

Special Access Scheme Medicines

SAS Solutions



Unregistered drugs

Before a drug can be supplied to patients in Australia, it must undergo stringent evaluation by the Therapeutic Goods Administration (TGA). If its manufacture safety, efficacy, and quality are satisfactory, TGA will approve it and include it in the Australian Register of Therapeutic Goods (ARTG). In some instances, a medicine might not be registered in Australia if it is new and is yet to be evaluated by the TGA. Or the manufacturer has elected not to register and market the drug within Australia for various reasons.

In certain circumstances, Australian legislation allows patients and healthcare professionals to access drugs not included in the Australian Register of Therapeutic Goods.

Unregistered drugs can be obtained through:

- the Special Access Scheme
- the Authorised Prescriber Scheme
- importation for personal use
- clinical trials

Special Access Scheme

The Special Access Scheme allows for the importation and supply of an unregistered drug for an individual patient under the supervision of a medical practitioner on a case-by-case basis. This is the most common scheme used by medical practitioners and healthcare professionals.

Circumstances, when a patient can access an unregistered drug may include:

- experimental or investigational products for terminally ill patients;
- a medication administered to a patient in a clinical trial but has not yet received TGA approval; or
- drugs available overseas but not marketed in Australia (including when similar registered products are in short supply in Australia).

Medsurge has extensive experience in accessing and importing superior quality SAS medicines. Our professional team comprises highly experienced experts and specialists who can provide you with the assistance you require to apply for unregistered medicines approval. Medsurge SAS solutions alleviate stress throughout the process allowing you to focus on delivering patient care.

Medsurge offers you a wide range of resources, expertise, and services to succeed in an administratively and legally complex landscape:

- Extensive global sourcing networks
- Fully integrated regulatory, quality, marketing, sales, and distribution services
- Importing and customs clearance
- Pharmacovigilance and ADR reporting

Contact us

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