Complementary Healthcare Council of Australia

# Guideline for the Sale and Supply of Practitioner Only Products

Edition 1, December

2011



This document provides guidance to the complementary medicine industry on the sale and supply of practitioner only products to health care professionals - including practitioner product guides and technical manuals.

**Title:** CHC Guideline for the Sale and Supply of Practitioner Only Products

**Publication date:** December 2011

**Review date:** December 2014

**Edition:** One

**ISBN:**

**Published by:** Complementary Healthcare Council of Australia

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# CHC Guideline for the Sale and Supply of Practitioner Only Products Product Guides and Technical Manuals

## 1 Objective

The objective of this document is to provide guidance to the complementary medicines industry on the appropriate content of practitioner only (PO) product guides and technical manuals to comply with the provisions in the *Therapeutic Goods Act 1989* ("the Act"), the *Therapeutic Goods Regulations 1990* ("the Regulations"), and the T*herapeutic Goods Advertising Code 2007* (TGAC), as amended from time to time.

Guidance was recommended for industry after it became evident that some practitioner only product guides were inappropriately promoting Listed practitioner only complementary medicines for indications that were not on the Australian Register of Therapeutic Goods (ARTG), including the treatment of serious health conditions.

This guidance document aims to assist sponsors in ensuring product guides and technical manuals meet the required advertising provisions, whilst still providing:

- an avenue to educate healthcare professionals;
- promote the sale and supply of practitioner only complementary medicines to healthcare professionals; and
- does so in a manner that promotes the quality use of therapeutic goods.

**Any advertising material (such as 'practitioner only product guides') which are non-compliant should be removed from circulation, and not re-distributed until amended, to ensure future and on-going compliance with the relevant advertising provisions or applicable legislation.**

This guide is intended to be used in conjunction with:

- The Therapeutic Goods Advertising Code;
- The Therapeutic Goods Act and Regulations;
- The Guidelines for Level and Kinds of Evidence to Support Claims and Indications for Therapeutic Goods; and
- The CHC Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products (under review).

## 2 Definitions

**Practitioner only product** – a complementary medicine listed or registered on the Australian Register of Therapeutic Goods and supplied exclusively to a healthcare professional.

**Practitioner only product guide** - a document that provides a list of company specific products available for supply to a healthcare professional. This guide is produced exclusively for healthcare professionals and is not distributed or available to consumers.

**Practitioner only technical manual** - a document containing technical, scientific or educational information about ingredients and/or health conditions, including serious health conditions. This manual is produced exclusively for healthcare professionals and is not

distributed or available to consumers. Technical manuals must not refer to or have a direct link to the product guide or a company branded product.

**Relevant Advertising Definitions**

**Section 3 of the Act**

***advertisement***, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

**Section 42AA of the Act**

**healthcare professional,** in relation to an advertisement, is a person who belongs to the professions or bodies described in section 42AA of the *Therapeutic Goods Act 1989*.

**Section 42B of the Act**

***broadcast media***, in relation to an advertisement or generic information, means any means (other than a means declared in the regulations to be an exempted means) by which the information is disseminated electronically in a visible or audible form or a combination of such forms.

***generic information*** in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, but does not include:

a. an advertisement about the goods; or
b. generic information included in an advertisement about the goods; or
c. bone fide news.

***mainstream media*** means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

***specified media***, in relation to an advertisement or generic information, means:

(a) mainstream media; or
(b) broadcast media; or
(c) cinematograph films; or
(d) displays about goods, including posters:
    (i) in shopping malls (except inside an individual shop); and
    (ii) in or on public transport; and
    (iii) on billboards.

**General notes on advertising**

Advertisements to consumers can be classified as either above the line or below the line material*:*

- ***above the line material,*** is taken to be advertisements for designated therapeutic goods published or inserted, or intended to be published or inserted, for valuable consideration, in specified media. Such advertisements require approval under Part 2, Division 2 of the Regulations.

