Clinical samples – Summary of legislation current at March 2018

	NSW	**QLD**	**SA**	**WA**
Legislation	*Poisons and Therapeutic Goods Act 1966* (**PTGA**) – Part 5 *Poisons and Therapeutic Goods Regulation 2008* (**PTGR**)- *Health Practitioner Regulation National Law* (NSW)	*Health (Drugs and Poisons) Regulation 1996* (**HDPR**) – Ch 3, Part 2	*Controlled Substances Act 1984* (SA) (**CSA**) *Controlled Substances (Poisons) Regulations 2011* (SA) (**CSPR**)	*Medicines and Poisons Act 2014* (WA) (**MPA**) *Medicines and Poisons Regulations 2016* (**MPR**)
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. 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 (PTGA, s18AA).	A restricted drug manufacturer, restricted drug wholesaler or a wholesale representative can supply restricted drugs (Schedule 4) A wholesale representative licence can be granted by the Chief Executive, Department of Health if the person is suitable and employed in a capacity requiring the person to possess restricted drugs.	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).
To whom can they supply?	Medical Practitioners, Dentists, Pharmacists, Veterinary Surgeons, Nurse Practitioners (under s17A(1) PTGA), Midwives (under s17A(2) PTGA), Optometrists (under s17B PTGA) and Podiatrists (under s17C PTGA).	Restricted drug manufacturers and restricted drug wholesalers can only supply restricted drugs to Medical Practitioners, Dentists, Veterinary Surgeons or wholesale representatives (r145 HDPR) Wholesale representatives can supply to dentists, medical practitioners, pharmacists or veterinary surgeons (r148 HDPR).	Registered Health Practitioner, or Veterinary Surgeon (s15 CSA). N.B. Nothing in the legislation empowers any person to give a sample of a Schedule 8 poison.	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 once (r81 MPR).
What records must be kept?	Date of supply. Name & address of person supplied. Name, strength and quantity of the substance supplied. Name of the supplier and address of the premises from which the goods were supplied. Copy of the invoice issued to the person supplied. Records must be kept for at least 2 years.	A wholesale representative must record on an invoice: A unique invoice number. Date of supply. Name & address of person supplied. Name, strength and quantity of the substance supplied. Invoice to be given to the person supplied and representative must personally receive a signed copy of the invoice from the person supplied. A copy of the signed invoice is to be sent to the representative's employer within 7 days after giving the drug to the practitioner. A wholesale representative must also keep a record of each restricted drug the representative:	Date of supply Name & address of person supplied Name, strength and quantity of the substance supplied. The date on which the sample was supplied. The trade name or the approved name of the sample supplied, or if it has neither a trade nor an approved name, its ingredients. The directions given for the safe and proper use of the drug Records must be made immediately after the drug is supplied Records must be kept in electronic form Records must me made of total amount of the drug now in stock on the premises from which the drug was supplied Records must be sent to the Chief Executive	The permit holder must make a written record of: Every pharmaceutical sample received or supplied by the permit holder; and Keep the record together with consignment notes, invoices, advice notes and request forms relating to the record for a period of at least 2 years commencing on the day the sample is received or supplied. A permit holder must keep a register of Schedule 8 medicines and Schedule 9 poisons at the premise from which the permit holder supplies with the name, strength, quantity, form and date of manufacture. For each supply, the permit holder must record: • Date of supply

		a) supplies; or b) returns to the representative's employer. A 'Return of Transactions' supplied to employer to account for all drugs at least every 7 days. Employers must retain records for at least 2 years.	of the SA Department for Health and Ageing in the month following the supply Records must be kept for at least 2 years (or 5 years in the case of Schedule 7 poisons).	• Name, strength, quantity and form • Name of the person supplied • Name of the person who sent the request • A number for the order • The quantity of the poison/medicine remaining on hand after the supply The record must be signed by the permit holder Information on the register must be kept for at least 5 years from the date on which the information is recorded (r144 MPR)
Loss or theft of samples	A person must immediately notify the Director-General 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 samples must be reported immediately to the employer and the nearest police establishment.	Loss or theft of samples must be reported immediately to the employer and the police.	Loss or theft of poisons to be notified to CEO of relevant WA Department as soon as reasonably practicable.
	NSW	**QLD**	**SA**	**WA**
Storage	A dealer who has possession of any restricted substance must keep the substance: a) in a room or enclosure to which the public does not have access,; b) apart from human or animal food; and c) in such a way that, if its container breaks or leaks, the substance cannot mix with or contaminate any human or animal food. (rs11 and 12 PTGR).	When a wholesale representative is not displaying or giving restricted drugs, the representative must keep the restricted drugs locked in a secure place out of public view (r149(1) HDPR).	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). Certain prescribed poisons must not be stored in retail premises unless stored in an area to which the public do not have access (r27(b)-(c) 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. The samples must be stored in a locked cabinet or refrigerator (r81 MPR), Must be stored in such a way that the medicine/poisons are clearly identifiable (r145(8) MPR)
Quantity	Not reflected in Regulations.	The HDPR does not set any particular limits of volumes or quantities of samples of S4 drugs a wholesale representative may have in their possession. The Queensland Department Health however, can set conditions on individual licence holders in this regard. Each application is assessed on its merits.	Not reflected in Regulations.	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. 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 who is authorised to be in possession of a	A person must not discharge, dispose of or	Drugs of dependence must only be	A Schedule 9 poison or Schedule 8

