THE LEGISLATIVE ASSEMBLY FOR
THE AUSTRALIAN CAPITAL TERRITORY

MEDICINES, POISONS AND THERAPEUTIC GOODS REGULATION 2008

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EXPLANATORY STATEMENT

Circulated by the authority of
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Medicines, Poisons and Therapeutic Goods Regulation 2008

Overview

The Medicines, Poisons and Therapeutic Goods Act 2008 (the MPTG Act) consolidated four Acts and their regulations regarding ACT law on medicines, poisons and prohibited substances. The Act repealed and replaced the *Poisons and Drugs Act 1978*, the *Poisons Act 1933,* the *Public Health (Prohibited Drugs) Act 1957* and significantly amended the *Drugs of Dependence Act 1989* to effect reforms required by the National Competition Policy Review of Drugs, Poisons and Controlled Substances legislation (Galbally Review) and to provide for a more unified and workable scheme. The Act adopts the Standard for the Uniform Scheduling of Drugs and Poisons (the SUSDP), developed by the National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* (Cwlth).

The objective of the Act, as recommended by the Galbally Review, is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse. The Act also has the purpose of ensuring that consumers of prescription and non-prescription medicines have adequate information to allow them to use medicines safely and effectively. The Act establishes an authorisation and licensing framework for medicines and poisons, as well as grounds and powers for disciplinary action to be taken against authorised and licences persons. The Act also controls the way in which medicines and poisons are dealt with through a range of offences, imposing a range of potential penalties, including the imposition of terms of imprisonment where appropriate. Enforcement of the offences is achieved through a comprehensive range of inspection and seizure powers, including the capacity to take and analyse samples.

In developing the Medicines, Poisons and Therapeutic Goods legislation an exposure draft of the Bill and Regulation was released in December 2006 and February 2007 respectively. Both were made available on the Legislation Register and forwarded to interested stakeholders. Comments were received from a number of interested bodies and considered in the further drafting of the Bill and Regulation. The Bill and Regulation have been developed to maintain, as much as possible, the status quo for health professionals in performing their duties.

The Regulation

The Medicines, Poisons and Therapeutic Goods Regulation provides the detail for the regulatory framework established by the Act. The Regulation ensures that health professionals will still be able to prescribe, administer and dispense medicines as they lawfully were able to do prior to commencement of the new legislation. The Regulation also contains the more substantive detail, specific requirements, or conditions for a range of activities and obligations contained within the Act. Some provisions of the Regulation prescribe additional information required for licences or authorisations, whereas other provisions impose statutory licence conditions. There are also provisions of the Regulation specifying requirements for activities such as labelling or packaging.

Provisions

Given the size of this Regulation, in places the sections are explained generally through an overview of the Chapter, Part or Division. Individual clauses are explained in detail, where appropriate.

Chapter 1 Preliminary

This Chapter contains the preliminary and formal provisions. Section 1 declares the name of the Regulation to be the Medicines, Poisons and Therapeutic Goods Regulation 2008. Pursuant to section 2, the Regulation will share the same commencement as the MPTG Act.

By virtue of the fact that the Act will commence on a day fixed by the Minister, by written notice, the date fixed by the Minister will essentially be the commencement date for the MPTG Act and this Regulation. The only exception is amendment 6.4 in Schedule 6 of the Regulation which will commence immediately after the MPTG Act commences.

On commencement the MPTG Act will amend the Health Professionals Regulation 2004, which includes the insertion into Schedule 11 of the Health Professionals Regulation 2004 a new Part 11.3. That new Part is to be amended by amendment 6.4 in Schedule 6 of this Regulation. Accordingly, amendment 6.4 in Schedule 6 of this Regulation cannot occur until the MPTG Act inserts the new Part 11.3 insertion into Schedule 11 of the Health Professionals Regulation 2004. It is for this reason that amendment 6.4 in Schedule 6 of this Regulation will commence immediately after the MPTG Act commences.

Sections 3 and 4 provide for the dictionary and the notes to the Regulation. Section 5 is essentially a reminder that the Criminal Code 2000 applies to offences against this Regulation, whereas section 6 provides an overview of matters to which the SUSDP does not apply.

Chapter 2 Medicines – authorisations generally

Chapter 2 addresses medicines generally, with Part 2.1 providing an overall overview of authorisations of medicines, and Part 2.2 explaining the inter-relationship with the *Health Professional Act 2004* and the MPTG legislation.

Part 2.1 Overview of medicines authorisations

Section 10 General overview of authorisations for medicines

This section reiterates that it is the MPTG Act that prohibits dealing with medicines without an authorisation, and section 20 of the MPTG Act sets out when a person is authorised to deal with a medicine.

Section 11 Overview of medicines authorisations under this regulation

Medicines authorisations under this Regulation that are specific to health-related occupations are listed in subsection 1 of this provision, as well as being connected to Schedule 1 of this Regulation. Other authorisations under this Regulation are listed in subsection 2.

