Consultation submission cover sheet

This form accompanies a submission on:

The document 'Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants)'	
Name and designation	Mrs Wendy Free
Company/organisation name and address	Quality Matters Safety Matters Pty Ltd
Contact phone number	07 3806 1297 / 0439 782 869

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: *(tick all that apply)*

Business in the therapeutics industry *(please tick sector):*

☐ Prescription medicines ☒ Complementary medicines ☐ OTC medicines

☒ Medical devices ☐ Blood, tissues, biological ☒ Other

☐ Sole trader ☒ Business with 2.5 employees

☐ Importer ☐ Manufacturer ☐ Supplier ☒ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

☐ Consumer organisation ☐ Institution (e.g. university, hospital)

☒ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☒ Other - *please specify*: Consumer and acts as agent for more than 50 sponsors/ manufacturers

It would help in the analysis of stakeholder comments if you provide the information requested below.

Comments

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
The proposed changes I(id implemented) are likely to result in a range of changes to the CM industry, some of which are obviously intentional but many of which will be consequential, and in my opinion detrimental. There will be significantyly more paperwork and significantyly greater complexity required buta a lower level of actual evidence required.
Whether or not you support the revised Evidence Requirements. If not supported, please provide reasons why.
The evidence requiremenst are not yet clear. I am not inagreement that less evidence is now required. Its my opinion that more, high quality evidence should be required but the proposed methodology is poorly aglined with these desires.
Any additional information on issues not asked in the above questions. If your comments relate to specific parts of the document please provide the page number and reference.

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Responses to
"***Evidence required to support indications for listed Medicines (excluding sunscreens and disinfectants) Version 2.0, Aug 2012***".

Preliminary Comments:
It has been noted that the publications proceeding this draft[1],[2], have both been entitled "Guidelines' where are this document appears to be designed for incorporation into legislation. A clear description of the process and anticipated outcomes of this incorporation would be beneficial in considering the range of impacts that could be anticipated; for example

- what mechanisms will be anticipated for updating and/or incorporating new SEE and/or removing the same?
- If a SEE is incorporated in a legislative instrument how will TGA maintain its capability to then determine that its content (or interpretation of the same) is (potentially) inappropriate in specific circumstances? (that is how will the TGA determine that they are not satisfied that there is evidence to support a claim?)

There appears to be a very poor level of correlations between Part A "requirements" and Part B "guidelines"; and disagreement within the document as to the actual expectations.

Section A appears to provide a requirement for a reduced data set to support claims when compared with previous editions of this document; however the documentation required to support this diminished data set is significantly greater (as it is described in section B).

It is the option of the author that this is very likely to add to costs of sponsors but could also contribute to poorer quality of evidence to support claims. It is also suggested that regulators review of the required data sets would be extremely time consuming and that it would be difficult to demonstrate that these reviews omitted critical or meaningful data, within the context of the exclusion criteria provided.

The grounds for excluding studies appear to be so broad and prescriptive that it will allow 'cherry-picking' of claims to suit ingredients and wide scale exclusion of potentially relevant studies (including those that showed little efficacy) based on criteria such as non-identical dosage.

If part B is considered to be relevant it appears that the range of claims able to be made using traditional evidence will be SIGNIFICANTLY greater than those permitted using scientific evidence; a circumstance that could contribute to the increased emergence of medicines with little or no scientific validation.

The document appears to be complex and contradictory in a number of places and if implemented in this form is likely to introduce a new level of complexity and uncertainty for the Australian marketplace.; without increasing the actual quality of data used to support indications.

The absence of guidance data in supporting 'marking indications' such as "9x more powerful than" is also noted.

[1] Guidelines for Levels and Kinds of Evidence to Support Indications and Claims For Non-Registerable Medicines, including ComplementaryMedicines, and other Listable Medicines Therapeutic Goods Administration October 2001
[2] Guidelines for levels and kinds of evidence to support indications and claims For Non-Registerable Medicines, including Complementary Medicines, and other Listable Medicines Version 1.1, April 2011

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Part A: Listable Indications

A.1 There appears to be inconsistency in the definitions of various words and terms. Specifically within the Act and Regulations the term **medicine** is linked with **active ingredients** and **therapeutic use** is linked with **indications**.

