



**ATMS**

Australian Traditional-  
Medicine Society



# White Paper 7

Understanding TGA Compliance

*for Natural Health Professionals*

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# Executive Summary

The Therapeutic Goods Administration (TGA) is the national regulator of therapeutic goods in Australia, overseeing medicines, supplements, devices, and advertising to protect public safety and ensure compliance with the Therapeutic Goods Act 1989. For natural health professionals, understanding TGA compliance is essential—not only to remain lawful, but also to safeguard professional reputation, protect patients, and retain eligibility for health fund recognition and insurance cover.



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Chief Executive Officer.

This paper provides natural health practitioners with a clear, evidence-based overview of TGA obligations, including:

- Legislative framework – how the Act, Regulations, and Advertising Code apply to natural health practice.
- When TGA rules apply – supply, advertising, endorsements, extemporaneous compounding, and importation.
- Product regulation – requirements for the Australian Register of Therapeutic Goods (ARTG), including listed, assessed listed, and registered medicines.



- Common risks – social media posts, mobile dispensaries, over-the-counter herbal sales, and CBD products.
- Enforcement and penalties – fines, civil penalties, and criminal charges, supported by recent case studies.
- Real-world practitioner scenarios – including guidance on mobile naturopathic dispensaries and CBD retail sales.
- Practical tools – a compliance checklist to support members in daily practice.

TGA compliance is not optional. Infringement notices, civil penalties exceeding AUD 1 million, and even criminal charges can be applied for breaches. Beyond financial cost, non-compliance risks loss of ATMS membership, health fund provider recognition, and professional insurance cover.

ATMS is committed to equipping members with clear guidance, education, and advocacy so that natural health professionals can practise safely, legally, and with confidence.





## 2. Legislative Framework

The regulation of therapeutic goods in Australia is governed primarily by the Therapeutic Goods Act 1989 (Cth) (the Act) and supported by subordinate legislation, codes, and related consumer protection laws. For natural health professionals, these frameworks determine when and how TGA compliance obligations apply.

### 2.1 Therapeutic Goods Act 1989

The Therapeutic Goods Act 1989 establishes the national regulatory scheme for medicines, devices, and other therapeutic goods. Its key provisions include:

- Requirement for therapeutic goods to be included in the Australian Register of Therapeutic Goods (ARTG) before supply (unless exempt).
- Controls on manufacturing, labelling, and distribution of therapeutic goods.
- Offences and penalties for unlawful supply, advertising, or importation.



## **2.2 Therapeutic Goods Regulations 1990**

The Therapeutic Goods Regulations 1990 provide additional detail on how the Act operates, including exemptions relevant to practitioners:

- Extemporaneous compounding exemption – allows practitioners to prepare and dispense a medicine for an individual patient following a consultation, without ARTG listing. This does not extend to wholesale or retail sales.
- Personal importation scheme – sets limits for patients importing therapeutic goods for personal use.

## **2.3 Therapeutic Goods Advertising Code (2021, amended 2023)**

The Therapeutic Goods Advertising Code provides mandatory standards for all advertising of therapeutic goods to the public. It ensures that claims are socially responsible, scientifically valid, and do not mislead consumers. Key requirements include:

- Truthfulness and balance – all information must be accurate and not exaggerated.
- Evidence-based claims – practitioners and companies must hold appropriate evidence to support any therapeutic claims made.
- Prohibited claims – advertising cannot suggest treatment, cure, or prevention of serious diseases such as cancer, diabetes, cardiovascular disease, or mental health disorders unless specifically approved by the TGA.



- Testimonials and endorsements – use of patient testimonials is tightly restricted; paid or incentivised endorsements must be clearly disclosed.
- Mandatory statements – some advertisements must carry specific warnings (e.g., “Always read the label” and “Follow the directions for use”).

## **2.4 Australian Consumer Law (ACL)**

TGA compliance overlaps with the Australian Consumer Law (ACL), which prohibits misleading or deceptive conduct in trade and commerce. Even if a claim does not breach the Advertising Code, it may still contravene the ACL if it misleads consumers. The Australian Competition and Consumer Commission (ACCC) works closely with the TGA in enforcement.