- ***below the line material,*** are brochures, leaflets, flyers, shelf talkers, newsletters, point of sale material, videos, audio tapes and catalogues as well as any magazines or journals that are not mainstream media.

- ***Internet advertising,*** although the internet is captured under the definition of broadcast media, Regulation 5BA currently exempts the internet (and other forms of broadcast media) from the mandatory preapproval requirement for advertisements in specified media.

*It is important to note that the status of advertising material can change depending on where it appears. For example if a poster normally displayed inside an individual shop (below the line material) is displayed in a shopping mall or on a billboard, it becomes above the line material and requires preapproval.*

# 3 Practitioner Only Products – General Information

## 3.1 Supply of Therapeutic Goods to/by Complementary Healthcare Professionals

Practitioner only products are only to be supplied to and dispensed by a healthcare professional as described in section 42AA of the *Therapeutic Goods Act 1989*. Retail sale of practitioner only complementary medicine products to patients should only occur after consultation with that person.

The practitioner should be required to demonstrate to the supplier that they are registered with a professional association, and identify the clinic or location where they conduct consultations, in order to qualify for supply of practitioner only products.

A voluntary restriction of supply to those bodies outlined in section 42AA of the Act is provided at Appendix 9. The list aims to ensure only those health professionals with the training and experience in ingestible medicine modalities are supplied PO products. A list of other modalities is outlined to which PO companies should review qualifying criteria on a case by case basis.

## 3.2 Advertising Therapeutic Goods to Complementary Healthcare Professionals

It is recognised that healthcare professionals typically possess a higher level of understanding and knowledge about disease states, and the ability to distil pertinent information about therapeutic products.

Advertisements for therapeutic goods directed exclusively to healthcare professionals are governed by industry codes of practice and are not subject to the *Therapeutic Goods Advertising Code.* For more information, please refer to the *CHC Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products*.

Any advertising and promotional material supplied exclusively to a healthcare professional is not exempt from the provisions of the TGAC if such material is to be subsequently used as product support information supplied by the healthcare professional to a consumer.

Information and indications within all promotional materials must be capable of substantiation, and as such the indications must not exceed those included on the ARTG in relation to a product as required under Section 22(5) of the Act.

Scientific and technical information that relates to individual ingredients or research information should not directly refer back to the product guide or a company branded PO product.

Section 22(5) of the *Therapeutic Goods Act 1989* remains applicable to advertising of practitioner only products direct to healthcare professionals, that is:

A person commits an offence if:

(a) the person, by any means, advertises therapeutic goods for an indication; and
(b) the therapeutic goods are included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion.

Where a PO product is limited to "For Practitioner Dispensing Only" or words to that effect, it must meet the same regulatory requirements as other complementary medicines. For example, all claims made must be capable of substantiation, and such substantiation must be provided without delay upon receipt of a request.

Advertising of therapeutic goods to healthcare professionals within the context of education or trade seminars may only refer to those indications for therapeutic use that have been accepted for inclusion on the ARTG . More information on education to healthcare professionals can be found in section 6 of this guideline.

### 3.3 Display of Practitioner Only Products

Practitioner only products should not be accessible or visible in any retail outlet, as they are not for self prescribing. Inappropriate display of PO only products would include positioning a PO product where it may be able to be self selected by a consumer, such as on the shelf amongst other retail products.

PO products should not be accessible until after a consultation with a healthcare professional or upon presentation of a current script written by a healthcare professional.

PO product guides are for the promotion of PO products to healthcare professionals and should not be on display or made available to consumers.

### 3.4 Requirements for Practitioner Only Product labels

From a regulatory perspective, the difference between ' For Practitioner Dispensing Only' complementary medicine products (or words to that effect), and other Listed or Registered complementary medicines, is that these products are for dispensing and are *not* required to include a statement of purpose on the label.

This labelling exemption is provided by section 3(2)(m)(ii) of the *Therapeutic Goods Order No. 69*.

