Listed medicines include sunscreens, herbal substances, minerals, vitamins, homoeopathic substances, and aromatherapy oils. Applications are self-assessed by the sponsor in accordance with a set of guidelines and submitted electronically using the Electronic Lodgement Facility (ELF). Sunscreen products must provide evidence of SPF testing with the application. Sponsors of other listed medicines are required to hold information to substantiate any claims that are made for the product. Labels of listed medicines must include the symbol AUST L followed by a unique number.

Registered medicines

Applications for registered goods are fully evaluated by the TGA, usually on the advice of one of several independent expert advisory committees. The evaluation considers all aspects of quality, safety and efficacy, including clinical trial data, pharmaceutical stability and the content of labels, package inserts and approved Product Information. Registered goods are recognised by the symbol AUST R followed by an individual number printed on the main label.

Government committees

This section provides brief information on some of the committees associated with the regulation of therapeutic goods in Australia. Further detail can be found through the relevant website.

Australian Drug Evaluation Committee

www.tga.gov.au/docs/html/adec/adec.htm

The Australian Drug Evaluation Committee (ADEC) provides advice on:

- the quality, risk–benefit, effectiveness and access within a reasonable time of any drug referred to it for evaluation
- medical and scientific evaluations of applications for registration of prescription drugs (e.g. new chemical entities, new forms of previously registered drugs and therapeutic variations to registered drugs).

ADEC subcommittees include:

- the Adverse Drug Reactions Advisory Committee (ADRAC)—see www.tga.gov.au/adr/adrac.htm
- the Pharmaceutical Subcommittee.

Medicines Evaluation Committee

www.tga.gov.au/docs/html/mecinfo.htm

The Medicines Evaluation Committee (MEC) provides independent scientific and policy advice on over-the-counter medicines. It evaluates applications for conventional non-prescription medicines and other medicines that are not assessed by either the ADEC or the CMEC (see below). The MEC provides advice on the safety, effectiveness and quality of any OTC medicine or ingredient (including excipients).

Complementary Medicines Evaluation Committee (CMEC)

www.tga.gov.au/docs/html/cmec/cmec.htm

The Complementary Medicines Evaluation Committee (CMEC) provides scientific and policy advice relating to controls on the supply and use of complementary medicines, with particular reference to the safety and quality of products and, where appropriate, efficacy relating to the claims made for products. The CMEC also evaluates ingredients used in complementary medicines, evaluates complementary medicines that are not eligible for listing, and recommends active substances used in complementary medicines that should be eligible for listing.

National Drugs and Poisons Schedule Committee (NDPSC)

www.tga.gov.au/ndpsc/index.htm

The main functions of the National Drugs and Poisons Schedule Committee (NDPSC) are to:

- make decisions in relation to the classification and scheduling of substances
- provide advice on restrictions on accessibility and availability of particular substances
- provide advice on policies relating to labelling, packaging and advertising of substances
- compile and maintain the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Note that the decisions of the NDPSC in relation to the SUSDP have no force in Australian law but are recommended for incorporation in state and territory drugs or poisons legislation (i.e. they are usually adopted in full or in part by the states and territories)
- facilitate the harmonisation between Australia and New Zealand, of legislative provisions relating to the classification and scheduling of substances.

National Coordinating Committee on Therapeutic Goods

www.tga.gov.au/docs/html/ncctg.htm

The National Coordinating Committee on Therapeutic Goods takes action necessary to coordinate legislative and administrative controls on therapeutic goods and poisons and makes recommendations to the Australian Health Ministers' Advisory Council as necessary.