

Name: Date:

Guide to understanding novel and emerging medicines

This guide explains novel and emerging medicines and their place in health care.

Novel = new

Emerging = developing

“Novel and emerging medicines” are medicines with limited evidence that are undergoing study or approval. Examples are:

- medicinal cannabis, psilocybin and MDMA¹
- some cancer medicines
- other medicines not yet available in Australia.

A novel or emerging medicine might be a suitable choice when:

- standard choices do not work
- standard choices cause very bad side effects
- the illness is rare and does not have standard treatments yet
- someone is very ill or has a life-threatening illness, and there are no other choices available
- it shows promise for better results and fewer side effects.

How to decide to use a novel or emerging medicine



Before we can use medicines to treat an illness, they must go through many thorough medical studies. We call the results of these studies **evidence**. These studies check:

- how safe a medicine is to use (**safety**)
- how well the medicine works (**effectiveness**).

Australia’s Therapeutic Goods Administration will not approve medicines without strong **evidence** (or proof) of safety and effectiveness. Novel and emerging medicines often lack strong evidence to be standard treatments. Because evidence is still growing, this may change over time.

Here are some of the key differences between standard, and novel and emerging medicines.

Evidence	Standard medicines	Novel and emerging medicines
Quality of the evidence	Strong	Weak
The amount of safety details we have	A lot	A little
Number of people used in studies	Large (more than 1,000 people)	Small (less than 1,000 people)
How it works	Well-understood	Not always clear
How well it works	Good evidence	Unclear or less evidence
Health professionals’ experience	A lot	A little

¹ Also known as 3,4-methylenedioxymethamphetamine.



Doctors choose the safest and best treatment by:

- checking the medical history
- looking at the choices available
- studying the **evidence**, and
- in some cases, they ask advice from others in the healthcare team.²

Studying a medicine's evidence is a complex process that needs expert training.

After looking at all the details, the doctor will talk with you or a carer about:



- how a novel or emerging medicine might help (**benefits**)
- the possible side effects (**risks**)
- what other choices there are and how they compare
- any questions you have.

Tell the doctor about all medicines and substances you are taking or using. This helps them check for side effects or interactions.

You or a carer and your healthcare team need to decide if the medicine is the right choice for you. If you all agree it is, your doctor will guide you on how to get it.



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If you want more information

There may be little information about novel and emerging medicines from very few studies. Stories on the television, the internet and social media sound hopeful, making some medicines popular. Remember, these stories are not always true because they:



- may leave out vital details or may not apply to you
- talk about medicines with little or no evidence
- show medicines with little or no safety details
- do not mention that people get money to promote the medicine
- do not mention the cost of the medicine, which may be expensive.

If you find information that you think could help, show it to a member of your healthcare team. They will help find the best and safest choice for you or the person you care for.



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² A healthcare team can have doctors, nurses, pharmacists and other health professionals (e.g. Aboriginal and Torres Strait Islander Health Workers/Practitioners).

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