS

GROOTE SCHUUR HOSPITAL OBSERVATORY EX OFFICIO: COMMISSIONER OF OATHS

FULL NAMES: VERZONICA MYRA SASINAV.

OFFICIAL CAPACITY: Ex Officio

AREA APPOINTED: HEALTH: W. CAPE

FULL STREET ADDRESS: CAROTTE SCHOOL (ISSPITM)

CAG MAUNCEMENT SCHOOL

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