Clinical samples – Summary of legislation current at May 2023

This table provides a high level summary of laws and regulations that apply to the provision and receipt of samples of prescription medicines for general guidance purposes.

In addition to the requirements under the laws of each State and Territory, as set out in the table below, the Medicines Australia's Code of Conduct also applies. A company must comply with both the requirements in the Code of Conduct and requirements imposed under the law of the relevant State/Territory. The following is an extract of the relevant obligations under the 20th Edition of the Code of Conduct (Section 6):

> *Companies may offer programs for the provision of a registered medicine at no cost or reduced cost. These programs must be only for the purpose of enhancing patient access or enabling prescribers to gain experience with the product to improve patient care.*
>
> - *Starter Pack definition and labelling requirements are specified under the current Therapeutic Goods Order.*
> - *Companies should ensure that they are kept informed of any changes in Commonwealth and State laws concerning the supply of starter packs. A summary of this information can be found in the Code Tool Kit.*
> - *Starter packs of products must be stored and supplied consistent with related product labelling.*
> - *Starter packs of products may only be supplied by representatives employed by the holder of a manufacturer's licence or wholesale dealer's licence or by authorised Company representatives.*
> - *A signed request from a healthcare professional to receive starter packs, including the name and address of person supplied and the name, strength and quantity of the starter packs supplied, must be submitted prior to supply.*
> - *A record of delivery, including the quantity and nature of starter packs, should be kept for a minimum of two years by the Company.*

	NSW	QLD	SA	WA
Legislation	*Poisons and Therapeutic Goods Act 1966* (**PTGA**) *Poisons and Therapeutic Goods Regulation 2008* (**PTGR**) As at the date this table was prepared, NSW had passed *the Medicines and Therapeutic Goods Act 2022* (NSW) but it is yet to commence and regulations have not yet been drafted. This Act will	*Medicines and Poisons Act 2019* (**MPA**) *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* (**MPPR**) *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**)	*Controlled Substances Act 1984* (SA) (**CSA**) *Controlled Substances (Poisons) Regulations 2011* (SA) (**CSPR**) Medicine Samples Policy Directive (**Directive**)	*Medicines and Poisons Act 2014* (WA) **(MPA)** *Medicines and Poisons Regulations 2016* **(MPR)**

	NSW	QLD	SA	WA
	ultimately repeal the PTGA and the PTGR.	Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8 (**the Code**) (r71, MPMR)		
Who can supply?	A manufacturer or wholesaler, or their agent, engaged in the manufacture or wholesale of any poison or restricted substance for therapeutic use (s132, PTGR). The Secretary of the Ministry of Health may, by writing to the relevant person, prohibit or restrict a person from possessing, supplying or prescribing a substance (s18AA, PTGA).	Holders of a manufacturing licence or wholesale licence; or A person employed to display or give starter packs to an entity permitted to supply a medicine by wholesale.	Representatives' licence - employed by the holder of a manufacturer's licence or wholesale dealer's licence.	Holders of a pharmaceutical samples permit to carry and supply pharmaceutical samples of Schedule 2, 3 and 4 poisons as a representative of a specified manufacturer or wholesale supplier (r79, MPR). An agent or employee of a permit holder, acting within the scope of the agent's or employee's actual or apparent authority, may do anything that is authorised by the permit (s36(4), MPA).
To whom can they supply?	Medical Practitioners, Dentists, Pharmacists, Veterinary Surgeons, Nurse Practitioners (s17A(1), PTGA), Midwives (s17A(2), PTGA), Optometrists (s17B, PTGA) and Podiatrists (s17C, PTGA).	Wholesale representatives may supply S2, 3 or 4 medicines other than monitored medicines to healthcare professionals including dentists, medical practitioners, veterinary surgeons, endorsed midwives and nurse practitioners. Holders of a manufacturing licence or wholesale licence may also supply to healthcare professionals. The medicine samples supplied by the wholesale representative must accord with that stated in the purchase order for the medicine from the practitioner (Schedule 14, r9, MPMR).	Samples must be received directly by a hospital or health service, and not directly by a prescriber (Directive). It is prohibited for any person to provide samples of an S8 poison (r46, CSPR).	A permit holder may only supply samples where they have obtained a signed request from a health professional authorised to administer, possess, prescribe, supply or use the medicine (r81 MPR).