## **2.5 Professional Standards and ATMS Code of Conduct**

Alongside statutory obligations, natural health professionals must also comply with:

- ATMS Code of Conduct – requiring honesty, integrity, and compliance with all legal obligations.
- Insurance conditions – professional indemnity insurers require practitioners to comply with the Act and related regulations. Breaches may void cover.
- Health fund requirements – recognition as a provider with private health insurers requires compliance with both TGA and ACL obligations.



## 3. When TGA Rules Apply & ARTG Requirements

TGA obligations extend beyond manufacturers and importers. Natural health practitioners can trigger compliance requirements when they supply, advertise, endorse, or import therapeutic goods. Understanding these circumstances is critical to avoiding inadvertent breaches.

### 3.1 When TGA Rules Apply

Practitioners must comply with the Therapeutic Goods Act and related regulations if they:

- Supply therapeutic goods – including dispensing, compounding, or selling herbal tinctures, supplements, or homeopathic preparations.
- Advertise therapeutic goods – any statement to the public that promotes the use or supply of a therapeutic good. This includes websites, social media posts, clinic flyers, podcasts, and even practitioner interviews.
- Import goods – personally importing therapeutic goods (e.g., herbal products from overseas suppliers) without ensuring ARTG inclusion or exemption.
- Endorse products – providing testimonials, quotes, or social media endorsements for products, whether or not payment is received.

Exemptions exist in narrow circumstances (e.g., extemporaneous compounding for an individual patient), but these do not extend to wholesale or retail sales.





### 3.2 The Australian Register of Therapeutic Goods (ARTG)

The ARTG is the official database of all therapeutic goods legally supplied in Australia. Products must generally be included on the ARTG unless specifically exempt. There are three main categories:

1. Listed Medicines (AUST L)
  - Low-risk products, such as vitamin supplements or some herbal medicines.
  - Claims limited to minor, self-limiting conditions.
  - Evidence of safety and quality must be held by the sponsor.
2. Assessed Listed Medicines (AUST L(A))
  - Still low-risk but with stronger therapeutic claims.
  - The TGA directly evaluates evidence of efficacy.
3. Registered Medicines (AUST R)
  - High-risk medicines, including prescription medicines and vaccines.
  - Subject to rigorous evaluation of safety, quality, and efficacy.

### 3.3 Practitioner Exemptions

Some situations allow practitioners to supply therapeutic goods without ARTG inclusion:

- Extemporaneous compounding – preparing a custom product for an individual patient following a consultation.
- Herbal dispensary supply – permissible only when linked to a consultation and compliant with hygiene, storage, and labelling requirements.



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- Personal importation by patients – patients may import small quantities for personal use under strict conditions, but practitioners cannot resell these products.

Importantly, retail sale of unlisted products (e.g., CBD oils, imported herbal formulas) is not permitted unless ARTG-approved.





## 4. Advertising Compliance Requirements

The Therapeutic Goods Advertising Code (2021, amended 2023) applies to all therapeutic goods advertising to the public. This includes websites, clinic brochures, podcasts, social media posts, and even practitioner interviews if they promote a therapeutic good.

### 4.1 What Counts as Advertising?

Any statement, picture, or design intended to promote the use or supply of a therapeutic good is considered advertising. This includes:

- Website descriptions of products or services
- Social media posts showing products with captions implying therapeutic benefit
- Flyers, posters, or newsletters distributed to clients
- Interviews, blogs, or podcasts where therapeutic claims are made

If the communication reaches the public (not just private one-to-one consultation notes), it is likely advertising under the Code.



## 4.2 Core Rules for Practitioners

Practitioners must ensure that advertising is:

- Truthful and evidence-based – claims must be backed by documented scientific or traditional evidence.
- Not misleading or exaggerated – avoid overstating benefits or implying guaranteed results.
- Appropriate to risk – only low-level, self-limiting conditions can be advertised (e.g., “relieves mild digestive discomfort” rather than “cures IBS”).
- Free from prohibited claims – practitioners cannot claim to treat, cure, or prevent serious diseases (e.g., cancer, diabetes, COVID-

Advertising must remain compliant with the Advertising Code and avoid:

- Serious disease claims – practitioners must not state or imply that natural therapies can treat, cure, or prevent conditions such as cancer, cardiovascular disease, diabetes, mental illness, or COVID-19.
- Unsubstantiated therapeutic claims – all claims must be supported by evidence, whether scientific studies or recognised traditional use evidence.
- Misleading representations – avoid suggesting that products are government-approved simply because they are listed on the ARTG.
- Testimonials and endorsements – the Code bans patient testimonials that may mislead, as well as endorsements by health professionals, celebrities, or social media “influencers.”
- Comparative superiority claims – practitioners cannot claim their product or modality is “better than” or “safer than” another unless robust evidence exists and the TGA permits.





