- choosing suitable medicines, if a medicine is considered necessary, so that the best available option is selected by taking into account
  - the individual
  - the clinical condition
  - risks and benefits
  - dosage and length of treatment
  - any co-existing conditions
  - other therapies
  - monitoring considerations
  - costs for the individual, the community and the health system as a whole
- using medicines safely and effectively to achieve the best possible results by
  - monitoring outcomes
  - minimising misuse, over-use and under-use
  - improving people's ability to solve problems related to medication, such as adverse effects or managing multiple medicines.

The definition of QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population.

National Medicines Policy groups

Many national and local groups are involved in the implementation of NMP. The government has established a structure through which it will be advised on the development of the NMP. This structure includes:

- a National Medicines Policy Executive
- a National Medicines Policy Committee
- an annual National Medicines Policy Partnerships Forum.

For further information see www.health.gov.au/internet/main/publishing.nsf/content/nmp-news.htm-copy2.

Therapeutic goods regulation

The Therapeutic Goods Act

The main objective of the *Therapeutic Goods Act 1989*[4] (the Act) is to establish and maintain a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods. The term 'therapeutic good' refers to ant product that claims to provide therapeutic benefit and includes medicines, medical devices and blood products. The Act provides for the setting of standards (including labelling, and recall procedures), licensing of manufacturers and inclusion of the goods in the Australian Register of Therapeutic Goods (ARTG).

The Act is administered by the Therapeutic Goods Administration and applies to things done by:

- corporations; and
- natural persons or corporations
  - in the course of interstate or international trade
  - in relation to the Pharmaceutical Benefits or Repatriation Pharmaceutical Benefits Schemes
  - in relation to the Commonwealth or any Commonwealth authority.

The Act is intended to operate in concert with state laws. Complementary therapeutic goods laws operate in Victoria, New South Wales and Tasmania. The effects of these laws are to:

- bring unincorporated manufacturers and sponsors of therapeutic goods who trade only in their own jurisdictions into the federal regime
- require wholesalers to comply with the code of good wholesaling practice
- impose controls on the supply of therapeutic goods by retail or in circumstances corresponding to retail supply, such as vending machines.

The Australian Register of Therapeutic Goods

Therapeutic goods that are manufactured or supplied in Australia must be entered in the ARTG or be included in one of several categories of goods that are exempted by the Therapeutic Goods Regulations 1990 from the need to be included in the ARTG. Personal imports, clinical trial drugs and extemporaneously prepared medicines for particular persons (for application to that person) are common examples of exempt goods. Unless exempt, medicines are entered as either 'registered' or 'listed' medicines, and medical devices must be included before they may be supplied in or exported from Australia.

Information on therapeutic goods is held on the database and in hard copy format. The ARTG can be accessed through the TGA's website (www.tga.gov.au/docs/html/artg.htm), although the information made available to the public is limited (as specified by the Therapeutic Goods Regulations 1990). The TGA is in the process of extending the range of information generally available to consumers on the public-access part of the ARTG.

Listed medicines

Listed medicines are generally recognised as low risk products. Listed medicines may only contain substances evaluated by the TGA as being low risk and must be manufactured under good manufacturing principles.