	NSW	QLD	SA	WA
What records must be kept?	A person who supplies by wholesale any medicine must issue an invoice to the person being supplied and must keep a copy of the invoice. The invoice must show: (a) the date of the supply, (b) the name and address of the person being supplied, (c) the name, strength and quantity of the substance supplied, and (d) the name of the supplier and the address of the premises from which the goods were supplied (r131, PTGR). Records must be kept for at least 2 years (r176, PTGR).	Supplier must keep a record of a notice given to the person supplied containing: • Unique identifier of the notice; • Date of supply; • Name and address of buyer; • The place to which the stock is delivered; • The details of the buyer's permission/authorisation to buy the stock; • Name, form and strength of the medicine supplied; and • The amount of stock of the medicines supplied. (r61, MPMR) A supplier must take all reasonable steps to make and keep records showing the details of any stock given to a wholesale representative of the supplier (r70, MPMR). A wholesale representative must, periodically but at least every 3 months, give the representative's employer a return about the transactions about the transactions carried out by the representative for the period carried out by the representative for the period (r232, MPMR). Records must be retained for at least 2 years (r244, MPMR)	Not reflected in legislation	The permit holder must: • make a written record of every pharmaceutical sample received or supplied by the permit holder; • keep the record together with consignment notes, invoices, advice notes and request forms for at least 2 years; and • provide the records to the CEO of the Department of Health on written request (r81(4), MPR).

	NSW	QLD	SA	WA
Loss or theft of samples	A person must immediately notify the Secretary if the person loses a prescribed restricted substance or if a prescribed restricted substance is stolen from the person (r67, PTGR).	Loss or theft of a diversion-risk medicine (those in Sch 2, Part 3 of the MPMR) that was in the possession of a wholesaler must be reported to the police service and to the chief executive by a wholesale representative (being a person employed to display or give starter packs of medicines (Schedule 14, section 7 of the Medicines Regulations)) (r23, MPMR).	Not reflected in legislation	Loss or theft of poisons to be notified to CEO of relevant WA Department as soon as reasonably practicable (r106, MPR).
Storage	A dealer who has possession of any restricted substance (ie a S4 poison) must keep the substance (a) in a room or enclosure to which the public does not have access; (b) apart from food intended for consumption by humans or animals; and (c) in such a way that, if its container breaks or leaks, the poison cannot mix with or contaminate any such food. (r29, PTGR). A person who is engaged in the supply by wholesale of therapeutic substances for human use must ensure that the recommendations and requirements of the Wholesaling Code of Practice are complied with (r133, PTGR).	The holder of a substance authority authorising the possession of an S4 poison must take all reasonable steps to ensure the S4 poison is stored in a way that prevents the poison from being accessed by a person who is not authorised to deal with the poison (r36, MPPR) A supplier must ensure stock of a medicine is sealed in a securely closed package that is likely to show if the package breaks or anyone tampers with it and clearly labelled (r64, MPMR). Additional requirements apply to S4 medicines stored in shared clinics (Part 2, Division 2, MPMR). Such requirements also deal with recordkeeping. Warehousing of medicines should be carried out in buildings or parts of buildings that have been built	Drugs must not be stored in a container that is normally used for containing food or beverages or is similar to a container that is normally used for containing food or beverages (r27(a), CSPR) and meet certain standards including labelling requirements (r26, CSPR).	Pharmaceutical samples must be stored at the specified premises except when the permit holder is carrying them in a vehicle in the course of the supply (r81, MPR). The samples must be stored in a locked cabinet or refrigerator (r81, MPR).