### 4.3 Social Media & Digital Advertising Risks

Social media is now the highest risk area for practitioner breaches. Common pitfalls include:

- Sharing patient “success stories” or before/after photos → this constitutes a testimonial and is prohibited.
- Reposting supplier or influencer content → practitioners are responsible for content they share, even if created by others.
- Linking directly to sales pages with unapproved claims → still considered advertising.
- Hashtags implying disease treatment (e.g., #anxietyrelief, #cureeczema) → breaches the Code.

Practitioners must monitor all platforms (Facebook, Instagram, TikTok, YouTube, podcasts, blogs) for compliance.



#### 4.4 High-Risk Phrases to Avoid

The TGA has identified several red flag phrases commonly used in non-compliant advertising, including:

- “Cures” / “Treats” / “Prevents” serious illness
- “Scientifically proven” (without evidence)
- “Guaranteed results”
- “Safe and natural alternative to prescription drugs”

Instead, practitioners should use measured language such as:

- “Traditionally used in Western herbal medicine to relieve mild digestive discomfort.”
- “May support relaxation in times of stress.”

#### 4.5 Member Scenario Example – Mobile Herbal Dispensary

An ATMS member recently asked whether they could run a mobile naturopathic dispensary supplying herbal tinctures after short “mini consultations.” ATMS advised:

- This is permissible only if each consultation is genuine (including history-taking, assessment, informed consent, and record-keeping).
- Any advertising must avoid terms like “on-the-spot remedies for chronic disease” or similar.
- The extemporaneous compounding exemption allows supply for individual patients but does not permit retail-style sales.
- The mobile clinic must meet council hygiene standards, safe storage, and accurate labelling requirements.



## 5. Common Compliance Risks for Practitioners

Even well-meaning practitioners can unintentionally breach TGA requirements. Below are the most common risk areas identified through TGA enforcement actions and ATMS member queries.

### 5.1 Social Media & Online Advertising

- Testimonials and reviews: Sharing or reposting client stories is prohibited. Even Google Reviews or Facebook comments left by patients should not be solicited or republished.
- Before-and-after images: Considered misleading advertising, particularly for skin, weight loss, or musculoskeletal conditions.
- Use of hashtags: Claims such as #curecancer, #anxietyrelief, or #diabetes support are non-compliant.
- Links to suppliers: Linking to product suppliers who make unapproved claims can still make the practitioner responsible.

### 5.2 Overstated Therapeutic Claims

- Using words like “cures,” “guaranteed,” or “proven” without high-level clinical evidence.
- Advertising benefits for serious conditions (e.g., cancer, infertility, heart disease, COVID-19).
- Claiming a therapy is a substitute for medical care or prescription medication.



### 5.3 Herbal Dispensaries & Extemporaneous Compounding

- Practitioners may compound and dispense medicines only for individual patients after consultation.
- Retail-style sales (e.g., “over-the-counter” or community stall sales) are not covered by the exemption.
- Labels must clearly show practitioner details, ingredients, dosage, and expiry.
- Storage, hygiene, and council requirements must be met for mobile or fixed-site dispensaries.

ATMS Example: A member sought advice about running a mobile naturopathic dispensary. ATMS clarified that “mini consultations” are acceptable only if they meet full professional consultation standards. Dispensing without consultation or selling premade tinctures retail-style is non-compliant.

### 5.4 CBD Products

- Cannabidiol (CBD) remains mostly Schedule 4 (Prescription Only) under the Poisons Standard.
- In 2020, low-dose CBD was down-scheduled to Schedule 3 (Pharmacist Only), but no products have yet been registered on the ARTG for sale in pharmacies.
- This means there are currently no legal CBD products available for retail sale in Australia.





- Only medical practitioners can lawfully prescribe CBD under the Special Access Scheme (SAS) or Authorised Prescriber scheme. ATMS Example: A member asked whether they could sell CBD in a clinic retail setting. ATMS advised:
- This is not permitted as no ARTG-approved CBD products exist for retail.
- Selling CBD without authorisation is a criminal offence under the Therapeutic Goods Act 1989.
- Doing so would also breach the ATMS Code of Conduct and void professional indemnity insurance.

