



Australian Government

Department of Health

Therapeutic Goods Administration

GMP information for manufacturers of compounded medicines and DAAs

Including information about the supply of
medicines by community pharmacists

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TGA Health Safety
Regulation



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This guidance is for both licenced manufacturers and community pharmacists involved in the manufacture of compounded medicines or dose administration aids (DAAs). It contains information about the compounding and supply of medicines by community pharmacists.

Much of this guidance is based on the previously published questions and answers on the code of good manufacturing practice for medicinal products. This information was published in response to questions received by the TGA.



This information is intended as general information only about the requirements of the therapeutic goods legislation. The contents do not constitute legal advice and should not be relied on as such.

Manufacture of compounded medicines

TGA licensed manufacturers of extemporaneously compounded medicines should refer to our [Compounded medicines and good manufacturing practice \(GMP\)](#).

In addition to the requirements of the therapeutic goods legislation, a pharmacist involved in the compounding of medicines should consider applicable State and Territory requirements, including requirements under the Health Practitioner Regulations Law. In particular, a pharmacist should consider the Pharmacy Board of Australia [Guidelines on compounding of medicines](#). These guidelines include detailed guidance on when it is appropriate for a medicine to be compounded and the requirements to be complied with when compounding medicines.

1. Does the issuing by TGA of a manufacturing licence to a site compounding medicines mean that medicines manufactured under the licence do not need to be included in the ARTG?

The holding of a manufacturing licence and the inclusion of therapeutic goods in the ARTG are separate matters.

Persons engaged in the manufacture of therapeutic goods in Australia must generally either hold a TGA issued manufacturing licence or be exempt from the requirement. In addition, before therapeutic goods may be imported, exported, manufactured or supplied in Australia, they must be included in the ARTG, unless the goods are exempt under one of the exemptions provided for under the legislation.

2. What exemptions exist in the therapeutic goods legislation to allow pharmacists to extemporaneously compound and supply medicines that are not included in the ARTG?

Schedule 8 of the [Therapeutic Goods Regulations 1990](#) provides exemptions from the requirement to hold a manufacturing licence. Item 2 of Schedule 8 of the *Therapeutic Goods Regulations 1990* is relevant to compounding by community pharmacists. Item 2 exempts pharmacists from the requirement to hold a manufacturing licence in certain circumstances. For example, when therapeutic goods (other than biologicals) are (i) produced by the pharmacist in a pharmacy where the pharmacist practices and the pharmacy is open to the public and (ii) the goods are supplied (other than by wholesale) on or from those premises.

Schedules 5 and 5A of the *Regulations* provide exemptions from the requirement to include therapeutic goods in the ARTG in particular circumstances. Item 6 of Schedule 5 of the *Regulations* is relevant to compounding by pharmacists. This item provides an exemption from the requirement for therapeutic goods to be included in the ARTG where the goods are

dispensed or extemporaneously compounded for a particular person for therapeutic application to that person.

3. Can a pharmacist: (i) arrange for a TGA licenced manufacturer to manufacture a medicine that is not included in the ARTG for a particular patient; and (ii) dispense that medicine to that patient once it has been manufactured.

Yes, if the medicine is extemporaneously compounded for an identified person for therapeutic application to that person.

4. Can a person with a TGA issued manufacturing licence manufacture and supply a medicine that is not included in the ARTG directly to patients?

Yes, provided that the medicine has been extemporaneously compounded for a particular person for therapeutic application to that person.

5. Can a person with a TGA issued manufacturing licence manufacture and supply a medicine that is not included in the ARTG directly to medical practitioners for use by the medical practitioners in their practice where there is no identified patient at the time the medicine is compounded for the medical practitioner?

No, such medicines would usually need to be included in the ARTG in relation to the person manufacturing and supplying the medicine.

6. Can a pharmacist undertake any anticipatory steps in the compounding of a medicine before receiving a prescription?

No. A pharmacist may be exempt from the requirement to include a medicine in the ARTG where it is extemporaneously compounded for a particular person for therapeutic application to that person. A pharmacist should therefore ensure that there is an identified person for whom the medicine is being compounded before undertaking any steps in manufacture. Pharmacists are not permitted to store excess quantities of compounded medicines in case additional prescriptions are subsequently presented by patients. (For further details, please refer to the Pharmacy Board of Australia [Guidelines on compounding of medicines.](#))

7. Can a person with a TGA issued manufacturing licence make a batch of a prescription medicine that is not included in the ARTG to keep stock in the pharmacy to give patients their prescription medicine?

The Pharmacy Board of Australia *Guidelines on compounding of medicines* includes requirements in relation to batch preparation. In relation to TGA requirements, the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990* do not specifically deal with batch preparation. If a TGA licensed manufacturer is relying on the exemption in item 6 of Schedule 5 (relating to extemporaneous compounding) to manufacture and supply a medicine that is not included in the ARTG, the manufacturer will need to ensure that there is an identified person for whom a medicine is being compounded at the time of the compounding. Manufacture may proceed in anticipation of an order where the TGA licensed manufacturer holds evidence that the identified patient is undergoing a defined course of treatment.

8. Is there a limited form of a TGA issued manufacturing licence that a pharmacist can obtain to enable a pharmacist to compound and dispense medicines?

No, there is not a limited form of a manufacturing licence for pharmacists to compound and dispense medicines. However, there are exemptions from the requirement to hold a manufacturing licence that will apply to pharmacists in certain circumstances. For example, a pharmacist is exempt from the requirement to hold a manufacturing licence to manufacture therapeutic goods (excluding biologicals) when the goods are produced in a pharmacy where the pharmacist practices and which is open to the public and supplied (other than by wholesale) on or from those premises.

9. Once a pharmacist obtains a TGA issued manufacturing licence, can the pharmacist manufacture and supply a medicine that is not included in the ARTG under a contract with a private or public hospital or with a public institution.

Generally yes but the exemption in the Therapeutic Goods Regulations that allows for this has certain requirements, the main ones being that there are no substantially similar goods included in the ARTG and that the medicine is manufactured in accordance with a formulation specified by the hospital.

10. Is a community pharmacy a public institution under the therapeutic goods regulations?

No, a community pharmacy would not normally be considered a public institution under the therapeutic goods legislation.

11. Do PQRs have to be performed for products for which there is no Marketing Authorisation, e.g. compounded medicines?

Yes. Product Quality Reviews are performed to demonstrate the consistency of the manufacturing process. Where no Marketing Authorisation is available, clauses 1.10.vi and 1.10.x do not apply, but a review of the process consistency, including all other elements of clause 1.10 should be performed and documented by the manufacturer.

Manufacturing Dose Administration Aids (DAA)

This section has been prepared to provide information to manufacturers of Dose Administration Aids (DAA). It contains answers to some frequently asked questions in relation to the preparation of DAAs. The information is intended as general information only about the requirements of the therapeutic goods legislation. The contents do not constitute legal advice and should not be relied on as such.

In addition to the requirements of the therapeutic goods legislation, a pharmacist involved in the preparation of DAAs should consider applicable state and territory requirements, including requirements under the [health practitioner regulations laws](#). In particular, a pharmacist should consider the Pharmacy Board of Australia [Guidelines on dose administration aids and staged supply of dispensed medicines](#).

12. When do persons packing medicines in Dose Administration Aids (DAA) require a licence?

Persons engaged in the manufacture of therapeutic goods in Australia are generally required to hold a manufacturing licence. There are, however, some circumstances in which a person is exempt from the requirement to hold a manufacturing licence. The exemptions are set out in Schedules 7 and 8 of the [Therapeutic Goods Regulations 1990](#). Whether an exemption applies depends on the circumstances of the particular manufacture.

Item 2 of Schedule 8 provides an exemption to pharmacists from the requirement to hold a licence for the manufacture of therapeutic goods if:

- a. the goods are not:
 - i. biologicals.
- b. the goods are produced by the pharmacist:
 - i. in a pharmacy where the pharmacist practices and the pharmacy is open to the public; or

- ii. on the premises of a dispensary conducted by a Friendly Society; or
- iii. on the premises of a private hospital; and
- iv. the goods are for supply (other than by wholesale) on or from those premises.

