

TGA THERAPEUTIC
GOODS
ADMINISTRATION

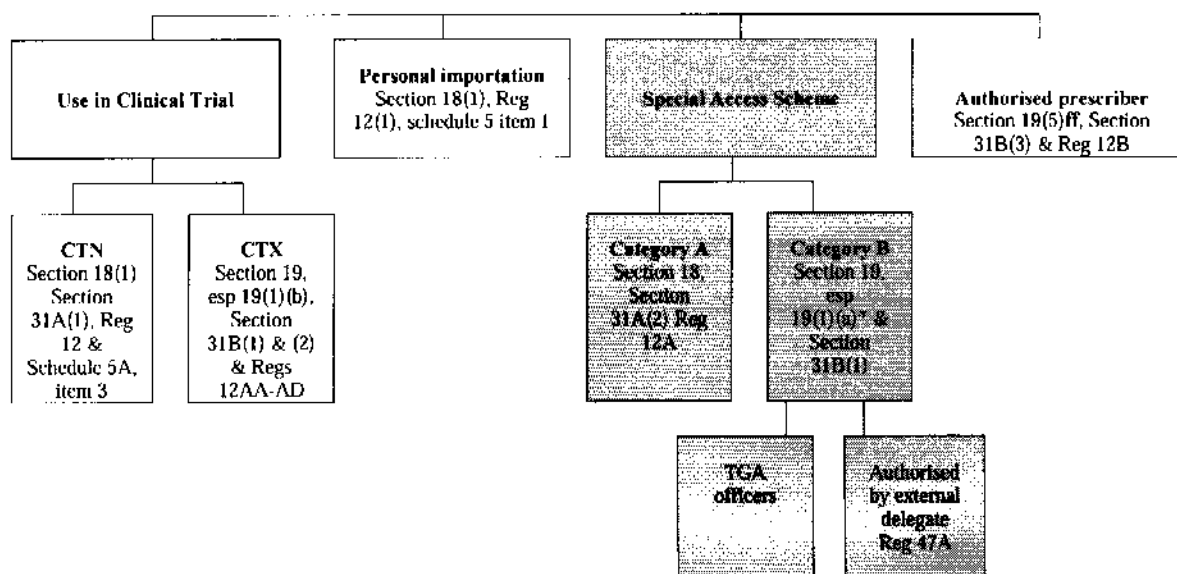


ACCESS TO UNAPPROVED THERAPEUTIC GOODS - THE SPECIAL ACCESS SCHEME (SAS)

**THE TGA IS A DIVISION OF THE COMMONWEALTH DEPARTMENT
OF HEALTH AND AGED CARE**

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Figure Access to unapproved therapeutic goods



* Section 19 (1)(a) allows supply for Category A and Category B patients but, in practice, category A cases are dealt with under s18 and reg12A.

A full copy of the legislation can be found on the TGA Website:

<http://www.health.gov.au/tga/docs/html/legis.htm>

Promotion of Unapproved Therapeutic Goods

The promotion of unapproved therapeutic goods is an offence under subsection 22(6) of the Act and carries a financial penalty. A person must not intentionally or recklessly make a claim, by any means, that the person or another person can arrange the supply of unapproved therapeutic goods.

Release of Information

Information provided to the TGA concerning the use of unapproved therapeutic goods in relation to the SAS will be treated as confidential within the constraints of Section 61 of the *Therapeutic Goods Act 1989* which prescribes certain circumstances in which information may be released.

The *Freedom of Information Act 1982* (FOI Act) also governs access to information. Section 27 of the FOI Act requires that consultation occur between the TGA and the owner of the information prior to release of that documentation.

In addition, the *Privacy Act 1988* places limits on the disclosure of personal information by parties in possession or control of records. Such parties cannot disclose personal information about an individual to a person, body or agency other than the individual concerned except under certain circumstances. These circumstances include situations where: