Enimera Regs+
Innovative solutions to Regulatory challenges

Fact Sheet

Medicinal Cannabis - Australian Regulatory Overview

Medicinal cannabis refers to a number of different forms of cannabis used for therapeutic purposes.

In Australia, regulation at both federal and state/territory level applies.

At the federal level, the Therapeutic Goods Administration (TGA) offers two pathways for medicinal cannabis products

	Access to TGA approved medicines	Access to TGA 'unapproved' medicines	
	New Medicine Application	Special Access Scheme	Authorised Prescriber
Applicant	'Sponsor'	Medical or Health Practitioner	Medical Practitioner
Scope	Approval of a new medicine	Approval to use for individual patients	Approval to use for a class of patients
		Allows the use of medicines not previously evaluated/approved by the TGA on the basis of unmet medical need	
Supply	Commercialisation within Australia	Limited to circumstances of unmet medical need	
Comment	Regulated as a Prescription Medicine	For products not evaluated by the TGA for quality, safety and efficacy	
	Evaluated for quality, safety and efficacy and approved if deemed overall benefit-risk is considered appropriate	SAS Category A – for seriously ill patients SAS Category B – for non-seriously ill patients	Requires Human Research Ethics Committee or specialist College endorsement

Further information

https://enimeraregsplus.com.au/medicinal-cannabis-how-to-begin-your-regulatory-strategy/

https://www.tga.gov.au/access-medicinal-cannabis-products-1

Enquire about a complimentary Regulatory Strategy assessment

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