

Submission to the TGA: Proposal to remove *Andrographis paniculata* from the Permissible Ingredients Determination

Attn: Stakeholder Engagement Team, non-prescription medicines, TGA

Organisation: Australian Register of Naturopaths and Herbalists (ARONAH)

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1. Introduction

The Australian Register of Naturopaths and Herbalists (ARONAH) welcomes the opportunity to provide feedback on the proposal to remove *Andrographis paniculata* from the Permissible Ingredients Determination.

As a body established to uphold the standards of education, conduct, and safety for the profession, modeled on the National Registration and Accreditation Scheme (NRAS), ARONAH is uniquely positioned to comment on the intersection of ingredient safety and professional regulation.

Although *Andrographis paniculata* is an ayurvedic herb, it is also used extensively within the Traditional Chinese Medicine professions, as well as naturopathic and Western herbal medicine professions. *Andrographis paniculata* is an important herb used primarily in supporting the immune system, reducing fever, and reducing inflammation. It also provides an important role in protecting the liver, and reducing platelets. It is in many over the counter herbal formulations to help treat and prevent the common cold and other viral infections.

2. Acknowledgment of Clinical Safety Data

ARONAH acknowledges the TGA's comprehensive safety review and the gravity of the adverse event reports (ADRs) cited. The documented cases of anaphylaxis and severe taste disturbances are of significant concern. We extend our deepest sympathies to those affected by these events, particularly the family involved in the 2024 fatality.

It is clear that the current regulatory status of *Andrographis paniculata* as a "low risk" (Listed) ingredient available for unsupervised retail purchase is no longer tenable. The failure of label warnings to prevent severe outcomes indicates that a more robust regulatory intervention is required.

3. The "Regulatory Gap" and the Case for Practitioner-Only Access

ARONAH submits that the current safety concerns are a symptom of a broader "regulatory gap" in Australia. *Andrographis paniculata* is a potent therapeutic agent that requires professional clinical oversight. This can be achieved through instituting a middle path between retail access to the herb and total ban of the herb from the market.

The problem with removal is that a total ban removes a clinically effective antiviral and anti-inflammatory tool from the Australian healthcare arsenal, potentially driving consumers toward less regulated international online markets.

Risk mitigation can be achieved via health consultations. Qualified naturopaths and Western herbalists are trained in the materia medica use of this herb, and in addition, to screen for atopy, assess patient history for hypersensitivity, and monitor for early-stage adverse reactions.

We propose a middle path, that *Andrographis paniculata* be restricted to Practitioner-Only access for those practitioners who have qualifications in herbal medicine, whether it be via a naturopathy or Western herbal medicine degree, or Traditional Chinese Medicine degree. This preserves the therapeutic benefit to the public while ensuring that the "point of sale" is moved from an unsupervised retail shelf to a supervised clinical environment with practitioners who have specific herbal medicine training and knowledge.

4. Practitioner-Only access: Statutory Registration as a Safety Solution

The TGA's primary challenge in implementing a "practitioner-only" restriction is the current lack of statutory registration for naturopaths and Western herbalists, whilst Traditional Chinese Medicine, a profession with similar treatment and prescribing regimes to naturopaths and Western herbalists, is statutorily registered.

- **Identification of Qualifications:** Without statutory registration of naturopaths and Western herbalists, the TGA lacks a definitive mechanism to identify who is a "qualified practitioner" within those professions.
- **The ARONAH Benchmark:** ARONAH was established specifically to bridge this gap. ARONAH members meet the minimum educational standards and adhere to professional codes of conduct equivalent to Ahpra regulated professions.
- **The CMBA Precedent:** We point to the success of the Chinese Medicine Board of Australia (CMBA). Their inclusion in Ahpra has allowed the CMBA to manage access to complex herbal medicines because there is a government-accredited register of professionals who hold Traditional Chinese Medicine qualifications and can be held accountable for their safe use.
- **Application for registration:** Australian Naturopathic Council (which includes ARONAH and the majority of Australian naturopathic associations), recently submitted an application for registration to all Health Ministers for naturopaths and Western herbal medicine practitioners to be included under the NRAS.

5. An Opportunity for Reform: Utilizing Schedule 1 for Professional Access

Rather than a blanket ban on *Andrographis paniculata*, the TGA has a significant opportunity to implement a nuanced regulatory solution by activating Schedule 1 of the *Poisons Standard*. Currently, Schedule 1 remains a "blank" schedule in the Commonwealth's *Therapeutic Goods (Poisons Standard) 2026*. However, the Victorian *Drugs, Poisons and Controlled Substances Act 1981* provides a proven legislative blueprint for its use. Under Section 12A of the Victorian

Act, Schedule 1 is designated for substances, often of plant origin, that should only be available through registered practitioners, such as those registered by the CMBA.

The Victorian model allows for "restricted herbs" to be prescribed by suitably qualified and registered practitioners (as outlined in Sections 13 and 13A), ensuring public safety without removing essential therapeutic tools from clinical practice. We propose that the TGA adopt a similar national framework by amending the *Poisons Standard* to repurpose Schedule 1 for practitioner-only access. Establishing a national approval process for herbs in this category would resolve the current "all-or-nothing" approach to scheduling, preventing the loss of traditional medicines while maintaining rigorous safety standards through professional oversight.

Attached is a discussion paper: Safe Access to Chinese Herbs, written by the Chinese Medicine Board of Victoria in 2004 which outlines this proposal.

ARONAH argues that under statutory registration, there is an opportunity for Traditional Chinese Medicine to be given this access, alongside naturopaths and Western herbalists in lieu of registration who are members of ARONAH or who have completed higher education with providers who meet ARONAH's education standards.

6. Recommendation

ARONAH recommends that the TGA considers a staggered approach:

1. Immediate removal of *Andrographis* from the general retail/self-selection list.
2. Retention of the ingredient for use by practitioners who meet the high-tier educational standards currently upheld by ARONAH, and the Chinese medicine board under NRAS.
3. A formal recognition that the statutory registration of naturopaths and Western herbalists would provide the TGA with the permanent safety infrastructure required to manage such high-potency ingredients in the future.
4. TGA offers their support in writing regarding the registration of naturopaths and Western herbalists under NRAS.

7. Conclusion

The safety of the Australian public is our primary objective. However, safety is not only achieved through bans, but through professional regulation. ARONAH remains committed to working with the TGA to ensure that Australian consumers have access to safe, regulated, and professionally administered herbal medicine.

Respectfully,



Jackie Arbuckle (chair)

on behalf of the ARONAH Board