The Act states that

> ***Therapeutic goods*** means goods:
> (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
> i) for therapeutic use;
>
> **Therapeutic use** means use in or in connection with:
> *(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or*
> *(b) influencing, inhibiting or modifying a physiological process in persons; or*
>
> **indications,** in relation to therapeutic goods, means the specific therapeutic uses of the goods.
>
> ***medicine means:***
> (a) therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and

The Regulations describe

> **Active Ingredient** for a medicine, means a therapeutically active component in the medicines final that is responsible for its *physiological or pharmacological action*.

The current draft 'requirements' begin to draw these definitions together. However it is considered possible that the full meaning of 'therapeutic use' may be difficult apply. Consider for example some common, current coded indications.

- May assist blood circulation, Protects capillaries
- Source of calcium. Women's calcium requirements are increased after menopause.
- Maintenance of healthy eyes
- Liver formula.
- For mineral (may state the mineral) supplementation.
- For vitamin (may state the vitamin) supplementation.

Each of these claims relates of influencing or modifying a physiological process, but appear to lack that action and effect structure. Is it the intent of this structure to make such simple indications more complex? Will there need to be an indication corresponding to each active ingredient?

Consider for example a vitamin and mineral supplement that also contains some herbal material, there will be a number of actives responsible for a wide range of physical and pharmacological actions; and together these will constitute therapeutic use, does it follow that an indication is required for each active? It may be that the specific 'therapeutic use' is supplementation; how would such an indication be conveyed in this structured context?

A.2 Traditional Medicines & Implying Efficacy (page 11)
It's difficult to understand how this 'requirement' could be implanted or policed on a practical level. If we consider the above definition of 'medicine'; being therapeutic goods that are in some way 'represented to achieve or be likely to achieve' an intended action on the human body; surely that is alone, an 'implication of efficacy'?

Similarly how can directions for use be properly applied to such as substance?

> **directions for use, in** relation to therapeutic goods, includes information on:
> (a) appropriate doses of the goods; and
> (b) the method of administration or use of the goods; and
> (c) the frequency and duration of treatment for each indication of the goods; and
> (d) the use of the goods by persons of particular ages or by persons having particular medical conditions.

Compliance with this requirement would appear to exclude the capability to include statements that refer to the Frequency and duration of treatment; for example take 1 capsule daily until symptoms abate; It is also noted that "If symptoms persist consult your medical practitioner" implies efficacy.

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A.3 Use of vague or ambiguous terms (page 11)
While it is agreed that vague terms should be avoided its potentially difficult to apply these requirements to products such as homeopathic medicines, which typically include vague descriptions as part of their overall symptom picture. It may be that in some circumstances it is proper to include a range of such terms in the indications, perhaps this 'requirement' is better placed in the guidance section?

A.4 Evidence requirements (page 12)
"*support all indications by……identification of evidence linking and ingredient (etc)..as described in an authoritative source*" appears to potentially REDUCE the amount of evidence to support a 'medium level' claim. Past guidance has indicated that at least 2 sources are required.

A.5 Criteria in a SEE (page 13)
Guidance on how SEE might be combined to create a valid data set would be beneficial, for example can claims be 'stacked' using multiple SEE? What about multiple SEE and Multiple ingredients? (how is that different from our current regime?)

A.6 Indications supported by evidence (page 15)
The statement "The search **must** extend retrospectively for at least 10 years from the present day", if taken in its literal sense indicates that every day that a product is listed, a full 10 years retrospective search must be undertaken. What is the intent of this statement; does it imply that searches must be current from the date of listing? Are they subject to review? Are they intended to be part of annual product quality review? This would be extremely costly (see previous response on this matter) and virtually impossible to comply with.

How does one define 'independent' in the context of "two independent reviewers"?

"Original research **must** be appropriately documented"; does this imply that in studies where NEGATIVE or unfavourable outcomes are obtained, the absence of 'adequate documentation' invalidates these studies? The statement also appears to imply that "original documentation" may be required as opposed to "peer-reviewed published" documentation.

(3.2.1.5) Relevance of studies identified
"Only studies determine to relevant to proposed listable indications are to be included in the analysis", appears to indicate that the 'balance of evidence' may no longer be a consideration, and that the overall medication regime is no longer a relevant part of verification of indications; instead of this statement, guidelines on valid ways to include and exclude studies would be beneficial.