Sponsors of 'Practitioner Only Products' (Listed or Registered complementary medicines) can opt to include a statement of purpose on their products if they wish. These statements must meet the same requirements as other complementary medicine products, Listed and

Registered, with regards to evidence substantiation for indications and reflect only those therapeutic indications included on the ARTG for that product. However, if a statement of purpose is not included on a practitioner only product, the dispensing pack must include the statement 'For Practitioner Dispensing Only' or words to that effect.

The TGO 69 states in section 3(2)(m), particulars to be included on a label are as follows:

(m). a statement of the purpose or purposes for which it is intended that the goods be used, except:

i. where the goods are specified in Schedule 4 or Schedule 8 of the Poisons Standard; or

ii. where the goods are a dispensing pack supplied solely to a ***complementary healthcare practitioner,*** and include on the label the words 'For Practitioner Dispensing Only' …

A dispensing pack, in relation to a complementary medicine, is defined in the Therapeutic Goods Order 69, Section 2, as 'a pack which is to be supplied solely to complementary healthcare practitioners for supply to a person after affixing an instruction label following a consultation with that person'.

A healthcare professional is required to affix an instruction label to the 'For Practitioner Dispensing Only' product following a consultation with a consumer, which ought to include information such as:

- the name and particulars of the consumer;
- the recommended dosage amount per day; and
- details of the practitioner including name contact details and practitioner association provider number.

## 3.5 Scripts for PO products

The practitioner, if prescribing a PO product, should write a script after the consultation. The script ought to specify:

- the client's full name and date of birth;
- the practitioner's contact details and association provider number;
- the date the prescription was dispensed and expiry date; and
- recommendations made including substance or product name and dosage level.

Where the dispenser is also the prescriber, the above information should already be included in the patient record. It is advisable for the dispenser to retain a copy of the prescription on file.

**Scripts for Extemporaneously prepared medicines**

In the case of a script for a extemporaneously dispended good, such as a herbal extract, details in addition to those above should include: the full Latin/binomial name and recommended dosage (mls/day).

Practitioner only products are designed for dispensing by a healthcare professional to ensure an appropriate level of supervision is maintained, including recommendations as to the adjustment of/duration of treatment, concurrent medication use, and referral to other healthcare professionals, if required.

**Provision of repeat prescriptions**
When there is no number of repeats specified on the prescription, the dispenser should fill the prescription once only.

If the client requests additional repeats, the dispenser should consult with the practitioner who wrote the prescription to determine whether additional repeats are required, otherwise the client should be referred back to their practitioner for advice.

**Expired and undated prescriptions**
The dispenser should not dispense an undated prescription or a prescription that has expired.

## 3.6 Adverse reactions

The dispenser should verbally instruct the consumer about what to do in the event of an adverse reaction to the prescription (see Appendix 1 for details).

## 3.7 Consultations

A consultation with a healthcare professional ought to provide a discreet area where patient privacy can be assured. The practitioner is expected to maintain accurate, complete and up-to-date clinical records; retain all patient records in a safe and secure area for the duration as required by state or federal law.

The healthcare professional should not conduct an initial consultation with a client via telephone or the Internet. A face to face consultation is preferred over videoconferencing or other telecommunications so as to allow for other clinical examination markers to be identified.

It should be noted that healthcare professionals and their clients can make contact with in-house healthcare professionals employed by sponsors, for general information with particular regard to issues such as product suitability etc.

## 3.8 Product guides/ technical manuals on company websites

Where the product guide and technical manual are available online, an appropriate degree of separation is required. That is they should be published in a separate section of the website and not be hyperlinked to one another. Access to the PO product guides and technical manuals should require a practitioner log in or password that the individual company disseminates after checking appropriate qualifications and ongoing qualifying criteria such as continuing education of the user.

The product guide or product pages should list company specific products with appropriate indications as reflected in the corresponding product ARTG entry.

Section 3(b) of the TGAC states advertisements for therapeutic goods directed exclusively to healthcare professionals are governed by industry codes of practice and are not subject to the TGAC. The CHC *Code of Practice for the Marketing of Complementary Healthcare and Healthfood Products* will outline additional information around requirements on promotion of therapeutic goods to healthcare professionals.