Section 12 General overview of authorisation conditions for medicines

This section essentially reiterates that section 44 of the MPTG Act requires a person authorised to deal with a medicine to comply with conditions to which the authorisation is subject. The section also draws the reader's attention to the fact that conditions on authorisations are additional to other restrictions that may be placed upon a person's authorisation under the MPTG legislation.

Part 2.2 Relationship with Health Professionals Act

Section 20 Medicines authorisations subject to Health Professionals Act restrictions

Part 2.2 and section 20, which is the only provision within the Part, confirm that a health professionals authorisation under the MPTG Act to deal with a medicine is subject to any and all conditions or restrictions to which the health professional is subject under the *Health Professionals Act 2004*. Accordingly, if a health professional is not complying with the *Health Professionals Act 2004* the health professional is also not complying with the MPTG legislation.

Chapter 3 Medicines – supply authorities

This Chapter contains provisions affecting authorisations to supply medicines. The prescribing of medicines is addressed in Part 3.1, requisitioning medicines in Part 3.2, and purchase orders for medicines are addressed in Part 3.3. Standing orders for medicines, including standing orders made by the Chief Health Officer and standing orders for institutions are the subject of Part 3.4. Supply authorities generally for medicines are within the final Part for the Chapter, Part 3.5.

Part 3.1 Prescribing medicines

Division 3.1.1 Authorisation to prescribe medicines

Pursuant to section 30, persons mentioned in column 2 of Schedule 1 of this Regulation may be authorised to prescribe a medicine. Prescribing a medicine is authorised if prescribing of the medicine is amongst the authorised dealings for the person listed in column 3 of Schedule 1 in relation to that person, and the prescribing is consistent with any listed restriction in column 3 of Schedule 1.

Additionally, where the prescription is a self-prescription the person must not be a trainee dentist or intern doctor. A self-prescription for a medicine must not be a restricted medicine. For section 30 a restricted medicine is an anabolic steroid, a benzodiazepine, a controlled medicine or a designated appendix D medicine.

The rest of the Division specifies the conditions to which a prescriber's authority is subject generally, or in relation to prescriptions for human use involving controlled medicines or designated appendix D medicines.

Generally, written prescriptions need to comply with sections 40 and 41 of this Regulation. Where a prescription is faxed to a pharmacist, the prescriber must send the original to the pharmacist within 24 hours. Oral prescriptions must also comply with section 41 of this Regulation, and a written version of the prescription must be sent to the pharmacist within 24 hours.

Controlled medicines prescriptions require an approval under Part 13.1 of this Regulation. Dronabinol for human use has additional conditions. Appendix D medicines prescriptions also require an approval, which is the subject of Part 13.2 of this Regulation.

Division 3.1.2 Prescriptions

This Division details the general requirements for written prescriptions, and the particulars that must feature in a prescription. Through the operation of the dictionary in the MPTG Act something is written even when in electronic form.

The general requirements are reasonably straight forward. The prescription must be signed, and if the prescription is amended at any point the amendment needs to be initialled and dated. Prescriptions must be written in terms and symbols used ordinarily in professional practice, thereby ensuring that any other professional handling the prescription can read and interpret the prescription accurately. Critically, if the prescription is for an unusual or dangerous dose the prescriber needs to underline the reference to the dose and initial beside it. This thereby indicates to any other professional dealing with the prescription that the dose was not an error.

The standard particulars for a prescription include the prescriber's name, qualifications and business address and telephone number, the date, and the form, strength and quantity of medicine to be dispensed.

There are also some particulars that are only needed for prescriptions by certain professionals, such as dentists or optometrists. Conversely, prescriptions for an in-patient in a hospital need not contain certain particulars.

Part 3.2 Requisitioning medicines
Division 3.2.1 Authorisation to issue requisitions
Section 50 Authorisation under sch 1 to issue requisitions for medicines – Act, s 41 (b)

Pursuant to this section, persons mentioned in column 2 of Schedule 1 of this Regulation are authorised to issue a requisition for a medicine if requisitioning the medicine is included in column 3 of Schedule 1 in relation to that person, and if the issue of the requisition is consistent with any listed restriction in column 3 of Schedule 1.

Section 51 Authorisation conditions for issuing requisitions for medicines – Act, s 44 (1) (b) and (2) (b)

This section imposes a condition on a person's authorisation under section 50, and the condition depends on whether the requisition was a written or oral requisition.

Written requisitions must simply comply with sections 55 and 56 of this Regulation. An oral requisition need only comply with section 56 of this Regulation, but the person issuing the requisition must have a belief formed on reasonable grounds that the requisition is reasonably necessary for the treatment of a person(s), and the quantity requisitioned is not more than is reasonably necessary for the treatment.