A.7 Assessing relevance for Scientific Indications
The 'interpretative approach' proposed in table 2 is considered to be 'less than objective';

- Identical active ingredient (excellent and good in relevance to medicine) would be statistically impossible to demonstrate, if taken in the literal sense[3]; so from a literal sense only "satisfactory or Unsatisfactory will be plausible responses.
- "Population studied is identical", again will be impossible to demonstrate, even for the same individuals as they will have aged in the time it has taken to complete and publish the study; there after what is the difference between 'clinical reasonable' and 'clinically reasonable to extrapolate'? How does this relate to 'differences of uncertain clinical significance' for example if the indication is for 'tension headache', and the test population was 95% women; does the indication only apply to women because the effect on men is ''differences of uncertain clinical significance'; if the population ratio was 75%/25% does the same apply?
- "Study directly measures health benefit" – how would this criteria be applicable to indications such as "may assist in", "helps relieve"? It appears that more definite indications are proposed; are we really happy with 'data mining' for 'post-hoc analysis', as a 'satisfactory' option?
- Relevance of context, under what circumstances could the 'unsatisfactory' criteria for relevance to the Australian context be reached?; as opposed to "probably applicable".

A.8 Levels of relevant evidence
If we hold level 1-4 evidence, do we still need to undertake the formalised review of the last 10 years – the current REQUIREMENTS appear to indicate that this is the case. Is this the genuine intent?

How does the requirement of 3.2.1.8 fit with 3.2.1.5? (if we've determined that its not relevant), using the defined exclusion criteria (say for example relevance to health benefit) then it will be excluded from

[3] Remember this will be a legislative instrument

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consideration. Is this the genuine intent? Consider the relevance of these circumstances where there are multiple active ingredients and we don't need an indication for each ingredient, and we want to 'claim stack'.

3.2.1.9 Why/How are we considering lower quality trials? We've already considered that 'original research must be appropriately documented' and that we can exclude trials based on 'arbitrary' criteria;

It is suggested that the practical application of these requirements will be poorly effective in reliably obtaining objective and scientifically valid indications.

Traditional Claims

A.9 Evidence report
Table 4 provides ambiguous terms unsuited to legislative controls. For example if the paradigm has been used for over 75 years how can it be relevant to the general Australian population? We're an aging population' we're gaining weight, we have markedly different dietary patterns; given these criteria it would seem impossible to legitimately link any target population to the current one. What criteria could or should be applied to definitively satisfying this criterion; do we really want to target medicines to distinct groups for example 'post menopausal women, 42 – 48 kg'?

How do we demonstrate in the legal sense that the goods have been used 'continuously' over for 75 years?; If we consider the current day this takes us back to 1937, do we allow for World wars when products were in short supply? If there was a day the product was not used, a week, a months, 2 seasons? While the intent of the requirements is appreciable, **the practical application of the requirements appears impossible**.

What does 'some dis-clarity with regard to characterisation of actives' mean? – is this really a satisfactory circumstance? (How does this relate to duration of use?)

A.10 3.2.2.7
Is it necessary to retype the EXACT terms used by each piece of evidence? (How does this provide value to the data set?) Surely if the exact terms are required, a copy of the reference is sufficient?

Part B – Guidance Materials

B.1 Its exceedingly frustrating to have 'restricted representation' used as example indications of compliant indication type, this reflects very poorly on the authors and provides a false sense of compliance to inexperienced individuals using this guidance[4].

B.2 Clarification on how indications based on BOTH scientific and traditional evidence may be made is merited, the data provided in the 4th paragraph of page 25 is particularly unclear.

B.3 What is mean by (page 27); "in general, must not refer to serious forms of illness"? Under what circumstances' could they refer to serious forms of illness? does this mean or infer that "restricted representations may be available for listed medicines?"

B.4 3.1.1
Requirement for 'review' of established sources of evidence? How and when is this review required (see comment a.6)

B.5 Table on page 29
- Where included in a SEE, the method of preparation is identical or comparable to that described; could this comparative be demonstrated via other means, for example chromatographic profiles? Standardisation?
- SAME route of administration- Could we have some criteria for equivalence here? For example is buccal the same as oral application? Is oral the same as nasal? Is mucosal application the same as topical application?
- Dosage range, is 5mL of a 10% tincture the same dosage as 2.5mL of a 20% tincture? (how much is a glass or cup - is it a metric or imperial cup – if we consider traditional medicines)
- Is topical application the same as 'external',

Perhaps 'closely similar' is a better guidance than 'the same'?

