AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
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AMA submission: Making public that a prescription medicine is under evaluation by the TGA

[redacted]

The AMA urges the TGA to carefully consider the implications of taking on the role of providing information to the public about medicines that it has accepted for evaluation.

The AMA appreciates news that a medicine, particularly an innovative medicine, is being evaluated by the TGA for potential registration in Australia, may be useful to health practitioners and patients in making better informed decisions about options for medical treatment and care. The AMA also appreciates the TGA's intentions in increasing transparency.

However, there are also risks to the public from the TGA providing this information prior to a decision being made.

Health practitioners and/or patients may anticipate the medicine will be approved, make a treatment decision on that basis, and then suffer a negative impact if the medicine is subsequently not approved.

The AMA also envisages the TGA – and the Government – would attract intense lobbying from interest groups, including patient, professional, political and other groups. While the TGA operates independently from government, lobbying by special interest groups successfully delayed for two years the implementation of the TGA's decision to up-schedule codeine. Responding appropriately to lobbying activities takes considerable time and resources – possibly delaying an assessment of a medicine rather than securing it.

On balance, the AMA recommends the TGA leaves the provision of information to the public about medicine applications to the medicine sponsor.

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Contact

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