### **5.5 Australian Consumer Law (ACCC Overlap)**

- Even if TGA rules are met, claims must also comply with the Australian Consumer Law (ACL), enforced by the ACCC.
- Misleading or deceptive conduct (e.g., “clinically proven” without evidence) can result in significant penalties.
- The ACL applies to all services, not just therapeutic goods, meaning that overpromising outcomes in consultations can also breach consumer law.



## 6. Enforcement & Penalties

The TGA has broad enforcement powers under the Therapeutic Goods Act 1989. Non-compliance can lead to warnings, fines, civil penalties, criminal charges, and reputational damage. ATMS members must be aware that even inadvertent breaches can have serious consequences.

### 6.1 Enforcement Powers

- Infringement notices – fines of up to AUD 3,960 (individuals) or AUD 19,800 (corporations) per breach.
- Civil penalties – for serious contraventions, up to 5,000 penalty units (currently over AUD 1.5 million for corporations).
- Criminal prosecution – reckless or intentional breaches may result in imprisonment, particularly where public safety is at risk.
- Publication of breaches – the TGA publicly lists enforcement actions, creating reputational damage for practitioners and their associations.



## 6.2 Recent TGA Case Examples

### 1. Unlawful CBD Advertising (2023–2024)

- Several companies were fined for advertising prescription-only CBD as if it were available “over the counter.”
- Penalties ranged from AUD 50,000–80,000 in infringement notices, plus product removal.
- Highlight: A Victorian business faced over AUD 60,000 in fines for advertising CBD oils online to the general public.

### 2. Medicinal Cannabis Claims (2023)

- A Sydney clinic was penalised for suggesting medicinal cannabis could treat cancer and epilepsy.
- The TGA issued fines totalling AUD 132,000.

### 3. Weight-Loss Medicines (2022–2023)

- Companies advertising prescription-only appetite suppressants online faced over AUD 600,000 in combined penalties.
- Key breach: claiming products were “safe, natural weight loss” when they were actually restricted medicines.

### 4. Practitioner-Level Example

- A natural health practitioner was issued infringement notices for using patient testimonials and before/after photos on social media to promote supplements.
- Although fines were smaller (AUD 7,920), their details were published by the TGA, leading to loss of client trust.



### **6.3 Insurance & Health Fund Implications**

- Professional indemnity insurers may refuse cover if a claim arises from unlawful advertising or supply.
- Health funds may suspend or terminate provider status if TGA breaches occur.
- ATMS membership requires compliance with all relevant laws – repeated breaches can result in disciplinary action or expulsion.







## 7. Practical Implications for ATMS Members

TGA compliance is not optional; it is a core professional responsibility. For ATMS members, this means translating the legislative framework and enforcement risks into everyday practice decisions.

### 7.1 Advertising & Marketing

- Review all websites, brochures, and social media posts to ensure no unapproved claims are made.
- Avoid testimonials, before-and-after photos, or exaggerated claims.
- Focus on general wellness language (e.g., “supports wellbeing,” “assists with relaxation”) rather than claims of curing or treating disease.

### 7.2 Dispensing & Compounding

- Herbal and nutritional products may be dispensed only after a consultation that meets professional standards.
- Over-the-counter sales without consultation breach both the Therapeutic Goods Act and ATMS Code of Conduct.
- All dispensed products must carry clear labelling, including practitioner details, dosage, and expiry date.



### **7.3 CBD & Restricted Substances**

- Do not supply or sell CBD unless it is an ARTG-approved product (none currently available for retail).
- Referring patients to their GP for medical prescription pathways (e.g., SAS or Authorised Prescriber) is the only lawful option.
- Breaching CBD rules risks criminal penalties and membership suspension.

### **7.4 Record-Keeping & Documentation**

- Maintain thorough clinical notes for every consultation, even short ones.
- Retain copies of product labels, batch numbers, and invoices for dispensed products.
- Document consent discussions and any advice given about products or therapies.

### **7.5 Insurance & Health Fund Eligibility**

- Non-compliance with TGA rules may invalidate insurance coverage if a claim is linked to unlawful practice.
- Health funds may revoke provider numbers if members are found breaching advertising or dispensing laws.
- ATMS membership, and the trust it conveys, requires strict adherence to compliance standards.