[4] http://www.tga.gov.au/industry/advertising-reg9-2010-12-013-healthworld.htm

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B.6 3.2.1.4
Considerable discussion is give to providing a sound scientific basis to identifying and assessing evidence, and while this is accepted standard practice for clinical practices its as yet unclear if this approach is directly valid to the complementary medicine environment. The systems described have been established specifically for scientifically prepared and published investigations and while this may be paired to the regime applied to complementary medicines validation it perhaps fails to consider that listed complementary medicines are intended to be an adjunct to registered medicines and clinical practice, not a replacement for them. It's the opinion of the author the validity of unequivocally applying this approach has yet to be verified.

B.7 Bottom of page 35 – Relance to target population;
If the REQUIREMENTS have been applied, its very difficult to appreciate under what circumstances 'biological plausibility could be merited", consider that we are allowed to use human data that has

- A 'comparable' active ingredient
- 'Some difference' between study populations
- 'post-hoc health benefit' and
- 'probably applicable to Australian Health care context'….

B.7 The relevance to health benefit appears to state that if other trials describe side effects, that have not been described in the relevant trials, these CANNOT be considered in evidence reviews.

B.8 **It is specifically refuted "that the average consumer is likely to expect that the product may assist in ALL symptoms associated with menopause";** The available data strongly indicates that the ONLY commonly shared symptoms of menopause are the cessation of menstruation and associated ovulation; it would be implausible to suggest that these symptoms could (or should) be redressed by complementary medication; there after there is a very wide range of the type, severity and duration of symptoms experienced by individual women. [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15] and the suggestion that 'the average' consumer is concerned about of the full range of symptoms is implausible.

B.9 Relevance to Health Benefit
The Guidance criteria described in the last paragraph of page 39 do not appear to comply with the 'requirements', as stated.
- Ideally the health benefit should be included in the study of the primary outcome. This ensures that the study is sufficiently powered to detect benefit that is statistically and clinically significant (3.2.1.8); where as the 'requirement' appears to allow[16]

- A 'comparable' active ingredient
- 'Some difference' between study populations
- 'post-hoc health benefit' and
- 'probably applicable to Australian Health care context'….

B.10 As described in A.7 true scientific application of the criteria contained within the table on page 42 does not seem possible or plausible, given that three of the four 'Excellent Criteria" could not be unequivocally substantiated in the scientific context; the relevant to medicine "good' also requires demonstration of 'identical; and a range of vague and ambiguous terms are used in a range of other 'good' and satisfactory criteria; and finally any studies that meet the unsatisfactory criteria will already have been excluded as be not relevant to the indication.

B.11 (3.2.1.6) Level of evidence
The guidance data provided in this section appears to contract the requirement provided in 3.2.1.4; *if a systematic review is used;* where as 3.2.1.4 appears to indicate that ALL relevant data from an objective, comprehensive, transparent and reproducible review of 10 years of literature is required.

[5] http://www.cks.nhs.uk/menopause/background_information/prevalence_of_symptoms
[6] http://www.ncbi.nlm.nih.gov/pubmed/20869181
[7] http://www.ncbi.nlm.nih.gov/pubmed/19281589
[8] http://onlinelibrary.wiley.com/doi/10.1111/j.1444-1683.2003.00093.x/abstract
[9] http://eprints.qut.edu.au/1150/1/1150.pdf
[10] http://www.apfmj.com/content/9/1/5
[11] http://www.amjmed.com/article/S0002-9343(05)00885-5/abstract
[12] http://www.jkscience.org/archive/volume91/menopausal.pdf
[13] http://contacto.med.puc.cl/interconsulta/intercon_sept_2010/Climacteric.pdf
[14] http://jco.ascopubs.org/content/13/11/2737.abstract
[15] http://bestpractice.bmj.com/best-practice/evidence/background/0804.html
[16] Table 2, page 16.

B.12 Assessing the significance of outcomes
As stated in previous correspondence, the use of the terms ‘statistically significant’ and ‘clinical significant’ are not uniformly applicable to all complementary medicines or indeed all indications. Consider if complementary medicines should be used in circumstances where the following indications are of ‘clinical significance’. In each of these cases, in order to achieve ‘clinical significance’ it seems to be apparent that medical intervention would be required to diagnose and treat the condition, not a desired attribute of complementary medicines and a circumstance in conflict with the ‘requirements’

- Relief of the symptoms of allergies
- May help increase joint mobility associated with arthritis
- To help maintain blood circulation to the peripheral areas of the body such as the legs, hands and feet.
- Aids or assists in the relief of constipation.
- Relief or treatment of diarrhoea
- Liver tonic. Aids digestion
- For the symptomatic relief of tinnitus.
- For the symptomatic relief of hangover
- Male support. Balances and supports normal male physiology and function.
- Relief of menstrual pain.

