Communicating About Clinical Trials and Unapproved Medicines

Medicines Australia

Companies can share facts about trials and access pathways but cannot promote prescription medicines - especially unapproved medicines or unapproved uses - to the public.

Clinical trials

Pharmaceutical companies run and fund many clinical trials. They can share basic, factual information such as:

- The purpose and design of a trial.
- Where it's registered (e.g. the Australian New Zealand Clinical Trials Registry).
- Notices that a trial is open for recruitment.
- General education about how clinical trials work.

Companies cannot give the impression that a medicine in a trial is already proven, approved, or guaranteed to become available. Your doctor is the best person to explain whether a trial may be suitable for you.

Why results aren't shared directly with the public

Pharmaceutical companies collect trial data, but they don't usually release results straight to patients or the general public. Rather, results will be shared through independent sources such as medical journals. These journals perform peer review, where experts verify that the findings are accurate, balanced, and scientifically correct.

This process helps protect public trust by making sure information comes from independent, peer-reviewed sources. If the same information is shared by the company who sells the medicine, this is much more likely to be perceived as promotion.

The Medicines Australia Code of Conduct supports this approach, allowing companies to share scientific information only with people who have a legitimate reason to use or understand it, such as doctors, researchers, or in some cases, patient organisations. Companies also decide whether the trial data is relevant to the stakeholder they are sharing it with.

Unapproved and off-label use of medicines

Information about medicines that are not yet approved in Australia - or information about uses outside their approved purpose - is handled very carefully. This type of information is called “off-label” or “unapproved use.” Because the safety and effectiveness of these medicines are not fully confirmed, companies can only share limited details with qualified people (such as medical officers in patient organisations), and always within strict rules to prevent promotion. Even doctors cannot be promoted to about off-label use.

The Therapeutic Goods Act sets strict limits to ensure this information is not promotional, and the Code (Section 7 – Scientific Exchange) provides extra guidance. Each company ultimately decides whether to share such information and with whom, balancing the need-for-information with compliance.

Access programs

It’s natural for patients to want information about new treatments. But until a medicine is approved by the TGA, companies are limited in what they can say publicly. They are not allowed to promote unapproved or prescription medicines to the public, even if the aim is simply to inform. Instead, companies usually provide information to healthcare professionals, or direct patients back to their doctor.

In some situations, patients may be able to get early access to an unapproved medicine through special programs—especially if the medicine is already approved overseas and there is a strong medical need. These programs are considered carefully, case by case. The best way to explore this is by speaking with your doctor, who can advise if such a program exists and whether it may be suitable.