*Industry should be aware that promotional information linked directly with specific products meets the definition of 'advertisement' and if not directed exclusively to healthcare professionals must comply with the TGAC.*

## 3.9 Extemporaneous Compounding

Concerns have been raised about the activities of some groups within the medicines sector, operating within the extemporaneous compounding exemption with regards to preparations containing medicines listed in the Poisons Standard.

Compounded complementary medicines can be advertised to healthcare professionals and to consumers. In practice, advertisements are often for a service that incorporates the use of these preparations rather than for the medicines themselves.

Item 6 of Schedule 5 to the Regulations exempts from inclusion on the ARTG "medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person."

Schedule 8 provides an exemption for certain persons from the operation of Part 3-3 (Manufacturing of therapeutic goods) of the Act. Item 4 of Schedule 8 to the Regulations lists certain complementary healthcare professionals and the circumstances where this exemption applies.

### Persons exempt from the operation of Part 3-3 of the Act

| Item | Persons | Matter in relation to which person exempted |
|---|---|---|
| 4 | herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation | where the preparation is for use in the course of his or her business and:<br>(a) the preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public; and<br>(b) the person carrying on the business:<br>(i) supplies the preparation for administration to a particular person after consulting with that person; and<br>(ii) uses his or her own judgment as to the treatment required. |
| 5 | a person who applies supplementary labelling to a manufactured product | the application of supplementary labelling, where the supplementary label contains only a name and address, the registration or listing number of goods, or the biological number of a biologic. |

Table 1 –extract from Schedule 8 of the Therapeutic Goods Regulations – Regulation 18

Item 4 of Schedule 8 to the Regulations provides, in effect, an exemption for these healthcare professionals from the need to comply with the Code of Good Manufacturing Practices if the above conditions are met.

In 2005, the TGA released a report which reviewed the practice of compounding chemists. Among other recommendations, this report suggested that consideration be given to advertisements directed at health professionals for extemporaneously compounded medicines being required to carry a warning that the preparation has not been assessed for safety and efficacy, and that the prescriber is strongly advised to obtain informed consent before prescribing the preparation.

The Australian Health Ministers' Advisory Council acknowledged that public health concerns existed and endorsed the continued development of appropriate regulation. The TGA is working with relevant stakeholders to address the health and safety risks of extemporaneous compounding of therapeutic goods. Extemporaneous compounding of scheduled medicines is currently subject to State and Territory legislation.

# 4 Practitioner Only Product Guide Requirements

A practitioner only product guide is a sponsor's document that provides a list of company specific products available for supply to a healthcare professional. The guide outlines information such as: the product name, description and formula; dosage and storage recommendations; therapeutic indications of use as per those detailed on the ARTG; specific warnings or contraindications, safety data, scientific research and/or mechanistic data.

## 4.1 Sale of Practitioner Only products

Practitioner only products have been designed specifically for dispensing by a healthcare professional. Therefore, practitioner only products are only available for retail sale to patients through prescribing by a healthcare professional after a consultation.

## 4.2 Advertising Provisions for Practitioner Only Product Guides

Practitioner only product guides are supplied to and intended for the use of healthcare professionals and as such should adhere to the relevant industry Codes of Practice.

If a product guide is *not* directed exclusively to healthcare professionals, ie where it is also available to consumers, it is captured by the definition of an 'advertisement' and as such must comply with the provisions of the TGAC. In interpreting the TGAC, emphasis should be placed on the object and the principles of the Code and the total presentation and context of the advertisement as specified in TGAC Section 1(3). Otherwise product guides directed exclusively to healthcare professionals are not required to comply with the TGAC but must adhere to the relevant industry Codes of Practice.

***The CHC's Code of Practice for the Marketing of Complementary Healthcare Products can be located here.***

Practitioner only product guides should restrict references to product therapeutic indications of use to those included on each product's ARTG entry in accordance with Section 22(5) of the Act. Should the sponsor choose to include the statement 'for Practitioner dispensing only' or words to that effect in the ARTG entry, then information around this product should be kept to a generic level- which still must comply with Section 22(5) of the Act.

