Background on the regulation of the supply and manufacture of medicines including medicines compounded by pharmacists

This document contains background information on the regulation of supply and manufacture of medicines[1] including compounding of medicines by pharmacists, which is set out in relevant legislation and administered by the responsible 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.

Compounding medicines for humans

Therapeutic goods legislation

The Therapeutic Goods Act 1989 (Cth)[2] (the Act) sets out the legal requirements for the import, export, manufacture (which includes compounding of medicines by pharmacists) and supply of therapeutic goods in Australia.

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

The Act details the requirements for listing, registering or including medicines, medical devices and biological products on the Australian Register of Therapeutic Goods (ARTG)[3] and many other aspects of the law including advertising, labelling, and product appearance. It also sets out the requirements for licensing manufacturing sites in Australia.

The Act is supported by the Therapeutic Goods Regulations 1990[4], and various Orders and Determinations that provide further details of matters covered in the Act.

Therapeutic goods orders (TGOs) are approved under section 10 of the *Therapeutic Goods Act 1989.* A TGO specifies an Australian standard for therapeutic goods or particular types of therapeutic goods (for example, prescription medicines). TGOs specify requirements relating to matters such as quality, procedures to be carried out in the manufacture of goods, labelling and packaging.

In addition to TGOs, monographs in the British Pharmacopoeia (BP), European Pharmacopoeia (Ph Eur), and United States Pharmacopoeia-National Formulary (USP) are defined in the *Therapeutic Goods Act 1989* to be 'default standards' and apply to therapeutic goods that are the subject of the relevant monographs.

Refer to Appendix A for a summary of the pathways for lawful supply of medicines in Australia, including medicines exempt from entry on the ARTG and TGOs applicable to compounded medicines.

Exemptions for pharmacists to compound medicines

The *Therapeutic Goods Act 1989* requires:

[1] Medicine is defined by TGA as meaning therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human

[2] Available at www.comlaw.gov.au/Series/C2004A03952

[3] Available at www.tga.gov.au/industry/artg.htm

[4] Available at www.comlaw.gov.au/Series/F1996B00406)

a. therapeutic goods (including medicines) to be entered on the Australian Register of Therapeutic Goods (ARTG)[5] before they can be supplied in Australia, unless exempt, authorised or otherwise approved, and

b. manufacturing of medicines in Australia to be in compliance with the Guide to Good Manufacturing Practice for Medicinal Products[6] and to take place in premises licensed by the Therapeutic Goods Administration (TGA), unless exempt.

The Therapeutic Goods Regulations 1990[7] 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 (other than medicines that are used for gene therapy, that are medicinal cannabis products or that contain glucagon-like peptide-1 (GLP-1) receptor agonist analogues) 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.

   Medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) that are compounded in a hospital in anticipation of being needed for therapeutic application to patients of the hospital are not required to be entered on the ARTG provided they are considered by the hospital's drug and therapeutic committee to be appropriate for compounding in anticipation of being needed to treat the patient.

b. Manufacturing of medicines:

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

   i. Practising:

      - in a pharmacy that 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 all requirements of the *Therapeutic Goods Act 1989* (Cth). Compounded goods are required to comply with all relevant TGOs (except for TGOs that are expressed as not applying to these goods) and relevant default standards. Similarly, advertising requirements in the *Therapeutic Goods Act 1989* (Cth) apply to goods not on the ARTG, including compounded medicines.

Additional requirements may apply to the supply of compounded medicines (for example, pharmacists may only compound a medicinal cannabis product with a prescription based on approvals under either the Special Access Scheme or Authorised Prescriber pathway). Refer to the relevant legislation for further information.

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

[5] Available at www.tga.gov.au/industry/artg.htm
[6] Available at www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm
[7] Available at www.comlaw.gov.au/Series/F1996B00406)

Compounding veterinary medicines

The *Agricultural and Veterinary Chemicals Code* (AgVet Code) exempts medicines from registration by the APVMA when compounded by a pharmacist in accordance with the instructions of a veterinary surgeon. To compound a medicine for animal use, the pharmacist must have received instructions from a veterinary surgeon.

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. 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.

Obligation to meet relevant legislation

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.

Premises regulation

Each state and territory has separate legislation, guidelines and/or requirements for pharmacy ownership and regulation of premises, including inspections.

When compounding medicines, in addition to complying with legislation relevant to the practice of pharmacy, pharmacists must meet the requirements for the pharmacy premises that apply in the jurisdiction where the premises are located.

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.

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

Appendix A

This appendix sets out pathways for supply of medicines (for humans) in Australia, relevant exemptions to therapeutic goods legislation that provide for pharmacists to compound medicines not included in the ARTG, the requirement for a licence under Part 3-3 of the Act, and the Therapeutic Goods Orders applicable to compounded medicines.

(*Note: This is not a comprehensive document of all legislative requirements. For further information refer to www.tga.gov.au/regulation-basics.)*

Lawful supply of medicines in Australia

The following table summarises the pathways for the supply of medicines set out in the *Therapeutic Goods Act 1989* (further information available at www.legislation.gov.au/Series/C2004A03952)

Summary	Section of the Act	TGA guidance
Approval for supply after evaluation by the TGA and registration on the ARTG Registered 'AUST R' medicines - Prescription medicines - Non-prescription medicines, including OTC pharmaceuticals and registered complementary medicines	25AB	
Approval for supply after certification by sponsor of the safety and quality and evaluation of efficacy claims by TGA, prior to listing on ARTG Listed Assessed 'AUST L(A)' medicines - complementary medicines	26AB	
Approval for supply after certification by sponsor and listing on ARTG, without prior evaluation by TGA Listed 'AUST L' medicines - complementary medicines - sunscreens	26A	
Approval for supply under specific circumstances, exemption from entry on the ARTG - Special Access Scheme Category A	18	Special Access Scheme
Approval for supply under specific circumstances, exemption from entry on the ARTG - Special Access Scheme - Experimental medicines (clinical trials) - Authorised Prescriber	19	Accessing unapproved products
Approval for supply under specific circumstances, exemption from entry on the ARTG - Medicine shortages: when medicines on the ARTG, or under evaluation by the TGA, are not available and an alternative medicine is necessary in the interests of public health	19A	Medicine shortages
An exemption from entry on the ARTG during a declared national emergency (these are identified in legislative instruments outlining the type of goods and any conditions on supply)	18A	-

The following table summarises the pathways set out in the Therapeutic Goods Regulations 1990 (further information available at www.legislation.gov.au/Series/F1996B00406).

Summary	Reference of Regulations	Specific item for example reference
Conditional exemptions in certain circumstances to supply medicines without entry on ARTG - licensed manufacturers supplying a hospital under contract	Schedule 5A	Item 5

Exemptions for compounded medicines

The exemptions applicable to pharmacists in the compounding of medicines are set out in the Therapeutic Goods legislation. The following table summarises the exemptions set out in the Therapeutic Goods Regulations 1990 (further information available at www.legislation.gov.au/Series/F1996B00406).

Summary	Reference of Regulations	Specific item for example reference
Exemptions to supply medicines without entry on the ARTG - Extemporaneously compounded medicines	Schedule 5	Item 6 Item 6A
Exemptions in specified circumstances to allow persons to manufacture in Australia without a GMP licence - Pharmacists, under specified circumstances	Schedule 8	Item 2 Item 3

Therapeutic goods orders applicable to compounding

Therapeutic Goods Orders may be applicable to compounded medicines depending on the circumstances (further information is available at www.tga.gov.au/therapeutic-goods-orders).