
AMA submission – TGA proposed changes to accessing unapproved therapeutic goods through the Authorised Prescriber and Special Access Schemes

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The AMA supports the TGA's proposed changes to the two prescriber initiated schemes for accessing therapeutic goods not approved for sale in Australia: the Special Access Scheme (SAS) and the Approved Prescriber (AP) scheme.

Special Access Scheme Category B (for non-life-threatening conditions)

The proposal to allow access to certain relatively low risk, unapproved therapeutic goods under the SAS through a notifications process appears sensible given that:

- it will apply only to unapproved therapeutic goods that have an established history of use for a given condition, e.g. are pharmaceuticals approved in other similarly regulated countries with an established history of safe use; and
- the TGA will regularly review the list of therapeutic goods that can be accessed in this way by applying the above criterion and monitoring any reports of adverse events.

The AMA notes that medical practitioners can already apply for access to an unapproved therapeutic good via a notification process under the SAS Category A (for life-threatening conditions).

Authorised Prescriber Scheme

The AMA supports the proposals to streamline the application process under the AP scheme to reduce the administrative burden on medical practitioners and reduce the access time for patients. We note that the duration of the AP approval would be extended up to three years for a medical device and up to five years for a medicine, provided there is a history of established use, as for the SAS category B notification process described above.

Online system development

As indicated in the TGA's consultation paper, it will be important that prescribers are consulted and involved in the development of any online system to ensure it is user friendly and compatible with existing prescriber software.

The AMA strongly recommends the TGA consults with the Medical Software Industry Association as early as possible in the development process.

Communicating the changes

The AMA supports the proposed communication approach. The AMA can also assist in publicising the changes through its regular membership communications.

Compliance

The AMA notes the TGA's intention to enhance guidance to users as well as monitoring systems to ensure compliance with scheme requirements. The AMA can also assist in communicating these activities to its members.

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