Item 3 of Schedule 8 provides an exemption to biomedical engineers, radiochemists and pharmacists in public hospitals from the requirement to hold a manufacturing licence for:

‘the manufacture of therapeutic goods, other than biologicals, by the person when employed by a public hospital or a public institution and produced by that person for supply in hospitals or public institutions in the same state or territory’

13. Do the medicines in the DAAs need to be listed or registered in the ARTG

Therapeutic goods manufactured in Australia are generally required to be listed or registered on the Australian Register of Therapeutic Goods (ARTG). There are, however, some specific circumstances where the goods may be exempt from the requirement to be listed or registered. The exemptions are set out in Schedules 5 and 5A of the [Therapeutic Goods Regulations 1990](#). Whether an exemption applies depends on the circumstances of the particular manufacturing activities.

Item 6 of Schedule 5 which provides an exemption for:

medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than:

- a. medicines that are used for gene therapy.

Item 5 of Schedule 5A which provides an exemption for:

Therapeutic goods, if:

- a. the goods are not any of the following:
 - i. biologicals;
 - ii. goods referred to in item 3;
- b. the goods are manufactured by a person under a contract between the person and a private hospital, a public hospital in a State or Territory or a [public institution](#) (the **relevant institution**); and
- c. the manufacture is in accordance with a formulation specified by the relevant institution; and
- d. the goods are for use by, or in connection with, a patient of:
 - i. the relevant institution; or
 - ii. if the relevant institution is a public hospital in a State or Territory—another public hospital in the State or Territory

where:

- a. there are no listed goods or registered goods that, in all relevant respects, are [substantially similar](#) to the goods; and
- b. the person:
 - i. manufactures the goods at premises in Australia; and

- ii. holds a licence, required by the Act, that authorises the manufacture, or a step in the manufacture, of the goods at those premises; and
- c. the person notifies the Secretary, in accordance with a form approved by the Secretary and within 15 days of the end of a quarter, of:
 - i. the goods manufactured under the contract during that quarter; and
 - ii. the relevant institution that entered the contract

14. I am a pharmacist. Can I engage the services of a third party to pack a DAA on my behalf (e.g. a TGA licenced facility or another pharmacy)?

Where permitted by applicable state and territory legislation, a pharmacist may engage the services of a third party to pack a DAA on their behalf (e.g. a TGA licensed facility or another pharmacy).

The supply pharmacist (who supplies the DAA to the patient or their agent):

- must ensure that the patient's right to privacy is understood, the patient or agent has consented if a third party is to be involved in the packing of the DAA, and a record of the consent is kept
- is responsible for ensuring the packing pharmacist has accurate details of the medicines to be packed
- must make an assessment of the measures, techniques and technology used by the packing pharmacist at the third party packing facility to check packed DAAs for accuracy, to determine whether additional checking of a DAA is required prior to its supply to a patient or their agent

AND

- is responsible for the quality use of medicines support for the patient, including provision of accompanying medicines information to the patient or their agent.

The direct supply of the DAA to the patient or their agent from the third-party packing facility is not permitted under the therapeutic goods legislation and must not take place, even if pharmacists are employed at that facility. It is the responsibility of the supply pharmacist to make the supply of the DAA to the patient or their agent.

A packing pharmacist who uses an automated or semi-automated dose packaging system on behalf of a supply pharmacist may need licensing by the TGA in jurisdictions that have laws to complement the *Therapeutic Goods Act 1989*. Please check the applicable laws in your state or territory.

15. Can I pack DAAs for another pharmacy for that pharmacy to supply to their patient?

When permitted by applicable state and territory legislation, a pharmacist may engage the services of a third party to pack a DAA on their behalf (e.g. a Therapeutic Goods Administration (TGA) licensed facility or another pharmacy).

