

Therapeutic Goods Administration
PO Box 100
WODENACT 2606

25 March 2019

Dear Sir/Madam

CONSULTATION: PRESCRIPTION MEDICATION UNDER EVALUATION

Painaustralia welcomes the opportunity to provide input to the Therapeutic Goods Administration's (TGA) consultation around whether the TGA should publish that a prescription medicine is under evaluation.

Painaustralia is the national peak body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain. Members include pain and other specialists, health practitioners, health groups, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue. As such, the issue of transparency and listing of new prescription medicines is important to our members and stakeholders.

Painaustralia agrees with the statement in the consultation paper that notes that the availability of information is a cornerstone of informed decision making. From a patient perspective earlier knowledge about potential availability of treatments, should they be approved, may be considered as part of discussion about options for medical treatment and care with their healthcare practitioners. It is equally important to ensure that consumers also have all the facts before they can make such informed decisions which will impact their treatment pathways.

Painaustralia support Option 2: listing of all applications accepted for evaluation. This will ensure the highest level of application transparency based on evidence of efficiency of applications and this option is also consistent with the approach used by some comparable overseas regulators.

Ensuring informed decision-making

There are few decisions in pharmacological management where there is only one unequivocally correct answer for everyone. This is especially true for the management of chronic pain, where at most clinical decision points, there are several possibilities that could be taken into account to address the issue or concern, including different treatments (e.g. different medications), non-pharmacological approaches, preventive strategies or lifestyle changes, in addition to the 'no active treatment' option, advice and reassurance.

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When considering the changes that will flow from the implementation of Option 2, it is important to recognise that there may be unintended consequences from the availability of this information, especially for a vulnerable consumer cohort.

Case Study: Prescribing of Medicinal Cannabis for Non-Cancer Pain

The majority of people who seek medicinal cannabis do so for pain management, and there is growing interest and expectation around the use of these products to treat a range of conditions.ⁱ

This may be due to increased information and awareness around the availability of medicinal cannabis, the recent establishment of a regulatory framework for these products, and interest in seeking out alternatives to opioids and other pain medications.

There is now widespread use of cannabis products and a high degree of community support for greater access to them for a range of reasons. This situation highlights the significant gaps in access to, and understanding of, best practice pain management amid a rising pain burden.

Despite the legalisation and decriminalisation of cannabis in some places here and overseas, there have only been a limited number of well-designed clinical studies on medicinal cannabisⁱⁱ and its role in treating chronic pain. There is little evidence about suitable doses of individual cannabis products, such as randomised controlled trials or systematic reviews, that enable definitive statements on effectiveness of medicinal cannabis. This lack of evidence makes it difficult for practitioners to prescribe, despite community expectations that these products will be made available to treat chronic non-cancer pain.

Overall in the case of cannabis medications, access to information around the availability of a potential new therapeutic good has raised consumer expectations. In reality, access remains highly regulated, is expensive, and is often not appropriate.

While Painaustralia supports current efforts to enable expedient access to medicinal cannabis where it has been correctly prescribed, we remain concerned about the unintended consequences of inappropriate cannabis prescribing on a uniquely vulnerable cohort of consumers.

The case study above highlights that often consumers only have access to limited information when considering their healthcare options, which offers them an incomplete picture, especially in regards to new and emerging therapeutic goods. It is crucial that consumers are supported and given well-designed, reliable, balanced, up-to-date information to help them make their decision and advocate for their healthcare.

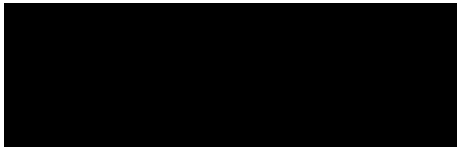
Informed decision making support for consumers

While Painaustralia is supportive of the implementation of Option 2, it is vital that this information be contextualised for consumers, to ensure that they understand the complexities of the evaluation process and do not misinterpret the information.

Case studies like the Spinraza listing included in the consultation paper are important, but it is equally important to highlight that not all evaluations progress to the listing stage or get listed on the Pharmaceutical Benefits Scheme. Consumer resources should be developed to support the implementation of Option 2 and enable informed decision-making.

We trust that the matters raised in our submission will be useful in helping the TGA finalise an option around the evaluation of prescription medicines and welcome the opportunity to discuss our submission with you further.

Yours sincerely



Carol Bennett
Chief Executive Officer

ⁱTherapeutic Goods Administration 2017. Guidance for the use of medicinal cannabis in Australia Overview. Access online [here](#).

ⁱⁱ Op. Cit TGA 2017.