Division 3.2.2 Requisitions
Section 55 General requirements for written requisitions

This section imposes just two requirements. The first is that a written requisition be signed by the person issuing the requisition. The other is if the requisition is amended at any time, for whatever reason, the issuer of the requisition initial and date along side the amendment. Through the operation of the dictionary in the MPTG Act something is written even when in electronic form.

Section 56 Particulars for requisitions

Requisitions must, under this section, contain the name of the person issuing the requisition and their capacity in which they are issuing the requisition. The date of issue must also be recorded, together with the form, strength and quantity of the medicine to be supplied on the requisition.

The pharmacy or ward to which the medicine is to be supplied must also be recorded. A ward is, according to the dictionary in the MPTG Act, an area of an institution used to accommodate or treat people, including an operating theatre and an opioid dependency treatment centre. Other areas of the hospital, such as the emergency department, would also be covered by this definition.

Part 3.3 Medicines purchase orders
Division 3.3.1 Authorisation to issue purchase order
Section 60 Authorisation under sch 1 to issue purchase orders for medicines – Act, s 38 (1) (b) and (2) (a)

Pursuant to this section, persons mentioned in column 2 of Schedule 1 of this Regulation are authorised to issue a purchase order for a medicine if issuing the purchase order is included in column 3 of Schedule 1 in relation to that person, and if the issue of the purchase order is consistent with any listed restriction in column 3 of Schedule 1.

Section 61 Authorisation conditions for issuing purchase orders for medicines – Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 60 is subject to two conditions. The first is that the purchase order issued complies with section 62 of this Regulation. The other is that the person must sign and send a document to the supplier acknowledging receipt of the medicine. This written acknowledgement must be sent not later than 24 hours after the person received the medicine.

Division 3.3.2 Purchase orders
Section 62 General requirements for medicines purchase orders – Act, s 38 (2) (c)

Purchase orders for medicines must, under this section, be signed by the person issuing the order. Furthermore, if the person issuing the purchase order amends the order at any stage, the person must record their initials and the date along side the amendment.

Subsection 2 specifies what information must be included in a purchase order for a medicine, such as the form, strength and quantity of the medicine to be supplied.

Part 3.4 Standing orders for medicines
Division 3.4.1 CHO Standing orders
Section 70 Authorisation of CHO to issue standing orders for supply of medicines in public health emergencies – Act, s 42 (b)

This provision authorises the Chief Health Officer to issue standing orders for the supply of a medicine in an emergency relating to public health. The provision also confirms that the authorisation under this section operates even if a public health emergency declaration under section 119 of the *Public Health Act 1997* is not in force.

Section 71 Authorisation of CHO to issue standing orders for administration of medicines in public health matters – Act, s 42 (b)

A standing order is, according the dictionary in the MPTG Act, a written order authorising the supply or administration of medicines as stated in the order, in stated clinical circumstances. This provision assigns the Chief Health Officer the power to issue a standing order for the administration of medicine in public health matters. This authorisation reflects the important role that the Chief Health Officer has in preventing, minimising or averting public health issues.

Section 72 Particulars for CHO orders for administration of medicines for public health matters

A standing order issued by the Chief Health Officer under section 71 of this Regulation must contain the particulars identified in this provision. Key particulars include a description of the public health matter, a description of the people to whom the medicine may be administered, the medicine and the dose and route of administration.

Division 3.4.2 Standing orders for institutions

Under this Division, a doctor, but not an intern doctor, may be authorised to issue a standing order for the administration of a medicine to patients at an institution. Under section 652 of this Regulation a correctional centre and a CYP detention place are also captured by the term institution. Such a standing order needs to be approved by a medicines and therapeutics committee for the institution, and the order needs to be signed by the chair of the committee. Section 75(2) establishes what is, for the section, a medicines and therapeutics committee.

The Division also specifies the particulars that must feature on a standing order for administration of medicines at institutions. This includes the dose and route of administration, the clinical circumstances in which the medicine may be administered, and each ward to which the order applies.

Part 3.5 Medicines supply authorities generally

Section 80 Cancellation of invalid supply authorities – Act, s 30 (2) (d)

From time to time situations may arise in which a supply authority needs to be cancelled. Section 80(1) deals with cancellations of paper-based supply authorities. The provision directs that the word "cancelled" is marked on the front of the supply authority, together with the person's name and business address. The person must also sign and date the cancellation.

Subsection 2 of the provision relates to cancellations of electronic supply authorities. In such circumstances the word "cancelled" is to be marked on the supply authority, and an electronic document containing the person's name, business address and signature is to be linked to the supply authority.

Section 81 Information for CHO about controlled medicines supplied on supply authorities – Act, s 31 (1) (b) and (4), def *required information*

Section 81 applies if a person supplies a controlled medicine on a supply authority. The section requires certain information to be given, in writing to the Chief Health Officer. The information includes the date of the supply, the name of the person to whom the medicine was supplied, and the form, strength and quantity of the medicine supplied. The information to be given to the CHO must be provided within 7 days of the end of the calendar month in which the supply took place.