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		for, or adapted to, this purpose (s1.1, Code). Storage facilities for medicines should protect the medicines from deterioration (s2.1, Code).		
Quantity	Not reflected in legislation	For an S4 medicine in a starter pack, other than a monitored medicine, not more than is reasonably necessary to meet the business needs of the representative for a 6-month period (Schedule 14, section 9, MPMR).	Not reflected in legislation	A sample of a Schedule 2, 3 or 4 poison should only be up to one-third of the size of the smallest trade pack of the medicine; or if it is not practical to produce a pack that is one-third of the size of the smallest trade pack of the medicine – the smallest trade pack of the medicine (r3, MPR). Not more than 100 samples of any single medicine or samples of not more than 5 different medicines may be stored at the specified premises at any one time (r81, MPR). No more than 25 samples of any medicine or samples of not more than 5 different medicines may be carried in a vehicle at any one time (r81, MPR).
Disposal	A person must not use or dispose of a restricted substance in any place or in any manner likely to constitute a risk to the public (r66, PTGR).	The holder of a substance authority authorising the possession of an S4 poison must take all reasonable steps to ensure waste from a S4 poison disposed of under the authority is destroyed under the supervision of an authorised supervisor for the authority (r38, MPPR).	A person must not dispose of a S4 poison in any manner that constitutes, or is likely to constitute, a risk to public health or safety (r48, CSPR).	Not reflected in legislation

	NSW	QLD	SA	WA
		Additional rules apply to the disposal of waste from a diversion-risk medicine (those in Sch 2, Part 3 of the MPMR). A wholesale representative must return to the representative's employer any starter pack of a diversion-risk medicine that is unwanted, expired or otherwise unused (r171, MPMR).		

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	TAS	VIC	NT	ACT
Legislation	*Poisons Act 1971* (PA) *Poisons Regulations 2018* (PR)	*Drugs, Poisons and Controlled Substances Act 1981* (Vic) (**DPCSA**) *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) (**DPCSR**)	*Medicines, Poisons and Therapeutic Goods Act 2012* (NT) (**MPTGA NT**) *Medicines, Poisons and Therapeutic Goods Regulations 2014* (NT) (**MPTGR NT**)	*Medicines, Poisons and Therapeutic Goods Act 2008* (ACT) **(MPTGA)** *Medicines, Poisons and Therapeutic Goods Regulations 2008* (ACT) **(MPTGR)**
Who can supply?	Holder of a licence to carry on business as a manufacturing chemist or a wholesale chemist (s16, PA).	A person with a valid manufacturer or wholesaler licence to supply the relevant scheduled medicines, issued under Part II, Division 4 of the DPCSA. (s20, DPCSA)	The holder of a manufacturer certificate of registration (s121, MPTGA NT) or wholesaler certificate of registration (s122, MPTGA NT) , or Schedule 4 supplier certificate of registration (s122A MPTGA NT) .	• Representative of a medicines wholesalers licence-holder. • Representative of a person authorised under corresponding laws to manufacture medicines (such representatives cannot, however, supply sample packs of a Schedule 8 substance). • Representative of a person authorised under corresponding laws to supply medicines by wholesale (Schedule 1, Part 1.12 MPTGR). However, a person who supplies medicines by wholesale under a corresponding law must not supply sample packs of a controlled medicine (ie a Schedule 8 medicine) (r270(b) MPTGR)
To whom can they supply?	Medical Practitioner, Dentist, Authorised Nurse Practitioner, Pharmacist, Veterinary Surgeon,	Healthcare professionals registered to practice in Australia who in the course of	Schedule 4 substances: an Authorised Health Practitioner (s55, MPTGA NT), Pharmacist	Ambulance officer, Dentist, Doctor, Health Practitioner, Medical radiation practitioners

