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## **Finasteride and Sanguinarine scheduling proposals AMA submission to the TGA Advisory Committee on Medicines Scheduling – proposals to down-schedule Finasteride and classify Sanguinarine as a schedule 10 substance**

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The AMA opposes the down-scheduling of Finasteride from Schedule 4 to Schedule 3 but supports the proposal to classify Sanguinarine as a Schedule 10 substance.

### **Finasteride**

The AMA opposes the down-scheduling of Finasteride so that it is available without a prescription in preparations containing not more than 1 mg per dose unit in packs not greater than 30 dosage units.

The treatment of hair loss is a highly lucrative and easily abused industry. People seeking help are often highly motivated to find a 'cure' and are easily exploited.

The AMA considers this is an attempt by the sponsor to widen its market penetration and little to do with improving outcomes for patients.

Assessment of alopecia firstly requires medical evaluation to rule out other causes.

Then, once medically confirmed, the key to successful use of hair loss medications is patient selection and patient education. It ties in closely with self-esteem and social functioning. Treatment requires a holistic approach. It requires a medical practitioner who can adequately inform the patient regarding appropriate treatment choices, reasonable expectations of treatment, and ongoing monitoring – most effectively done by general practitioners.

Further, there are side-effects associated with use of Finasteride which can have an impact on overall health and confirms the need for medical practitioner oversight.

AMA members report seeing symptoms related to libido and sexual function (e.g. erectile dysfunction) as well as depression in patients taking Finasteride, even at the low dose proposed.

A general practitioner seeing a patient with these symptoms will not be aware if their patient is taking Finasteride on the advice of their pharmacist, and that the Finasteride could be causing these symptoms.

In summary, there appears to be no public benefit in making this medicine available through pharmacists except for achieving additional sales. Rather there are several potential risks to patients resulting from its use without medical advice, including: undiagnosed and therefore untreated causes of alopecia; inappropriate treatment choice for a specific patient; and potential additional medical treatment for unrecognised side-effects resulting from fragmentation of care.

### **Sanguinarine**

The AMA supports the classification of Sanguinarine, except in preparations containing 0.1 per cent or less, as a Schedule 10 substance in the interests of protecting public safety. AMA members report seeing serious harms to their patients from its use, and consider it is a noxious and dangerous product.

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