	drug of addiction must not willfully destroy the drug or allow the drug to be destroyed unless the destruction is carried out by or under the direct personal supervision of a police officer, an inspector or a person authorised under Part 8 of PTGR (r125 of the PTGR).	use a controlled or restricted drug in a way that a) endangers the life or safety of a person or domestic animal; or b) exposes food, drink or a condiment or another drug or a poison to the risk of contamination by the controlled drug; or c) allows access to the controlled drug to someone not endorsed to possess it. (rs130 and 219 of HDPR). Also, a person must not destroy a controlled or restricted drug unless they are endorsed to do so. (rs51 and 146 of HDPR).	destroyed by a police officer, authorised officer, or if witnessed in accordance with r45 of CSPR.	medicine must be destroyed by either the permit holder or a health professional; investigator or a police officer and witnessed by a health professional, investigator or police officer who is not destroying the sample. (r145 MPR)

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	TAS	**VIC**	**NT**	**ACT**
Legislation	*Poisons Act 1971* *Poisons Regulations 2008* (**Poisons Regulations**)	*Drugs, Poisons and Controlled Substances Act 1981* (Vic) (**DPCSA**) *Drugs, Poisons and Controlled Substances Regulations 2017* (Vic) **(DPCSR**) Medicines Australia Code of Conduct 18th Ed., 2015 (**Code**) - enforced in relation to Schedule 2, 3 and 4 medicines as a condition of the licence of manufacturers and wholesalers)	*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 manufacturer's licence or wholesale dealer's licence, or a representative of such a person.	A representative employed by the holder of a manufacturer's licence or wholesale dealer's licence or by authorised company representatives (including agents working under a contract to, but not directly employed by, the holder of a manufacturer's licence or wholesale dealer's licence. (r7.1, Code)	The holder of a manufacturer certificate of registration or wholesaler certificate of registration or retailer licence (for Schedule 2 and Schedule 7 substances) or specific licence for either Schedule 7 or Schedule 8 substances.	• 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 (r270(b) MPTGR)
To whom can they supply?	Medical Practitioner, Dentist, Authorised Nurse Practitioner, Pharmacist, Veterinary Surgeon, Licensed Wholesale Chemist, Licensed Manufacturing Chemist or an Authorised Officer of a medical institution.	At the request of Health Care Practitioners including Medical Practitioners, Dentists, Veterinarians, Hospital Pharmacists and Nurse Practitioners. Samples can only be supplied for the following reasons: • for immediate use in the surgery for relief of symptoms, or • for the use of alternative treatments, prior to a prescription being written or • for after-hours use or • for gaining familiarisation with products (r7.3, Code).	Schedule 3 substances: Health Practitioners, Veterinarians. Schedule 4 substances: an Authorised Health Practitioner, Pharmacist, Aboriginal and Torres Strait Islander health practitioners, Nurse and Midwife, Dentist, Optometrist (unrestricted substances only), Veterinarian, or Podiatrist. Schedule 8 substances: an Authorised Health Practitioner Pharmacist, Nurse, Dentist (unrestricted substances only), or Podiatrist (unrestricted substances only), or Veterinarian.	Ambulance officer, Dentist, Doctor, Health Practitioner, Midwives, Nurses, Optometrist, Pharmacist, Podiatrist, Veterinary Surgeon, First Aid-Kit Licence holder.
What records	On each occasion upon which the person supplies a	A representative authorised to distribute	The nature of the dealing.	For Schedule 8 substances (controlled

must reps keep?	clinical sample, a record of the supply must be made showing: a) the date of the supply; and b) the name ,address, occupation of the person to whom the substance was supplied; c) the purpose for which the poison was supplied; and d) the name and quantity of the substance supplied. The supplier must keep these records in a book (s28 *Poisons Act*) Except in the case of the supply of a clinical sample 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. Records should also be made of the disposal of unwanted substances. Records should be kept for 2 years (r78 of the Poisons Regulations). Where a hazardous poison is supplied as a result of a written communication received by the supplier, the supplier must preserve that communication for 5 years (Schedule 29 *Poisons Act*).	samples on behalf of a company must obtain a signed request from a person authorised to receive samples, including the a) name and address of person supplied, b) name and address of the supplier, c) name, strength and quantity of the starter packs supplied. The healthcare professional must write the quantity requested and sign the request/receipt form. Immediately upon supplying the samples, an authorised representative of a company must certify that the samples have been delivered. Authorised representatives must make a record of every starter pack received or supplied together with request forms, consignment notes, invoices and advice notes. Records should be made of the return and disposal of unwanted samples. Companies must keep all records of the request, supply, return and disposal of starter packs for at least 2 years. Reconciliation of records should be carried out at least every 3 months. Records should also be made of the disposal of Schedule 8 poisons. (r7.7 Code; r108 DPCSR)	The date of the dealing. The name of the substance, and the form, strength and quantity, dealt with. The name and address and, if applicable, authorisation or licence number of the person supplied. The quantity of the substance held after the dealing. (rs52, 55 and 59 of the MPTGR NT for Schedule 8, Schedule 9 and other substances respectively). In the case of Schedule 8 and 9 substances, if the dealing was destroying the substance: the name of the person who destroyed the substance; and the name of the authorised officer who witnessed the destruction (r69, MPTGR MT) Records should be kept for 2 years (r61 of the MPTGR MT).	medicines): • The nature of the dealing. • The date of the dealing. • The name of the medicine or prohibited substance, and the form, strength and quantity, dealt with. • The name and address and, if applicable, authorisation or licence number of the person supplied. • The quantity of the substance held after the dealing (r543 of the MPTGR). The register should be kept for 2 years after the last entry in the register (s56 of the MPTGA).

