# BACKGROUND ON THE REGULATION OF COMPOUNDING BY PHARMACISTS

Pharmacy Board of Australia

This document contains background information on the regulation of compounding by pharmacists, which is set out in relevant legislation and administered by specific entities. It provides an explanation of the regulatory environment in which the Pharmacy Board of Australia's (the Board's) *Guidelines on compounding of medicines* should be applied by pharmacists when compounding medicines.

## Therapeutic goods legislation

The *Therapeutic Goods Act 1989* sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia.

The *Therapeutic Goods Act 1989* (Cth)[1] requires:

a) therapeutic goods (which includes medicines) to be entered on the Australian Register of Therapeutic Goods (ARTG)[2] before they can be supplied in Australia, unless exempt, and

b) manufacturing of medicines to be in compliance with the *Guide to Good Manufacturing Practice for Medicinal Products*[3] and to take place in premises licensed by the Therapeutic Goods Administration (TGA), unless exempt.

## Exemptions for pharmacists

The *Therapeutic Goods Regulations 1990*[4] provide the following exemptions relevant to pharmacists in relation to the extemporaneous preparation (compounding) of medicines for human use:

a) Australian Register of Therapeutic Goods (ARTG):

Compounded medicines are not required to be entered on the ARTG before they can be supplied provided they are extemporaneously compounded by a pharmacist for a particular person, for therapeutic application to that person.

b) Manufacturing of medicines:

A licence from the TGA is not required when a pharmacist is:

i. Practising:

- in a pharmacy which is open to the public, or
- on the premises of a private hospital.

*(Note: supply must be on or from those premises, and must not be by wholesale).*

OR

ii. Employed in public hospitals or public institutions, and medicines are manufactured for supply in public hospitals or public institutions in the same state or territory.

Despite the exemptions listed above, compounded medicines are not exempted from meeting the quality standards or advertising requirements set out in the *Therapeutic Goods Act 1989* (Cth).

This information is subject to possible change with amendments to TGA legislation. Refer to www.tga.gov.au for further information.

The *Therapeutic Goods Act 1989* (Cth) is given effect in all states and territories by complementary legislation, except in Queensland and Western Australia.

## Compounding veterinary products

The *Agricultural and Veterinary Chemicals Code* (AgVet Code) authorises a veterinary surgeon to instruct a pharmacist to compound a veterinary medicine for animal use. In order to compound a medicine for animal use, the pharmacist must have received instructions from a veterinary surgeon. This contrasts with the *Therapeutic Goods Act 1989* (Cth) which does not prevent pharmacists from compounding non-prescription medicines for human use for individual patients without an instruction from another health practitioner.

1 Available at www.comlaw.gov.au/Series/C2004A03952
2 Available at www.tga.gov.au/industry/artg.htm
3 Available at www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm
4 Available at www.comlaw.gov.au/Series/F1996B00406)

While this instruction is not required to be in writing, the Australian Pesticides and Veterinary Medicines Association (APVMA) advises that best practice would indicate the provision of precise written instructions to evidence any transaction (refer to the APVMA website[5] for further information). Where state or territory requirements exist regarding the instructions required from a veterinary surgeon for supply of a compounded veterinary product, these must also be complied with. Penalties may be applied in the case of non-compliance.

## Premises at which medicines may be compounded and supplied to patients

The *Therapeutic Goods Regulations 1990* outline the following circumstances under which premises do not require a licence from the TGA to compound medicines:

1. *Community pharmacies and private hospitals*

   Pharmacists practising in community pharmacies or private hospitals may only supply medicines which have been compounded at the community pharmacy or private hospital where they are practising.

   Additionally, pharmacists cannot lawfully compound medicines at a community pharmacy or private hospital for supply by wholesale, unless their premises are licensed by the TGA for the manufacture of therapeutic goods, or licensed/registered by the relevant state or territory authority. Pharmacists must ensure that state and territory legislation is complied with when practising in these licensed/registered premises.

2. *Public hospitals and public institutions*

   If employed in a public hospital or public institution, pharmacists may manufacture therapeutic goods for supply in a public hospital or public institution in the same state or territory.

Pharmacists may be subject to action by the TGA if found to be supplying compounded medicines outside of these circumstances.

(Refer to www.tga.gov.au for further information).

## Obligation to meet relevant legislation, guidelines published by the Pharmacy Board of Australia and professional practice standards and guidelines

When compounding, in addition to the legislation outlined above, pharmacists have obligations to comply with requirements regarding issues such as advertising and workplace/premises under other relevant state, territory and Commonwealth legislation.

Pharmacists are also expected to comply with all relevant professional practice standards and guidelines, and guidance published by the Board. The Board has published its *Guidelines on compounding of medicines.* The guidelines specify the relevant practice standards and guidelines which pharmacists must comply with when compounding medicines.

Regardless of the type of premises where a pharmacist practises, for example public hospital, public institution or privately operated pharmacy, there is no difference in the quality of compounding service expected by the Board.

### Audit

The state/territory pharmacy premises regulatory authority or responsible body may conduct audits/inspections of approved and/or registered premises and their associated facilities.

These state/territory based authorities cooperate closely with the Board to ensure the safety of the Australian community and assist in resolving matters such as non-compliance with the Board's ***Guidelines on compounding of medicines*** and other guidelines set by the Board and the authorities themselves.

*Note: the information provided in this background information sheet was considered to be true and correct at the time of publication.*

5 Available at http://apvma.gov.au/node/6881