It should be noted that listed PO products (AUST L) are not permitted to make high level claims. The Regulations (Schedule 4, Part 1, Item 3) make medicines that include prohibited or restricted representations ineligible for listing.

With regard to mechanistic data, the TGAs *Guidelines for the Levels and Kinds of Evidence to Support Indications and Claims* states:

> 'Types of quantifiable scientific evidence include clinical trials in humans, epidemiological evidence, animal studies and other evidence of biological activity. The greater the consistency of evidence across all these kinds, the greater the strength of the evidence. The strength of evidence will allow greater or lesser latitude in the nature of any claim and the wording that can truthfully be used.'

A product guide is required to be a separate publication to a technical manual so that scientific information on individual ingredients or health conditions that are not on the ARTG (technical manual) are not linked to a specific company product. For example, product information should not be accompanied or linked in any way to technical information on health conditions that have not been included on the ARTG and/or are serious in nature.

PO product guides are for the promotion of PO products to healthcare professionals and ought not to be on display or made available to consumers, including retailers. Product guides can be supplied in hard or electronic mediums direct to a healthcare professional.

### 3.5 Scientific information in an advertisement directed exclusively to HCP

Practitioner only product guides should adhere to the CHC's Code *of Practice for the Marketing of Complementary Healthcare and Healthfood Products* which states that:

> 'Literature references, information, findings or conclusions from independent research, surveys or scientific studies must be presented in a balanced, objective and accurate manner.'

The inclusion of scientific information within a product guide must support the immediate ARTG claims including structure and function claims and information. Substantiation of the claims must be provided as required.



# 5 Practitioner Only Technical Manual Requirements

### 5.1 General guidance for PO Technical Manuals

Technical manuals are a publication intended for the ongoing education of healthcare professionals. Technical manuals can contain technical and scientific information about individual complementary medicine ingredients and research linked to health conditions that are not included on the ARTG. They are not required to comply with the TGAC, however they must comply with other relevant requirements including but not limited to Section 22 (5) of the Act, and relevant provision of the Australian Consumer Law (ACL).

The ACL applies nationally and in all States and Territories, and to all Australian businesses. More information on ACL can be found at Appendix 10. The Australian Competition and

Consumer Commission (ACCC) states that with regard to the ACL "If the overall impression left by an advertisement, promotion, quotation, statement or other representation made by a business creates a misleading impression in your mind—such as to the price, value or the quality of any goods and services—then the conduct is likely to breach the law".

The technical manual is to be a separate publication to a practitioner only product guide and **must not** contain information that can be directly linked to a specific company product, product range or the product guide, such as displayed on the following page or hyperlinked (with respect to websites). This is because products must only be associated with those therapeutic indications of use that have been included on their ARTG entry. Further, Listed medicines cannot be associated with serious health conditions.

The technical/scientific information and research related to ingredient(s) is to be separate from the marketing of a formulated product that may contain the 'researched' ingredient.

The technical manual may display the company logo or branding within the publication so long as it does not refer the practitioner directly to a specific product outlined in the product guide.

Under Part 2, Division 4 of the Regulations, generic information about ingredients or components of therapeutic goods directed to consumers is required to comply with the principles stated in subsections 4 (1), (2), (3), (4), (5) and (6) of the TGAC. In practice, it means that the requirements of sections 5 (prohibited and restricted representations) and 6 (the minimum requirements) do not apply to generic information. For the purpose of this guideline, generic information also relates to technical and scientific information directed to a healthcare professional.

# 6 Practitioner Only Educational Events

## 6.1 General guidance for PO Educational Events

Educational events are important for the dissemination of knowledge and experience to healthcare professionals. Therefore, the primary purpose of an educational meeting must be the enhancement of healthcare, and Sponsor involvement must have the objective of providing current, accurate and balanced healthcare education in an ethical and professional manner.