This provision reflects the seriousness and level of public health concern associated with controlled medicines. The effect of the section is to enable the Chief Health Officer, through the information required to be provided, to monitor the details, such as quantities, of controlled medicines that are being supplied in the ACT.

Some persons authorised under a Commonwealth or State law to manufacture or supply controlled medicines by wholesale, are required to report to the Therapeutic Goods Administration the supply of a controlled medicine on a supply authority. Some medicine wholesalers must do the same.

The section also clarifies that persons who report such supply to the Therapeutic Goods Administration do not have to comply with this section. This recognises that to apply this section to those persons would be an unnecessary duplication of a reporting requirement and an unwarranted additional administrative burden.

Chapter 4 Supplying medicines

While Chapter 3 addresses supply authorities for medicines, other aspects of supplying medicines is addressed within Chapter 4. This includes supplying medicines though purchase orders and standing orders, supplying without prescription in emergencies and the supply of medicines for disposal.

Part 4.1 Preliminary

Section 100 Overview of supply authorisations for medicines

Supply authorisations for medicines under this Regulation are listed in this section.

Part 4.2 Medicines – supply authorisations under Sch 1

Division 4.2.1 Sch 1 medicines supply authorisations

Section 110 Authorisation under sch 1 to supply medicines – Act, s 26 (1) (b) and (2) (b)

Pursuant to this section, persons mentioned in column 2 of Schedule 1 of this Regulation are authorised to supply a medicine if the supply is included in column 3 of Schedule 1 in relation to that person, and if the supply is consistent with any listed restriction in column 3 of Schedule 1.

Division 4.2.2 Dispensing medicines

This Division governs the dispensing of medicines. As only a pharmacist may dispense medicines the requirements imposed by this Division only concern pharmacists.
The Division instructs how medicines are to be dispensed, as well as the authorisation conditions that apply to the dispensing of medicines. Section 122 in the Division specifies what must noted, in writing, on a prescription if an oral direction is given by the prescriber to change details of the prescription.

The Division also contains the requirements that must be met in regard to the labelling of dispensed medicines, the marking of dispensed prescriptions, and the details required for written records of medicines dispensed. Through the operation of the dictionary in the MPTG Act something is written even when in electronic form.

Division 4.2.3 Supplying medicines on requisitions

Authorisations to issue a requisition are addressed in section 50 of this Regulation. This Division governs the supply of medicines on requisitions.

The Division details the requirements for supply of medicines on a requisition, and the authorisation conditions that apply. The Division also contains the requirements that must be met in regard to the labelling of medicines supplied on requisition, the marking of filled requisitions, and the details required for written records of medicines supplied on requisition. Through the operation of the dictionary in the MPTG Act something is written even when in electronic form.

Division 4.2.4 Supplying medicines on purchase orders

The issue of purchase orders is addressed in Part 3.3 of this Regulation. This Division governs the supply of medicines on a purchase order. This Division details the requirements for supply of medicines on a purchase order, and the authorisation conditions that apply.

Under this Division, a person who supplies a medicine to someone else on a purchase order is required to make a written record of the supply. The information required to be kept under this provision includes the date of the order, the date the order is supplied, and the form, strength and quantity of the medicine supplied. For obvious reasons, the details of the person to whom the medicine was supplied is also required to be recorded.

Through a comparison of the record made under this section with the purchase order to which the supply relates, discrepancies and variations should be identifiable. Identification of such variances and discrepancies may enable the identification of medicines being misused, redirected or unusual supply patterns. Therefore, the keeping of such records is required from a regulatory perspective.

Under section 11 of the *Electronic Transactions Act 2001* records can be kept in an electronic format provided certain criteria can be met. Accordingly, a requirement to keep a written record is met if the record is kept in an electronic form.

Division 4.2.5 Supplying medicines on standing orders

The issue of standing orders is addressed in Part 3.4 of this Regulation. This Division governs the supply of medicines on a standing order.

The Division details the requirements for supply of medicines on a standing order, and the authorisation conditions that apply. The Division also contains the requirements that must be met in regard to the labelling of medicines supplied on a standing order and the details required for written records of medicines supplied on standing order . Through the operation of the dictionary in the MPTG Act something is written even when in electronic form.

Division 4.2.6 Supplying medicines during consultations

This Division governs the supply of medicines, such as 'sample packs', during consultations. The Division details the authorisation conditions that apply, as well as the requirements that must be met in regard to the labelling of medicines supplied during consultations, and the details required for written records of medicines supplied during a consultation.

It must be noted that under the MPTG Act, the definition of supply does not include administration of the medicine. The requirement for the appropriate supply and prescription of medicines in section 7 of the MPTG should also be noted.

