

# RGH Pharmacy E-Bulletin

Volume 29 (5): March 10, 2008

A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

Editor: Assoc. Prof. Chris Alderman, University of South Australia – Director of Pharmacy, RGH

© Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia 5041

## Australian Special Access Scheme

The Australian community has an expectation that therapeutic goods (medicines and medical devices) available for use in Australia are safe and of high quality. The objective of the *Therapeutic Goods Act 1989* (the Act) is to provide a national framework for the regulation of therapeutic goods in Australia, so as to ensure their quality, safety, efficacy and timely availability. The Therapeutics Goods Administration (TGA), is the national regulatory authority for therapeutic goods in Australia, and is responsible for administering the provisions of the Act. In part, this involves the pre-market evaluation and approval of therapeutic goods intended for supply in Australia. Therapeutic goods approved by the TGA are included on the Australian Register of Therapeutic Goods (ARTG), only then can they be supplied in, or exported from, Australia.

The Special Access Scheme (SAS) is one mechanism that allows individual patients to gain limited access to unapproved therapeutic goods in Australia. With the exception of drugs of abuse (where the manufacture, possession, sale or use is prohibited by State or Territory law) any unapproved therapeutic good can potentially be imported and/or supplied via the SAS. Arrangements for access to unapproved therapeutic goods under the SAS vary according to the health status of the individual. Two classifications for access are defined in the legislation and guidelines - the choice of classification lies with the treating medical practitioner.

*Category A* – for “persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment”

*Category B* - all other patients

A medical practitioner can supply a non-approved product to a Category A patient without seeking prior approval from the TGA, providing the TGA is notified within 28 days using a Category A “Authority to Supply” form. As unapproved products have undergone little or no evaluation of quality, safety or efficacy by the TGA, the medical practitioner is in effect the approving authority in that he/she is prepared to prescribe the product.

A medical practitioner is required to seek and be granted approval from the TGA before supplying a non-approved product to a Category B patient. Applications must address specific criteria relating to the patient, the product and the prescriber. The application should contain adequate clinical justification for the use of the product, including an outline of the seriousness of the patient’s condition being treated; and an indication of how the product is to be used (including an appraisal of the efficacy and safety of the proposed use of the product). The application must be received from a medical practitioner with qualifications and/or expertise appropriate to the condition being treated and the proposed use of the product.

The prescriber has the added responsibility to ensure the patient or patient’s guardian has given appropriate informed consent prior to treatment. Informed consent should be freely given and in line with good medical practice. The treating medical practitioner is also primarily responsible for reporting adverse drug reactions arising from the use of an agent procured through the SAS. It is mandatory that the treating medical practitioner reports the details of any actual or suspected adverse drug reaction to the TGA within 15 days of first knowledge.

Final responsibility for the use of an unapproved product within an institution always rests with that institution. Medical practitioners working in an institution may also need approval from that institution’s Drug and Therapeutics Committee prior to using an unapproved therapeutic good. Applicants should liaise with the Pharmacy Department before submitting an SAS application.

Acknowledgment – This E-Bulletin is based on work by Kate Dreyer, Drug Distribution Coordinator, RGH

**FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: [chris.alderman@rgh.sa.gov.au](mailto:chris.alderman@rgh.sa.gov.au)**  
Information in this E-Bulletin is derived from critical analysis of available evidence – individual clinical circumstances should be considered when making treatment decisions. You are welcome to forward this E-bulletin by email to others you might feel would be interested, or to print the E-Bulletin for wider distribution. Reproduction of this material is permissible for purposes of individual study or research.