

29 April 2026

Submission to the Therapeutic Goods Administration

ATMS Response to Consultation on *Andrographis paniculata* – Practitioner Access and Public Health Implications

Dear Delegate of the Secretary of the Therapeutic Goods Administration (TGA),

Re: Proposal to remove *Andrographis paniculata* as a low-risk ingredient

On behalf of the **Australian Traditional Medicine Society (ATMS)**, we appreciate the opportunity to provide input regarding the proposed removal of *Andrographis paniculata* (*Andrographis*) from the list of permitted ingredients in listed medicines (Therapeutic Goods (Permissible Ingredients) Determination).

ATMS represents over 8,500 qualified natural medicine practitioners across Australia, including naturopaths, herbalists, nutritionists, and traditional medicine practitioners who utilise evidence-based and evidence-informed complementary medicines in clinical practice.

Background

Andrographis paniculata (*Andrographis*) is a herb found in a range of listed medicines that are intended for the relief of cold and flu and can be purchased at pharmacies, supermarkets and health food stores without a prescription. *Andrographis paniculata* is currently listed as a “low-risk” ingredient in listed medicines and is included in the Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2026 as an active ingredient. *Andrographis paniculata* currently has specific requirements listed in the Determination.

The following warning statement is required on the label:

- (ANDROG) ‘*Andrographis* may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention’ (or words to that effect).

When for oral use, the following warning statement is required on the medicine label:

- (ANDROT) 'Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice' (or words to that effect).

On 8 April 2026, the TGA issued a media release stating that it had begun a consultation on a proposal to remove *Andrographis paniculata* (Andrographis) from the list of permitted ingredients in listed medicines. The proposal to remove Andrographis from the permitted ingredients list follows a number of reports of anaphylaxis. Anaphylaxis can be a life-threatening allergic reaction requiring immediate emergency medical treatment.

ATMS Position

ATMS does **not support the proposed removal** of *Andrographis paniculata* from listed medicines.

We acknowledge the importance of patient safety and the role of the Therapeutic Goods Administration (TGA) in the manufacturing, supply, and regulation of therapeutic goods, and ensuring that these goods are safe, effective, and of high quality, including monitoring adverse events. However, we believe that the proposed regulatory action does not reflect the **full clinical context of use**, nor does it appropriately balance **risk, practitioner oversight, and public health outcomes**.

Clinical Use and Established Role

Andrographis paniculata (Andrographis) has a long-standing history of use across multiple traditional systems of medicine, including:

- Traditional Chinese Medicine
- Ayurvedic medicine
- Western herbal medicine

In contemporary Australian clinical practice, Andrographis is widely utilised by qualified practitioners to support:

- Immune function
- Upper respiratory tract conditions
- Recovery from common viral illnesses

Importantly, its use within practitioner-led care involves:

- Individualised patient assessment
- Consideration of contraindications and sensitivities
- Appropriate dosing and formulation
- Monitoring for adverse reactions

This clinical governance framework significantly differs from general consumer self-selection.

Safety Considerations and Risk Context

ATMS acknowledges reports of hypersensitivity and anaphylactic reactions associated with *Andrographis paniculata*.

However, we note:

- The reported incidence remains low relative to population exposure
- A significant proportion of adverse events involve multi-ingredient products
- There is no clear causal pathway established for all reported cases

As with many substances (including commonly used foods and medicines), rare adverse reactions do not inherently justify complete market removal, particularly where risk can be effectively mitigated.

Concerns Regarding Proposed Removal

The proposed removal presents several unintended consequences:

1. Impact on Patient Care

Patients currently benefiting from TGA listed medicines containing *Andrographis* would lose access to a well-established therapeutic option.

2. Shift to Unregulated Markets

Restricting access may drive consumers toward:

- Unregulated imported products
- Online sources lacking quality assurance
- Products without appropriate safety warnings

This outcome would increase, not reduce, public health risk.

ATMS Recommendation

ATMS strongly recommends that the TGA consider risk mitigation strategies in place of removal, including:

- Enhanced and prominent warning statements on all Andrographis-containing products
- Clear front-of-pack advisory labelling regarding hypersensitivity risk
- Continued post-market surveillance and adverse event monitoring
- Practitioner education and guidance to support safe prescribing
- Consumer education via TGA media release regarding hypersensitivity risk

These measures provide a proportionate, evidence-informed regulatory response that maintains both consumer safety and practitioner capability.

Practitioner Context – A Critical Gap in the Review

We note the statement that:

“Implications for the use of Andrographis by traditional practitioners is outside the scope of this safety review.”

ATMS considers this a significant limitation.

The exclusion of practitioner use:

- Omits a major component of real-world clinical application
- Fails to consider risk mitigation already embedded in practitioner care
- Limits the ability to assess the true benefit-risk balance

We strongly encourage the TGA to incorporate practitioner-based evidence and clinical experience into its final determination.

Conclusion

While the risk of anaphylaxis associated with *Andrographis paniculata* is a legitimate safety concern, it does not necessitate complete removal from therapeutic use via listed medicine restrictions. ATMS supports a regulatory approach that:

- Protects public safety
- Maintains access to clinically valuable therapies
- Recognises the role of qualified practitioners in mitigating risk

The proposed removal of *Andrographis paniculata* as a low-risk ingredient does not, in our view, achieve this balance.

We respectfully request that the TGA reconsider this proposal and pursue a risk-managed, evidence-informed alternative that preserves both patient access and practitioner scope of practice.

Yours sincerely,



Annie Gibbins

Chief Executive Officer

Australian Traditional Medicine Society (ATMS)