Application of the ‘qualifier’ ‘determining clinical significance’, clinical benefit, cost and side effects while applicable to registered medicines does not appear to accompany the wider community’s desire for ‘natural medicines’. While an appreciable degree of efficacy is always merited, the guidance provided appears not to appreciate this most significant attribute of complementary medicines.

B.13 Further incontinency is noted in the example provided on page 63.
Where as previous reference to a disease have indicated that ALL symptoms should be addressed, this example (alleviating symptoms of common cold) does not address ALL of the symptoms of the common cold (for example sneezing, nasal congestion etc)

The guidance provided for substantiating claims related to traditional medicines appears to enable significantly more latitude than does the analogous guidance for scientific medicines. This observation includes

- Can claim with evidence for only some of the symptoms in a named disease
- Can say <u>treatment</u> of stomach aches (page 57)

Additional Sources (SEE)
Natural Medicines Comprehensive Database

ABC of Dermatology 4th Edition Paul K Burton, ISBN 0-7279-1696-3
ABORIGINAL PHARMACOPOEIA by Dr Ella Stack
An Investigation into the Therapeutic Properties of Honey RIRDC Publication No. 09/0180
Antioxidants in food (ISBN: 1 85573 463 X) CRC Press
Bailey's Industrial Oil and Fat Products, Sixth Edition, Six Volume Set. Edited by Fereidoon Shahidi.
Bioactive Marine Natural Products, D.S. Bhakuni ISBN 1-4020-3484-9 (e-book)
Biologically Active Natural Products: Edited by Stephen J Cutler ISBN 0-8493-1887-4
BMJ Clinical Evidence
Botanical Medicine From Bench to Bedside Raymond Cooper
Clinical Botanical Medicine 2nd Edition Eric Yarnell
Clinical Gudie to nutrition and Dietary Supplements in disease Management J Jamison ISBN 0-443-07193-4 (alk. paper)
Compendium of HPLC applications for Traditional Chinese Medicines and Chmeical Drugs in China Pharmacopeia ISBN 7-117-07114-1.
Complementary and Alternative Medicine Steven B Kayne ISBN 978 0 85369 763 3
Cosmetic Dermatology ISBN 3-540-23064-5 Springer Berlin Heidelberg New York
CRC HANDBOOK OF Medicinal Spices James A. Duke ISBN 0-8493-1279-5
Dermatologic, Cosmeceutic, and Cosmetic Development Therapeutic and Novel Approaches Edited by Kenneth A. Walters ISBN--10: 0--8493--7589--4
Dietary Supplements 3rd Edn Pamela Mason ISBN ISBN 978 0 85369 653 7
Drug discovery and evaluation Vogel (Springer database)
Duke's Handbook of MEDICINAL PLANTS OF LATIN AMERICA James A. Duke ISBN 978-1-4200-4316-7
DUKE'S HANDBOOK OF Medicinal Plants OF THE Bible ISBN 978-0-8493-8202-4
Encyclopedia of Dietary Supplements Second EditionEdited by Paul M. Coates et al ISBN-13: 9781439819289
ENCYCLOPEDIA OF HUMAN NUTRITION ISBN 0-12-150110-8 (set)
Encyclopedia of Pain ISBN-13: 978-3-540-43957-8
Essentials of Chinese Medicine (2 volumes) Z Liu ISBN 978-1-84882-592-5
Essentials of Complementary and Alternative Medicine Wayne Jonas
Ethnopharmacology of Medicinal Plants: Asia and the Pacific, C Wiart 1-59745-160-6 (e-book)
Functional foods (ISBN: 1 85573 503 2) CRC Press
Functional Foods G Mazza
HANDBOOK OF Medicinal Herbs SECOND EDITIONJames Duke ISBN 0-8493-1284-1
Handbook of Essential Oils Science, Technology and applications K. Hu¨snü Can Baser Gerhard Buchbauer ISBN 978-1-4200-6315-8
Handbook of food and Nutrition 2nd edition Carolyn Berdanier
Handbook of FOOD-DRUG INTERACTIONS B McCabe CRC Press ISBN 0-8493-1531-X
Handbook of herbs and spices K. V. Peter (2 volumes) ISBN-0 8493-1217-5
Handbook of PREBIOTICS AND PROBIOTICS INGREDIENTS Health Benefits and Food Applications SUSAN SUNGSOO CHO ISBN-10: 1-4200-6213-1
Handbook of Prebiotics Glenn R Gibson ISBN 978-0-8493-8171-3
Handbook of Vitamins Robert B Rucker ISBN 0-8247-0428-2
Health Benefit its of Australian Native Foods – An evaluation of health-enhancing compounds ISBN 1 74151 932 2
Herbal and Traditional Medicine Molecular Aspects of Health Lester Packer ISBN: 0-8247-5436-0
Herbal Medicinal Products including Herbal medicine Products and Food Supplements Maria Spiteri
Herbal Medicines, Joanne Barnes, ISBN 978 0 85369 623 0
HERBAL PRODUCTS, Toxicology and Clinical Pharmacology SECOND EDITION
Herbs and natural supplements. An evidence-based guide 2nd Braun and Cohen.
Honey Scientific Report Office of Complementary Medicines December 1998
Illustrated Phytotherapy Thos Deschauer
Indian medicinal Plants CP Khare ISBN: 978-0-387-70637-5
LEUNG'S ENCYCLOPEDIA OF COMMON NATURAL INGREDIENTS USED IN FOODS DRUIGS AND MEDICINES IA Khan
Medicinal and Aromatic Plants——Industrial Profiles, Edited by Dr Roland Hardman (Volumes 1 ->)
Medicinal Plants in Folk Tradition an Ethanbotany of Britian and Ireland David E Allen
Medicinal Plants of Asia and the Pacific Wiart ISBN-13: 978-0-8493-7245-2

