The Pharmacy Guild of Australia

POSITION STATEMENT

Unapproved Products

Position

The Pharmacy Guild of Australia (Guild) strongly supports the registration system in Australia for the marketing and supply of medicines and other therapeutic products. Australia has a robust system managed by the Therapeutic Goods Administration (TGA) which facilitates the efficient marketing, distribution and supply of therapeutic products throughout Australia. Our system is also recognised internationally for its high standards and quality that balances patient safety while optimising patient access.

The Guild recognises the value of allowing Australians to access unapproved products in exceptional circumstances and supports exemptions that permit:

- extemporaneous compounding by pharmacists for medicines that are not commercially available in Australia
- arrangements that support the importation and use of unapproved products that are assessed and registered in other countries with acceptable quality, efficacy and safety –
    - when approval in Australia has not been sought for commercial reasons
    - to assist with supply disruptions of registered products in Australia
- exceptional prescribing and access arrangements to unapproved products for specific individuals to treat serious medical conditions in circumstances when a suitable product is not commercially available in Australia

In recent years, there has been a significant uptake in the use of unapproved medicines. This commenced with medicinal cannabis and now includes nicotine vapes, psilocybin and 3,4-methylenedioxy-methamphetamine (MDMA). The Guild notes that all of these medicines also have a history of dependence, diversion and/or abuse and access has either been significantly restricted or prohibited.

The Guild strongly believes that while some people may benefit from access to these new treatment options, we must be careful not to undermine or destabilise Australia's long-established and effective medicine registration process, particularly where the evidence base is low.

We are particularly concerned with the use of 'authorised, unapproved products' which provides a cover of legitimacy to the supply of these medicines in Australia and also facilitates the prescribing and supply for a range of 'off-label' indications with little or no evidence to support their use; this represents a complete breakdown of the regulatory system that exists to keep Australians safe through the evaluation, assessment, registration and monitoring of therapeutic goods[1]. The current arrangements that allow the long-term marketing of unapproved medicinal cannabis or nicotine vapes in Australia does little to incentivise companies to invest in research and proceed through the formal registration process with evidence to support the efficacy of their products.

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While an international company may decide it is not financially viable to register their product for marketing in Australia, it is particularly concerning when Australian companies are satisfied for their products to remain 'unapproved' yet still readily available for use by Australians and/or other international markets.

The Guild recognises that undertaking research and registration can be costly and time consuming, but we are also concerned with the number of companies that have their unapproved products listed for use in Australia. This system unfairly benefits an increasing number of companies that by-pass the registration requirements and associated costs that medicine companies with registered medicines must manage. Companies that invest in research and registration should be rewarded by having greater access to the Australian market.

We are also very concerned with the aggressive marketing tactics and unlawful promotion of unapproved products and related clinical services, including websites with virtual prescribing and supply arrangements offering discounted consultations, lack of referrals, reports of unsafe prescribing practices or same day deliveries.[2]The Guild supports strong action by the regulators against these practices with strict penalties.

The Guild does not support these current arrangements that allows for the long-term supply and use of unapproved products in Australia. More needs to be done to prevent this process and rather facilitate registering products with an appropriate evidence base. Our recommendations are:

- Products on a TGA authorisation list for unapproved products must:
    - be determined based on registration and approval by other regulators in comparable countries, in particular Canada, Ireland, New Zealand, the United Kingdom and United States and
    - restricted for indications with an appropriate evidence base
- The TGA authorisation list must not be used as a long-term pseudo-registration scheme for marketing and supply in Australia by companies that are not progressing with a formal registration application for their products.
- The Government to fund generic research for medicinal cannabis and nicotine vapes to develop an evidence base that can be used to assist Australian companies to formally register their product expeditiously and more cost-effectively.

Background

For marketing in Australia, medicines must be approved by the TGA for inclusion on the Australian Register of Therapeutic Goods (ARTG). For scheduled medicines, ARTG inclusion is as a registered product requiring the TGA to evaluate and approve the product for its quality, safety and efficacy for the listed indications. When registered, the medicine must be packaged, labelled, distributed, promoted and supplied within Australia according to relevant laws under the *Therapeutic Goods Act 1989*. There must also be compliance by all elements of the medicine supply chain with relevant medicines and poisons laws in all states and territories.

Registered products can also be used for non-listed indications under a practice known as 'off-label prescribing'. In this circumstance, the prescriber determines the need for the product based on their individual clinical knowledge and experience, typically involving international and/or recent evidence supporting the 'off-label' usage.

There have long been exemptions to the registration and listing requirement for exceptional circumstances, such as:

- the importation and marketing of overseas registered products to address local supply disruptions known as Section 19A medicines – these medicines may have exemptions to the packaging and labelling requirements for registered products
- the Special Access Scheme and Authorised Prescriber arrangement to enable access to overseas products for specific individuals or conditions

- personal importation scheme allowing individuals to import most medicines from overseas for personal use
- compounding by pharmacists for individual patients for medicines unavailable in Australia

The TGA regulates the importation and use of unapproved medicines in Australia[3] and works with other regulators from comparable countries such as the Food and Drugs Administration (FDA) in the United States. The FDA has exceptional arrangements for the use of unapproved drugs, balancing its goal to eliminate unapproved prescription medicines from the market with patient access to medically necessary drugs. The FDA recognises the potential patient harm from unapproved drugs and works to protect patients from the risks they pose.[4]

In recent years, the TGA has implemented further system changes to enable access to high profile unapproved product ranges, namely medicinal cannabis, vapes, MDMA and psilocybin[5]. System changes have included:

- the use of a list of 'authorised unapproved products' to facilitate more efficient prescribing without the need for ethics approval or specialist endorsement e.g. medicinal cannabis[6] and vapes[7] - these products either have an established history of use without significant safety concerns or have been assessed by the TGA for safety and quality; there is no assessment for efficacy
- the development of product standards for 'authorised unapproved products'
- enabling some medicines to be compounded and dispensed by pharmacists because no equivalent product is available in Australia[8] e.g. medicinal cannabis

Pharmaceutical Benefits

For a medicine to be listed on the Pharmaceutical Benefit Scheme (PBS), it must be registered and included on the ARTG. As such, unapproved products cannot be listed on the PBS.

Related Statements

Cannabis Use

Authority

Endorsed

National Council – May 2025

Reviewed

Policy and Regulation Sub-Committee – May 2025

References

[1] Therapeutic Goods Administration (TGA) | Australian Government Department of Health

[2] We looked at 54 medicinal cannabis websites to see if they followed the rules. Here's what we found; Jan 2025

[3] Unapproved therapeutic goods | Therapeutic Goods Administration (TGA)

[4] Unapproved Drugs | FDA

[5] Unapproved therapeutic goods | Therapeutic Goods Administration (TGA)

[6] Medicinal cannabis products by active ingredients | Therapeutic Goods Administration (TGA)

[7] Notified vape list: goods for smoking cessation or nicotine dependence | Therapeutic Goods Administration (TGA)

[8] Extemporaneous compounding | Medicinal cannabis reforms: Frequently asked questions | Therapeutic Goods Administration (TGA)