	TAS	VIC	NT	ACT
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.	Loss or theft of starter packs must be reported immediately to the employer and the police (r11, Code)	Loss, or theft of a regulated substance recorded on a register must be reported to the Chief Health Officer as soon as practicable (but no later than 7 days after the person becomes aware of the loss or theft).	Loss or theft of samples must be immediately notified to the chief health officer, and also a police officer in the case of theft. The notice must be in writing no later than 7 days after becoming aware of the loss (within 24 hours in the case of theft).
Storage	Securely locked with the key either held by the representative or in a place not readily accessible to other persons. (r25 Poisons Regulations).	Where the starter packs are stored other than at a wholesaler, they must be stored in a locked storage facility in accordance with the storage conditions on the label (r7.11 Code) Starter packs must be transported and stored in a manner which maintains the storage conditions on the label (r7.10, Code) When sent by mail or courier, starter packs must be packed so as to be reasonably secure against the package being opened by young children (r7.11 Code).	Schedule 2, 3 and 4 substances to be stored in a way that prevents unauthorized access. Schedule 7 substances to be locked in a container that is securely attached to a building. Schedule 8 substances must be stored in accordance with the storage requirements specified in the Schedule 8 Code of Practice (r31 of the MPTGR NT). A delivery person must not leave the substance unattended, other than in a locked building or vehicle.	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). Schedule 8 substances must be stored in a vault that is fitted with an alarm system (r531 MPTGR).
Quantity	Not reflected in Regulations.	Samples should not exceed 1/3 of the PBS primary quantity for each strength of a product. Primary quantity means most commonly prescribed PBS quantity. For non-PBS products, samples should be no larger than 1/3 of the smallest trade pack. Where it is not practical to produce a 1/3 pack, the smallest trade pack may be used (r7.4, Code)	Not reflected in Regulations.	Not reflected in Regulations.
Disposal	Disposal of Schedule 8 substances should be carried out according to a method approved by the Department of Health and Human Services, or by any 2 health professionals working jointly to destroy the narcotic substance, or by an enrolled nurse working jointly with a health professional to destroy the narcotic (r34 Poisons Regulations).	Schedule 8 or Schedule 9 poisons can be destroyed: • by a Nurse Practitioner or Authorised Midwife in the presence of another person who is a registered Medical Practitioner, Pharmacist, Veterinary Practitioner, Dentist, Nurse or Registered Midwife, or • by a Registered Medical Practitioner, Veterinary Practitioner, Dentist or Pharmacist in the presence of another person who is a Registered Medical Practitioner, Pharmacist, Veterinary Practitioner,	The destruction of Schedule 8 substances must be witnessed by one of the following persons: (i) an authorised officer; (ii) a health practitioner; (iii) a veterinarian. (r19 of the MPTGR NT). 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 (Schedule 34(3) of the MPTGA). When discarding a Schedule 8 substance, it must be destroyed so that it is unable to be used. (r390 of the MPTGR) Controlled medicines must be discarded in the presence of certain witnesses: a) an ambulance officer; b) an approved analyst; c) Dentist d) Doctor

		Dentist, Nurse or Registered Midwife, • or, for unused contents of a previously sterile container (or unused portion of a tablet or lozenge) that are not required for administration to a patient, a Registered Medical Practitioner, Pharmacist, Veterinary Practitioner, Dentist, Nurse or Registered Midwife, and • the details of the destruction are recorded in accordance with DPCSR r115. Stock returned to the employer must be destroyed in an environmentally friendly manner (Code)		e) Medicines and Poisons Inspector f) Midwife g) Nurse However, a person otherwise authorized to witness the destruction of a controlled medicine must not act as the prescribed witness if the person is: a) related to, a close friend of or employed by the person discarding the medicine; or b) the supervisor of the person discarding the medicine; or c) supervised by the person discarding the medicine (r545 of the MPTGR). A person who is authorised to administer a controlled medicine may discard the residue of the medicine after administration in the presence of a person who is not a prescribed discarding witness if no other prescribed witness is reasonably available to witness the discarding of the medicine (r390, MPTGR)