Section 163 imposes additional requirements when the medicine to be supplied during a consultation is a controlled medicine for human use. First and foremost, the supplier must have a controlled medicines approval under Part 13.1, and comply with each condition of the approval. The remaining conditions apply depending on whether or not the approval under Part 13.1 was for a particular form of the medicine, a particular strength of the medicine, or a particular quantity.

Where a controlled medicine is supplied for human use during a consultation, the prescriber must give to the CHO, within 7 days of the end of the calendar month in which the supply took place, information required under section 164(2). This information includes the prescriber's name, business address and telephone number, the date of supply, and the form, strength and quantity of the medicine supplied. Critically, the name and address of the person to whom the medicine was supplied must also be recorded. Through the operation of the dictionary in the MPTG Act something is written even when in electronic form.

Division 4.2.7 Selling pseudoephedrine by retail

Pseudoephedrine-based products are legally available over the counter in pharmacies for the treatment of ailments such as colds and flu. However, a significant and growing problem within Australia is the diversion of pseudoephedrine for illegal manufacture into methamphetamines, such as 'speed' and 'ice'. Pseudoephedrine is the key chemical ingredient in the manufacture of methamphetamine.

Large quantities of Pseudoephedrine-based products are used in the illegal manufacture of methamphetamines. As the purchase of large quantities from a single source is of itself naturally suspicious and likely to be reported to law enforcement authorities, a practice referred to as "pseudo running" has resulted. "Pseudo runners" travel from pharmacy to pharmacy accumulating enough pseudoephedrine-based products to manufacture a significant quantity of methamphetamines. By spreading out purchases, the volume of pseudoephedrine-based products being purchased by a single individual becomes extremely difficult to detect.

This division requires ACT pharmacists to record sales of pseudoephedrine which will be accessible by law enforcement agencies to identify and track suspicious sales. In addition to imposing this requirement on pharmacists, the Regulation also gives pharmacists the legal authority to request and record personal information, and to refuse sales of pseudoephedrine where required information is not provided. Division 4.2.7 also specifically enable members of the public to access records relating to them, and to request corrections if necessary. This is supported by a review mechanism should the pharmacy that created the record refuse to change a record as requested by a member of the public. The review mechanism created empowers the Chief Health Officer to consider written positions from both the buyer and the seller, and to direct alterations to the record if the Chief Health Officer considers it appropriate to do so.

Section 170 Meaning of *retail sale* – div 4.2.7

This section stipulates that for Division 4.2.7 the phrase "retail sale" does not include supply on prescription.

Section 171 Authorisation conditions for retail sale of pseudoephedrine – Act, s 44 (1) (b) and (2) (b)

Under this section, a persons' authorisation to supply pseudoephedrine under section 110 of this Regulation is subject to conditions under Division 4.2.7 when sold by retail sale.

Key conditions include that the pseudoephedrine is supplied in accordance with section 7 of the MPTG Act, and that the seller complies with section 172 of this regulation. Additionally, pseudoephedrine records must be kept at the seller's business premises, unless the Chief Health Officer has given written approval for records to be kept at another place. Records must also be kept for a period of 2 years from the date the sale is made.

A further condition is that if a buyer requests to see a record pertaining to them that was made by the seller, the seller must allow the buyer to see the record within a reasonable period. It is important to note that in order to see a record made about them a buyer must attend the seller's business that made the record. A seller is under no obligation to come to the buyer. Furthermore, a buyer can only see records of sales made from that business, and a seller cannot change a record made by a different seller.

What amounts to a reasonable period is not specified by the legislation. As such, determining what a reasonable period is will be dependent upon a common understanding of the phrase applied in the individual circumstances of each situation. This approach recognises that the nature of a seller's business will limit when it is reasonable to give a buyer access to a record. It would be an unreasonable imposition upon a seller's business if a buyer were entitled to immediate access to a record. To do so would make no allowance for requests made during peak periods of trade, or shortly before the close of trade for the business.

In determining what should amount to a reasonable period for the purposes of this section, regard should also be had to the availability of the buyer to return at a more appropriate time. In most circumstances a reasonable period will be the earliest opportunity that is manageable for both the seller and the buyer. To achieve this it is possible, as well as appropriate, for the seller and buyer to agree upon a suitable time to arrange for the buyer to see the record.

Having inspected a record a buyer may, if they believe the record to be incorrect, request that the seller change the record. If the seller is satisfied that the record is incorrect, it is a condition upon the seller's authorisation under section 110 of this regulation that the seller amend the record. Possible examples could be minor spelling errors of a person's name or address. More often than not, a clear discrepancy between details on a receipt for purchase and on the record made concerning the purchase would warrant a correction of the record.

Section 172 Requirement to tell buyer about pseudoephedrine sales record

This section applies if pseudoephedrine is to be sold by retail to a customer, referred to within the sections as the buyer. The section requires that before a sale can proceed the seller must inform the buyer of certain information. Under section 172 the buyer must be informed that the seller is required to make a record of the sale, and that if the buyer refuses to, or cannot provide the required information, the seller cannot sell the customer pseudoephedrine. This requirement ensures that the customer knows that the seller is legally obligated to make a record and legally obligated not to sell pseudoephedrine unless the record is made.