	TAS	VIC	NT	ACT
	Licensed Wholesale Chemist, Licensed Manufacturing Chemist or an Authorised Officer of a medical institution (ss25A – 25C, PA).	their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Victoria. Healthcare professionals may request to receive starter packs by signing a request form including the name and address of person supplied and the name, strength and quantity of the starter packs supplied.	(s56, MPTGA NT), , Nurse and Midwife (s63 - 64, MPTGA NT), Dentist (s66, MPTGA NT), Optometrist (unrestricted substances only) (s68, MPTGA NT), Veterinarian, or Podiatrist (s69, MPTGA NT).	Midwives, Nurses, Optometrist, Pharmacist, Podiatrist, Veterinary practitioners, First Aid-Kit Licence holder.
What records must reps keep?	A person who sells or supplies a S4 poison must keep a record showing the date of the sale or supply, the name and address of the purchaser or the person to whom the substance is supplied and the name and quantity of the substance sold or supplied (94, PR). A manufacturer or wholesale dealer of a S4 poison, who provides a free sample must make a record of the supply showing the date of the supply, the name and address of the person to whom the substance was supplied and the name and quantity of the substance so supplied (r95(2), PR). Except in the case of the supply by registered or certified mail, a person supplying the substance must obtain a receipt at the time of supply from the person to whom the supply was made (r95(3), PR).	Both the recipient and the Company must keep required records for at least 3 years. (reg 109(4), DPCSR) Required records include the date of each transaction (which includes the manufacture, preparation, use, transfer within and between premises, administration, sale, supply, disposal or destruction of a Schedule 4 poison), the name, form, strength, quantity of the medicine, the name and address of the person to whom the medicine was supplied and the supplier.	The holder of a Schedule 4 authorisation must keep a register in relation to each supply of a S4 substance setting out: • the nature of the dealing; • the date of the dealing; • the name of the substance, and the form, strength and quantity, dealt with; and • the name and address of the person to whom it was supplied (r47, MPTGR NT). In addition, suppliers must keep records of: • the name and address and, if applicable, authorisation or licence number of the recipient; • the quantity of the substance held after the dealing (r59, MPTGR NT).	The following records must be kept for medicines supplied under requisition: • the date of the requisition; • (the name of the person who issued the requisition; • the date the requisition is filled; • the medicine, and the form, strength and quantity of the medicine, supplied; and • the name or initials of the person supplying the medicine. (r130(d), MPTGR)

	TAS	VIC	NT	ACT
			Records should be kept for 2 years (r61 of the MPTGR NT).	
Loss or theft of samples	The licence holder shall immediately notify the Chief Pharmacist in the Department of Health and Human Services should any theft or loss occur of substances included in this licence. This is a condition of wholesale chemist licences issued under s16 of the Poisons Act 1971.	Company (being the poisons licence holder) must notify the Secretary and a police officer of the loss by them or theft from them of a poison immediately after becoming aware of it (reg 153). A person must also notify the Secretary where records relating to Schedule 4 poisons are lost, destroyed or stolen (reg 113).	A person who maintains a Scheduled substance register must, if it becomes aware of a substantial risk that a Scheduled substance in relation to which the register is maintained has been lost, misappropriated or stolen report it to the Chief Health Officer as soon as practicable (but no later than 7 days after the person becomes aware of the loss, misappropriation or theft) (r71, MPTGR NT).	Not reflected in legislation
Storage	A chemist, medical practitioner, dentist, endorsed midwife, authorised nurse practitioner, veterinary surgeon, optometrist, podiatrist must keep S4 poisons in either a storeroom or dispensary that the public does not have access to (s43(2), PR). Poisons must be kept apart from other goods suitable for human or animal consumption in such a way that, if the container of the poison breaks or leaks, the poison will not intermix with or contaminate those goods (s43(4), PR).	Schedule 4 poisons must be in a container labelled with the date of the making of a record of the sale or supply and with directions for use (reg 72). Schedule 4 poisons must be stored in a lockable storage facility and all reasonable steps must be taken to ensure that the storage facility remains locked and secured to prevent access by an unauthorised person (reg 73 and 75). A person who is permitted to be in possession of a Schedule 4 poison must take all reasonable steps to restrict access to that poison to persons authorised (reg 154).	Schedule 4 substances to be stored in a way that prevents unauthorised access (r25, MPTGR NT). A delivery person must not leave the substance unattended, other than in a locked building or vehicle. Scheduled substances received at a hospital must be stored in an area and in a way to prevent unauthorised access to them (s98, MPTGA NT).	Generally: medicines must be stored within the manufacturer's recommended storage temperature range; and in any other environmental condition that is necessary to preserve the medicine's stability and therapeutic quality (r515 of the MPTGR). The medicine must be stored so that public access to it is restricted (except if for retail sale) (rs520 – 521 MPTGR).

	TAS	VIC	NT	ACT
Quantity	Not reflected in legislation	Not reflected in legislation	Not reflected in legislation	Not reflected in legislation
Disposal	Disposal of relevant substances directed by the Secretary must be recorded in a database maintained by the Secretary (r124, PR).	Not reflected in legislation	Disposal should be carried out in accordance with the *Waste Management and Pollution Control Act 1998* (NT), where a regulated substance is a listed waste under that Act.	A medicine must not be discarded in a way that creates a risk to the health or safety of people or is likely to cause damage to property or the environment (s34(3) of the MPTGA).