Advertising of therapeutic goods to healthcare professionals within the context of education or trade seminars may only refer to those indications for therapeutic use that have been accepted for inclusion on the ARTG.

Research, which includes reference to prohibited and restricted representations (serious forms of diseases or conditions), may only be presented or discussed as long as there is no link or reference to a company branded product in the presentation or discussion.

All research information must be truthful, valid and not misleading. In this instance, the Sponsor may advertise in the room as long as the advertising materials comply with the TGAC and the indications are consistent with what has been entered on the ARTG.

Trade displays, if in a public area, must comply with the TGAC and must include the name of the sponsoring company.

A Sponsor company's obligations when running educational events are covered by industry Codes of Practice. Please refer to the 'promotion to healthcare professionals' section of the CHC *Code of Practice for the Marketing of Complementary Medicines and Health food Products*.

Practitioner only products that are available for purchase at educational events can be supplied to final year health professional students for educational and personal use.

*Industry should be aware that promotional information linked directly with specific products meets the definition of 'advertisement' and if not directed exclusively to healthcare professionals must comply with the TGAC.*

# 7 Sanctions and Enforcement

## 7.1 Sanctions and Enforcement

The offence provision at Section 22 (5) of the Act states that, 'a person commits an offence if':

(a) the person, by any means, advertises therapeutic goods for an indication; and
(b) the therapeutic goods are included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion.

Further, under Section 28(5)(ab), it is a Condition of acceptance onto the ARTG that "*the person in relation to whom the subject goods are registered or listed will not, by any means, advertise the subject goods for an indication other than those accepted in relation to the inclusion of the goods in the Register*".

A breach of a Condition of listing or registration constitutes grounds for the TGA to **CANCEL** the listing or registration of a complementary medicine from the ARTG; an action that means it would be illegal to supply that product on the Australian market.

Further details on sanctions and enforcements in relation to therapeutic goods directed exclusively to healthcare professionals, will be outlined in the CHCs *Code of Practice for the Marketing of Complementary Medicines and Health Food Products*.

# 8 Questions & Answers

***Can Practitioner Only Products be supplied to final year health professional students?***
Yes, for educational purposes. The POP Company should request the student to demonstrate they are in their final year of study or have commenced clinical training.

***Can warning statements be included on product information?***
Warning statements are not to be placed on product guide information if it includes restricted representations. It is the CHCs interpretation that it is acceptable to include warning statements, including the mention of drug classes in the case of contraindications, in the Technical Manuals but not Product Guides.

### Practitioner Only Product Guides

***Is it acceptable to have a diagram of the biochemical pathway for action of a company's product displayed in the product guide?***
Information about mechanistic actions for the indications of a listed medicine on the ARTG or product guide is acceptable provided that:

- it does not imply or refer to the treatment of a disease or ailment (as it may render a medicine ineligible for listing); and
- it does not imply or refer to a serious form of disease or ailment included in Appendix 6 of the TGAC (again it may render a medicine ineligible for listing and/or breaching the TGAC if used in advertising); and
- the statements are true and correct and the sponsor holds evidence to substantiate them; and
- the statements do not breach other legislative requirements.

### Practitioner Only Technical Manuals

***If a product is broken down to its individual ingredients and case studies are presented to practitioners around the ingredients would this be considered as advertising?***
Advertisements for therapeutic goods directed exclusively to healthcare professionals are governed by industry Codes of Practice and are not subject to the *Therapeutic Goods Advertising Code*. Research which includes reference to prohibited and restricted representations (serious forms of diseases or conditions) may only be presented or discussed as long as there is no link or reference to a company branded product in the presentation or discussion.

***Can a company logo be used in the Technical Manual?***
A company logo on a Technical Manual is acceptable. However, there should be no direct link between educational material and products.

***If after a post market review, therapeutic indications for the PO product are required to be amended, can these be made at the next print run and what period of time is reasonable?***
If a breach of the advertising requirements is found in a product guide, depending on how serious the breach, the company will be asked to remove it from circulation, or amend at the next print run, or issue a label update.