Additionally, the customer must be informed that the record may be made available to a limited group of people, primarily law police officers, other pharmacists and the Chief Health Officer and his staff. Additionally, a customer must be informed that the Pharmacy Guild of Australia may also have access to the information recorded.

The Pharmacy Guild of Australia developed and administers the Project STOP database. Project STOP is a tool that pharmacies can elect to use to record sales of pseudoephedrine. However, a seller does not need to utilise the Project STOP system to comply with the requirements of this Regulation. Furthermore, this Regulation should not be read in such a way as to infer that it obligates or encourages the use of the Project STOP system. It is up to individual sellers to determine how best to comply with the requirements of this Regulation.

By informing the customer of these matters the customer is made aware of the reason behind the record being made, and also assured that the record cannot be used by any other persons or for any other reason. Finally, under subsection 1(d), the customer must be advised that they have the right to access the record and have any mistake corrected.

Section 173 Required information for pseudoephedrine sales record

The required information to be recorded is stated in section 173. Records kept in accordance with this provision must be in English and in writing. The records must also be made in such a way that the records are easily retrievable.

Under section 11 of the *Electronic Transactions Act 2001* records can be kept in an electronic format provided certain criteria can be met. Accordingly, the requirement for records to be in writing and the on-line Project STOP system are not incompatible.

Information to be recorded includes the date of sale and the brand name, dosage form and quantity of pseudoephedrine sold. Information about the buyer must also be recorded, including the buyer's name and address, the kind of identification produced and the unique identification number from the identification shown. Through the range of information collected in the record of sale enforcement authorities should be able to identify persons who make, or attempt to make, an unusually high number of purchases or quantities of pseudoephedrine.

In addition to requiring that the record of the sale include the type of identification shown, the section also prescribes what types of identification can be lawfully accepted. In doing so the section distinguishes between a *photo identification document* and a *non-photo identification document*.

The provision permits a seller to accept only two types of non-photo identification. The first is a person's birth certificate provided that it identifies the issuing jurisdiction and the date it was issued. Provided it meets these criteria birth certificates issued by any Australian State or Territory can be accepted, as can any foreign issued birth certificate. The other form of non-photo identification that can be accepted is a seniors card issued by the ACT, the Northern Territory or another Australian State.

Section 174 Failure to amend pseudoephedrine sales record

Section 174 applies if a buyer has requested a seller change a record under section 171 of this regulation and the seller has refused the request. If this situation arises, a buyer can write to the ACT Chief Health Officer asking that the Chief Health Officer direct the seller to change the record. An application to the Chief Health Officer must be in writing, and should provide as much detail and supporting evidence as the buyer is able to provide. For example, if the date of sale or quantity of pseudoephedrine purchased is disputed, the buyer should attach a copy of the sales receipt to support the application.

Having received a written application, the Chief Health Officer must give a copy of the application to the seller identified in the application. In providing a copy of the application to the seller the Chief Health Officer must ask the seller to make the amendment sought and notify the Chief Health Officer that the change has been made, or send written reasons to the Chief Health Officer stating why the amendment sought should not be made. A written response detailing why the seller believes the record should not be amended as sought should be provided to the Chief Health Officer within 10 working days.

Section 175 Pseudoephedrine sales record – decision by CHO

Under this provision the Chief Health Officer must consider an application received from the buyer and any response submitted by the seller, and then make a decision. Under section 175 the Chief Health Officer can direct the seller to change the record in accordance with the application, or refuse the application.

Crucially, the Chief Health Officer may also direct the seller to change the record in a way other than in accordance with the application. This enables the Chief Health Officer to determine that the information recorded about the sale should remain unchanged, but that a notation be added to the record that the buyer disputes all or part of the record.

This approach may be necessary where a buyer disputes the quantity purchased, or even the sale itself, but cannot provide sufficient evidence that contradicts the record. What ever the decision of the Chief Health Officer, written notice of the decision must be provided to both the seller and the buyer.

Pseudo runners may attempt to avoid detection through the use of fake or stolen identification. As a result, there is the possibility that a buyer may be able to show that they did not or could not have made a sale to which their details are recorded. In such circumstances it is possible that the buyer's identify, or an identifying document, has been stolen or reproduced by a pseudo runner. Should such a situation occur, it would be necessary for records to remain unaltered despite the provision of clear evidence by the buyer that they did not make the purchases recorded.

Division 4.2.8 Supplying pharmacist only medicines

Section 180 Authorisation conditions for supply of pharmacist only medicines - Act, s 44 (1) (b) and (2) (b)

An authorisation under section 110 of this Regulation is subject to the condition that the person personally hand the medicine to the customer who is personally in attendance, and that the customer is given adequate instructions on the medicine's use at the time of supply. The instructions provided may, under this section, be given either orally or in writing.