The packing pharmacist at the third party packing facility is responsible for ensuring DAAs are prepared in a timely and accurate manner according to the patient's current medication regimen.

The direct supply of the DAA to the patient or their agent from the third-party packing facility is unlawful and must not take place, even if pharmacists are employed at that facility. It is the responsibility of the supply pharmacist to make the supply of the DAA to the patient or their agent.

A packing pharmacist who uses an automated or semi-automated dose packaging system on behalf of a supply pharmacist may need licensing by the TGA in jurisdictions that have laws to complement the *Therapeutic Goods Act 1989*.

- Where both pharmacies are in the same state and only trade in that state, and are not incorporated bodies, such as where one pharmacy contracts another to pack medicines into DAA packs and supply them only in the same state, then their operation **may not** come under the scope of Commonwealth law, thus will not require a GMP licence. However, the co-regulatory scheme requires those individual trading entities to comply with all state laws that will apply to them.
- Where the pharmacies are not in the same state (or are trading across state boundaries) then the operations would come under the scope of the Commonwealth law, and thus a GMP licence would be required.



The DAA must be supplied to the patient from the supply pharmacy as they have the prescription and have contracted out the packaging.

Determination of ‘public institution’

The key questions to consider in determining whether an entity is a ‘public institution’ in the application of item 5c, Schedule 5A and item 3, Schedule 8 of the [Therapeutic Goods Regulations 1990](#) are in the table below.

Key questions to consider	Could be considered a ‘public institution’ if all three criteria below are met	Would probably not be considered a ‘public institution’ if any of the criteria below are met
How is the entity controlled?	The institution is controlled by the government or other public entity. AND	It is controlled by private individuals, an independent, commercial company, or a corporate body.
How is the entity funded?	The institution is funded by the government or other public entity; and Any profits are directed towards the services the institution provides to the public. AND	The institution is established by a private entity and/or is for profit of particular individuals.
Who has access to its services?	The institution serves the public generally or a large proportion of the public.	The institution only serves or is accessible by a small portion of the public. Individuals are selected for reasons of private concern or as members of some private class.

Determination of ‘substantially similar’

Whether there are listed or registered goods that are substantially similar, in all relevant respects, to the medicines in the Dose Administration Aids (DAA) for which the exemption is said to apply, requires a relative assessment; it is a factual question to be decided on a case by case basis having regard to the relevant essential characteristics of those two therapeutic goods.

The TGA therefore makes an assessment of whether the medicines in the DAA for which the exemption is said to apply are substantially similar, in all relevant respects, to listed or registered goods, by considering a number of factors that characterise the essential features of therapeutic goods, including but not limited to, whether these goods have:

- a different formulation, composition or design specification; or
- a different strength or size (disregarding pack size) ; or
- different dosage form; or
- different indications; or
- different directions for use; or
- a different type of container (disregarding container size).

The exemption applies if the listed or registered goods are not similar, to a considerable degree, to medicines in the DAA.

If the listed or registered goods are substantially similar, in all relevant respects, to the medicines in the DAA, the latter must be entered onto the ARTG before they can be lawfully supplied.

To fulfil the requirement of the exemption one of the criteria is that the private hospital or the public hospital in a State or territory, or the public institution, must be able to specify the full formulation of each product, including active ingredients, excipients and their quantities. If the product to be packed into final packaging is already registered or listed on the ARTG, this criterion could be met, for the purpose of DAA, by providing the ARTG listing or registration number of the medicine.

For example, a manufacturer or pharmacy is engaged by an institution to repackage a medicine presently registered on the ARTG with container types (e.g. bottles or blister packs) into DAA packs or sachets. The benefit of the DAA packs or sachets to the institution, in terms of its capacity for more efficient and effective control over the administration of the medicine, particularly one that reduces the likelihood of administration error, is of such significance that the registered medicine would not be substantially similar to the repackaged medicine. The latter would, therefore, be exempt from the ARTG, provided all other criteria and conditions of item 5, Schedule 5A of the *Therapeutic Goods Regulations 1990* are met.

Version history

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