# 9 Appendix

## 9.1 Voluntary restriction of supply of PO complementary medicine products

Section 42AA of the Act exempts advertisements directed exclusively to specified healthcare professionals from the requirements of Part 5-1 of the Act, including members of the bodies listed in Schedule 1 of the Regulations. It does not apply to the supply of product.

From a regulatory perspective there is no restriction on the supply of therapeutic goods to a retailer or a practitioner providing the relevant statutory requirements relating to entry in the ARTG, labelling and advertising have been satisfied. This is, of course, provided that the therapeutic good is not scheduled as a prescription-only, pharmacist-only or pharmacy medicine (or otherwise not permitted under State and Territory legislation).

The restriction of supply is a commercial decision made by the sponsor of the goods and the TGA has no objection to this voluntary restriction upon supply. The Act does not regulate healthcare practice issues, nor does it inhibit related operations.

Further, there is no requirement in the Act that complementary healthcare professionals be 'registered' and the Act does not recognise the status of any healthcare professionals. The questions of registration or accreditation of healthcare professionals is a State and Territory matter and has no connection with the Commonwealth Act and Regulations.

For the purpose of voluntary restriction of supply of practitioner only complementary medicine products, the following list outlines those bodies the CHC recommends industry supply or review for supply of practitioner only medicines. Supply of POP to healthcare professionals should include those professionals with the training and experience in ingestible medicines. A review for supply relies on company discretion and should be conducted on a case-by-case basis.

| Professions considered acceptable for supply of POP | Professions considered as requiring a review for supply of POP |
|---|---|
| Naturopaths | Psychologist |
| Herbalists | Optometrists |
| Homeopathic Practitioners | Physiotherapists |
| Nutritionists | Nurses |
| Traditional Chinese Medicine Practitioners | Midwives |
| Medical Practitioner | Dental Hygienists |
| Dentist | Dental Prosthetists |
| Pharmacist | Dental Therapists |
| Chiropractors | Persons engaged in Wholesaling Therapeutic goods |
| Osteopaths | Podiatrists |
| Purchasing Officers in Hospitals | Kinesiologists |



## 10 Other Resources

This guideline does not attempt to cover practitioner practice issues or business law. Further information may be found below.

The Australian Consumer Law (ACL) aims to protect consumers and ensure fair trading in Australia. The regulators of this law include: the Australian Competition and Consumer Commission (ACCC), the Australian Securities and Investments Commission (ASIC), and each state and territory consumer protection agency.

Avoiding unfair business practices- A guide for businesses and legal practitioners
http://www.consumerlaw.gov.au/content/the_acl/downloads/business_practices_guide.pdf

ACCC information on Misleading & deceptive conduct:
http://www.accc.gov.au/content/index.phtml/itemId/815335

Advertising guidelines for registered Chinese Medicine practitioners -Trade Practices Act and Therapeutic Goods Advertising Code (pg 6)
http://www.cmrb.vic.gov.au/information/p&c/practiceconduct/GuidelineAdvertising-Dec2004.pdf

Australian Natural Therapist Association-Code of Professional Ethics:
http://www.australiannaturaltherapistsassociation.com.au/downloads/ANTA_codeofethics.pdf

Australian Traditional Medicine Society-Code of Conduct:
http://www.atms.com.au/about/About_Code.asp

National Herbalist Association of Australia-Code of Ethics:
http://www.nhaa.org.au/index.php?option=com_content&view=article&id=81&Itemid=76

Coded Indications that refer to Biomarkers:
http://www.tga.gov.au/industry/cm-notices-biomarkers-110705.htm

**Complaints about complementary medicines may be directed to:**

The Secretariat
Complaints Resolution Committee (CRC)
PO Box 450
Mawson ACT 2607
Phone: + 61 2 62604022
Fax : +61 2 62604122
Email: standards@chc.org.au

Complaint Submission Form

**Guidance on how to complain:**

Quick guide on how to make a complaint
Quick guide on how to respond to a complaint