The only situations in which this section does not apply is in regard to the supply of pharmacist only medicine at an institution or on a supply authority.

Part 4.3 Authorisations to supply without prescription in emergencies

Part 4.3 applies to prescription only medicines other than an anabolic steroid, a designated appendix D medicines, and a benzodiazepine. Within this Part the permissible medicines are referred to as designated prescription only medicines. As controlled medicines are not considered a prescription only medicine under section 11 of the MPTG Act, this Part does not apply to controlled medicines.

This Part authorises a pharmacist to supply a designated prescription only medicine without a prescription in an emergency situation under section 251, subject to certain conditions identified in section 252. The Part also details the labelling requirements involved in the supply of medicines without a prescription in an emergency. Additionally, a pharmacist that supplies a designated prescription only medicine under section 251 of this Regulation must make a written record of the supply. Under the *Electronic Transactions Act 2001* if something is kept in an electronic form it is considered to be written.

Part 4.4 Authorisation to supply medicines for disposal

Section 260 Authorisation to supply medicines to pharmacists for disposal - Act, s 26 (1) (b)

This provision gives a generic authorisation to supply a medicine to a pharmacist so that the pharmacist may dispose of the medicine. This provision recognises the importance of enabling the proper disposal of medicines that are old, no longer needed, or for which the manufacturer's pack or labelling has been lost. The provision also recognises that surrender of a medicine for disposal to a pharmacist is supported by the Australian Government through the Return of Unwanted Medicines program.

Section 261 Authorisation to supply medicines to commercial disposal operators for disposal - Act, s 26 (1) (b)

This provision gives a generic authorisation to supply a medicine for the purposes of disposal to a person holding an environmental authorisation for the disposal of medicines, or to an adult acting on their behalf.

Like with section 260, this provision recognises the importance of enabling the proper disposal of medicines that are old, no longer needed, or for which the manufacturer's pack or labelling has been lost. The provision also recognises that surrender of a medicine for disposal to a commercial disposal operator is more desirable than the medicine ended up in landfill or in waste water.

Part 4.5 Wholesale supply of medicines under corresponding laws

This Part contains only one section; section 270. This provision imposes conditions upon persons who supply medicines by wholesale under corresponding laws. A key condition is that the person, and all of their employees and agents, comply with the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use, and the Medicines Australia Code of Conduct.

The Part also requires that a medicine in the person's possession is stored within the storage temperature range for the medicine recommended by the manufacturer of the medicine. Certain medicines may become ineffective or possibly even harmful if they exceed or fall below a particular temperature range. Compliance with any other environmental condition that is necessary to preserve the stability and therapeutic quality of a medicine is also required. Such a condition could be a simple as keep out sunlight or storage in a dry location. Nevertheless, as failure to observe such a condition could possibly make the medicine harmful or reduce the medicine's therapeutic quality, it is critical that such conditions are observed.

The section also directs that sample packs of controlled medicines must not be supplied. Also, a medicine must not be supplied to another person unless that person is authorised to possess the medicines and the supply conforms with section 140 of this Regulation.

Chapter 5 Administering medicines

This Chapter provides for the administration of medicines by certain persons. Part 5.1 addresses persons in health-related occupations. Part 5.2 enables some persons, in limited circumstances, to administer medicines themselves. These limited sets of circumstances covers the administration of the medicine by the person to themself, to an animal to which they are in charge, or to assist another person administer a medicine to themself.

Part 5.1 Authorisations for health-related occupations

Section 350 Authorisation under sch 1 for people in health-related occupations to administer medicines - Act, s 37 (1) (b) and (3) (b)

Pursuant to this section, persons mentioned in column 2 of Schedule 1 of this Regulation may be authorised to administer a medicine. Administering a medicine is authorised if administration is amongst the authorised dealings for the person listed in column 3 of Schedule 1 in relation to that person, and if administration of the medicine is consistent with any listed restriction in column 3 of Schedule 1.

A person who administers a medicine who is not authorised to do so may have breached section 37(1) or section 37(3) of the MPTG Act. Similarly, a person who is authorised to obtain a medicine by Schedule 1, but does not comply with a restriction to which the authorisation is subject, may also have breached the MPTG Act.

Section 351 Authorisation conditions for administration of medicines at institutions by people in health-related occupations - Act, s 44 (1) (b) and (2) (b)

An authorisation under section 350 is subject to the conditions imposed by this provision. Where the medicine is administered under a standing order to a patient at an institution, the administration must be recorded in the patient's medical records (eg medication chart). In this provision an institution includes correctional centres and CYP detention places.

For controlled medicines to be administered to a patient at an institution there are further conditions. In this scenario the medicine is not to be removed from a storage receptacle until immediately before it is administered. The administration must be witnessed by another person, preferably by a prescribed witness. Finally, the administration must be recorded in the patient's medical records and the applicable controlled medicines register as per the requirements in section 543 of this Regulation.