Medicinal Plants of the Bible ,Zohary
Medicinal Plants of the World I Ross (3 volumes)
Modern Phytomedicine Iqbal Ahmad
Natural Products from Plants, 2nd Edition Cseke et al ISBN 978-0-8493-2976-0
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Nutrient and Herbal Therpaies for Children and Adolescents for Children and Adolescents, George M. Kapalka, ISBN : 978-0-12-374927-7
Nutrient Drug Interactions K Meckling ISBN 978-1-57444-915-0
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Nutritional Supplements in Sports and Exercize M Greenwood, ISBN: 978-1-58829-900-0
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Phytomediciens of Europe L Lawson
PRD for Herbal medicine, J Gruenwald et al
Stockley's Herbal Medicines Interactions, Elizabeth Williamson, ISBN 978 0 85369 760 2
Textbook of Natural Medicine, J Pizzorno (2 volumes)
The A-Z of essential Oils EJ Bowels
The Clinical Practice of Complementary, Alternative, and Western Medicine W. John Diamond, M.D. ISBN 0-8493-1399-6
The complete Guide to Aromatherapy S Baattaglia
The Encyclopedia of Complementary and Alternative medicine T NAVARRA ISBN 0-8160-4997-1
The Encyclopedia of Vitamins, Mineral and Supplements T Navarra, ISBN 0-8160-4998-X
The Handbook of Clinically Tested Herbal Remedies M Barrett
The History of Medicine (Multiple Volumes) Kate Kelly
The Medicinal Plants of North Amercia AW Smith
The Medicinal Plants of the Phillippines TH Pardo de Tavers
The Oxford Book of Health foods JG Vaughan, ISBN 0-19-280680-7
The Use of Australian Honey in Moist Wound Management, RIRDC
The Value-adding Potential of Prebiotic Components of Australian Honey RIRDC
Toxicology and Clinical Pharmacology of Herbal Products
Edited by Melanie Johns Cupp, PHARMD, BCPS ISBN 0-89603-791-6
Toxicology and Clinical Pharmacology SECOND EDITION, Timothy S. Tracy, eISBN 10-digit: 1-59745-383-8
Traditional Sudanese Medicine Dr Ahmad Al Safi
Understanding Normal and Clinical Nutrition, SHARON RADY ROLFES
Useful Australian native Plants, The Technological Museum of NSW JH Maiden (1889)
Useful Plants & Drugs in Iran and Iraq David Hooper (1937)
WHO Medicinal Plants in China
WHO Medicinal Plants in PNG
WHO Medicinal Plants in the Republic of Korea
WHO Medicinal Plants of the South Pacific
(Homeopathic sources?)

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