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Andrographis Update

Earlier this year the Therapeutic Goods Administration (TGA) conducted a consultation with interested parties on a proposal to restrict public access to Andrographis paniculata (Andrographis). This was based on the notion that it posed a threat to human health due to a number of reported severe allergic reactions, including a reported anaphylaxis-associated fatality. The ATMS and others contributed to this consultation (see the ATMS submission at https://www.atms.com.au/wp-content/uploads/2026/05/ATMS-Response-to-Consultation-on-Andrographis-paniculata.pdf) and in late September this year, the TGA announced its conclusion to that consultation, which was that it would restrict public access to Andrographis (see the TGA notification at https://www.tga.gov.au/news/news-articles/andrographis-removed-listed-medicines-framework-because-allergy-risk).

What's changing?

As a bit of background to this, all therapeutic goods sold in Australia, apart from a very small number of exceptions, are required to be listed or registered with the TGA's Australian Register of Therapeutic Goods (ARTG). All therapeutic goods sold at a retail level in Australia contain active ingredients that are limited to what's available through the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Schedules), what's not prohibited under various importation and quarantine restrictions, and what's published in the TGA's list of Permissible Ingredients- these are ingredients that are allowed to be used in ARTG listed medicines.

Up until September this year the use of Andrographis in therapeutic goods available for retail sale in Australia was not limited by any of the abovementioned pieces of legislation or legislative instruments. After the 17th of September this year, the TGA has decided to remove Andrographis from the list of Permissible Ingredients.

What are the general effects of this?

As a result of this change, no new medicines that contain Andrographis will be able to be listed on the ARTG, which means that they won't be available for retail purchase in Australia. The TGA has stated that all of the listed medicines currently sitting on the retail shelves of pharmacies and healthfood stores across Australia that contain Andrographis (there are around 80 of them), which are currently unaffected by this change, should have their ARTG listings voluntarily cancelled and should be recalled by their sponsors where appropriate and that a failure to do this may result in some

form of punitive action by the TGA, including compulsory recalls or ARTG cancellations if this hasn't occurred by the middle of October this year.

If a sponsor was particularly keen on selling a retail product containing Andrographis, this could still be done but it'd require product registration on the ARTG rather than product listing. Medicines that are registered on the ARTG are not affected by the Andrographis prohibition. But, a potential sponsor of such a medicine would need to be armed with very large amounts of money, robust human clinical trials that validated the product indications, and great deal of patience to make it through the registration process.

The removal of easy public access to Andrographis products by Australian consumers may also lead to an increase in the consumption of unregulated products purchased online from overseas suppliers. This potentially carries a high level of risk because such products may not be manufactured to adequate safety standards, may not carry appropriate warning statements, may contain dangerous contaminants, may contain either deficient or excessive amounts of active ingredients or incorrect ingredients, and may not be adequately labelled.

How does this affect healthcare practitioners?

According to the TGA's notification regarding Andrographis, the only class of medicines affected are those that are listed on the ARTG, that is, products that are sold predominantly as retail products in Australian healthfood stores or pharmacies, or online from legitimate Australian suppliers. So, for the most part, healthcare practitioners are not affected by the TGA's decision. We still have access to Andrographis-containing practitioner-only products that ARE NOT listed on the ARTG, and we still have access to Andrographis as a herbal raw material, in forms such as liquid herbal extracts. And unless or until the Poisons Schedule status of Andrographis changes, this should remain the case.

Yours sincerely,



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