## 7.6 Professional Reputation

- TGA publishes all enforcement actions online, meaning even minor infringements can damage professional credibility.
- Clients increasingly seek practitioners who are transparent, compliant, and ethical.
- Compliance is therefore not just a legal issue but a strategic advantage for building trust and sustaining practice growth.





## 8. Compliance Checklist & References

This checklist provides ATMS members with a practical tool to quickly assess whether their practice, advertising, and product use meet TGA requirements

### 8.1 Compliance Checklist for Practitioners

#### Advertising & Marketing

- Have I removed testimonials, before/after photos, and exaggerated claims from all advertising?
- Are my health claims truthful, evidence-based, and not misleading?
- Am I avoiding references to serious diseases (e.g., cancer, diabetes, depression) unless TGA-approved?
- Do my social media posts comply with the Therapeutic Goods Advertising Code 2021 (as amended 2023)?

#### Product Supply & Dispensing

- Am I only supplying products that are ARTG-listed or compounded under exemptions?
- Do I provide full consultations (not over-the-counter sales) before dispensing herbal or nutritional medicines?
- Are all my dispensed products properly labelled with practitioner details, dosage, and expiry?
- Am I keeping accurate batch, invoice, and client records for dispensed products?



### **Restricted Substances (e.g., CBD)**

- Am I avoiding selling or advertising CBD or other prescription-only medicines?
- Do I refer patients to appropriate medical prescription pathways where relevant?

### **Record-Keeping & Professional Standards**

- Are my clinical records thorough, accurate, and secure?
- Do I have documented consent for all treatment and product recommendations?
- Am I complying with the ATMS Code of Conduct in addition to TGA laws?

### **Insurance & Health Funds**

- Do I understand that non-compliance may invalidate insurance coverage?
- Am I meeting health fund requirements for provider recognition and lawful practice?



## 8.2 References & Resources

- Therapeutic Goods Administration (TGA) – <https://www.tga.gov.au>
- Therapeutic Goods Act 1989 (Cth) – Federal Register of Legislation  
<https://www.legislation.gov.au/C2004A03952/latest/versions>
- Therapeutic Goods Regulations 1990 – Federal Register of Legislation  
<https://www.legislation.gov.au/F1996B00406/latest/versions>
- Therapeutic Goods Advertising Code (2021, amended 2023) – TGA Advertising Code <https://www.tga.gov.au/how-we-regulate/advertising/applying-advertising-code>
- Australian Register of Therapeutic Goods (ARTG) – <https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg>
- Australian Competition & Consumer Commission (ACCC) – <https://www.accc.gov.au>
- ATMS Code of Conduct – <https://www.atms.com.au/sign-in/>



## 9. About ATMS

The Australian Traditional-Medicine Society (ATMS) is the leading professional association for natural medicine practitioners in Australia. Founded in 1984, ATMS has been at the forefront of advocating for, supporting, and promoting high standards in natural healthcare for over 40 years. Our members include accredited practitioners, students, and industry professionals committed to delivering safe, effective, and evidence-informed natural medicine.

As a not-for-profit, membership-based organisation, ATMS is dedicated to ensuring professionalism, ethical practice, and continued education within the natural medicine industry. We engage with government bodies, regulatory agencies, and industry partners to advance the recognition of natural medicine and advocate for policies that support our members and the wider community.

ATMS exists to:

- Promote natural medicine as a vital part of Australia's healthcare system.
- Represent practitioners at all levels of government, industry, and regulation.
- Support members by providing education, professional development, and advocacy.
- Encourage the highest standards of professionalism and ethical practice.





We believe in freedom of choice in healthcare and work to ensure that natural medicine remains accessible, recognised, and respected.

## **OUR VALUES**

### **Integrity**

- We build trust through responsible action.
- We embrace freedom of choice and respect diversity in healthcare.

### **Excellence**

- We strive for the highest standards in practice, education, and research.
- We continuously adapt, learn, and grow to meet the evolving needs of our members.

### **Leadership**

- We advocate, collaborate, and engage with government and industry stakeholders.
- We aspire to lead through innovation, research, and professional support.

### **Passion**

- We believe in the power of natural medicine to improve lives.
- We honour traditional principles while embracing evidence-informed practice.

### **Member-Focused**

- We prioritise the growth, success, and recognition of our members.
- Our members are at the heart of everything we do.




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## 10. Contact Us


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