The only exception to the recording of the administration in a controlled medicines register is when the medicine was administered from a dose administration aid dispensed for the patient at a residential aged care or residential disability care facility, or to a detainee at a correctional centre or CYP detention place.

Part 5.2 Other administration authorisations

Section 360 Authorisation for self-administration etc of medicines - Act, s 37 (2) (b) and (3) (b)

Section 360 is limited to situations where the medicine was obtained from someone who is authorised to supply the medicine. If the medicine was improperly obtained, specifically having been supplied by a person who is not authorised to supply a medicine, this section would not make the use of that medicine lawful.

Subsection 2 sets out four situations in which a person will be authorised to administer a medicine themselves. The first two situations covered permit a person who is a prescriber, being a person authorised to prescribe, to self administer. For medicines, other than a restricted medicine, it is permissible for a prescriber to self administer. For restricted medicines, defined in section 30 of this regulation, a prescriber may also self administer provided that the medicine has been prescribed or supplied by another person who is authorised to prescribe, with the exception of a trainee dentist, intern doctor, related person or employee.

Some of the persons to whom the exception applies are selected as their level of knowledge, experience, qualification or certification, are such that they may not adequately question the appropriateness of the supply of the medicine. Persons related to or employed by the prescriber are selected as their relationship may make them susceptible to pressure or influence by the other person.

Not surprisingly, the section permits a person who is not a prescriber, which will cover most people, to self administer a medicine provided it has been supplied to that person for their own use. Similarly, a person who is the custodian of an animal may administer a medicine to that animal if the medicine was supplied for that animal's use.

The definition of custodian in the dictionary covers the lawful owner of the animal, or where the parent or guardian of the lawful owner. However, the definition would also cover persons who have lawful custody of an animal, thereby extending to dog catchers, the RSPCA, refuge shelters, kennels, canneries and stables.

Section 361 Authorisation for administration of medicines by assistants - Act, s 37 (1) (b)

The effect of this provision is to authorise persons to administer a medicine to someone else. This is permissible if the person being assisted asks for assistance in taking the medicine. This could arise if the person is in a distressed state, or if the person simply needs assistance due to their age or a physical impairment. It is also permissible in situations where the person needing the medicine is under a legal disability, and the assistance is authorised by the person's parents or guardians. This scenario could arise at a child care centre, where the parent's have given the centre permission to administer a particular medicine should the need arise.

Whatever the situation, the provision requires that the medicine has been obtained by the person to be assisted, or by someone authorised to supply that person, such as a parent. Furthermore, the medicine must only be administered in accordance with the directions on the medicine's label.

The section provides instruction on who is considered a person under a legal disability, which includes persons with impaired decision-making ability. Impaired decision-making ability is also defined in the section.

Chapter 6 Obtaining and possessing medicines

The MPTG Act contains a number of offences for obtaining or being in possession of certain medicines without lawful authority. Section 35(1) of the MPTG Act contains an offence for obtaining a declared substance without authorisation to do so. Similarly, under section 35(2) of the MPTG Act a person who obtains a declared substance when they are not authorisation to obtain such a substance also commits an offence. To be in possession of a declared substance without an authority to possess that substance is an offence pursuant to section 36 of the MPTG Act.

What constitutes a declared substance is explained by the MPTG Act. The purpose of this Chapter of the Regulation, in conjunction with Schedule 1 of the Regulation, is to establish the persons who are authorised to obtain or possess such medicines and substances.

Section 370 Authorisation under sch 1 to obtain and possess medicines - Act, s 35 (1) (b), (2) (b) and s 36 (b)

Pursuant to this section, persons mentioned in column 2 of Schedule 1 of this Regulation may be authorised to obtain a medicine. Obtaining a medicine is authorised if obtaining the medicine is amongst the authorised dealings for the person listed in column 3 of Schedule 1 in relation to that person, and if the medicine was obtained in a way that is consistent with any listed restriction in column 3 of Schedule 1. A person who obtains a medicine who is not assigned the authority to do so by Schedule 1 may have breached section 35(1) of the MPTG Act. Similarly, a person who is authorised to obtain a medicine by Schedule 1, but does not comply with a restriction to which the authorisation is subject, may also have breached section 35(1) of the MPTG Act.

Section 371 Authorisation to obtain and possess medicines for certain personal use-related dealings - Act, s 35 (1) (b), (2) (b) and s 36 (b)

The effect of this provision is to authorise persons to obtain medicines if the medicine is to be used for their own personal use. Similarly, this section authorises a person to obtain a medicine as agent for another person, in circumstances where the medicine is for the personal use of that other person. Pursuant to subsection 1 of this provision, this authorisation is conditional upon the medicine being obtained from a person who authorised to supply the medicine.

It is this section that prevents a person filling a prescription at a pharmacist, either for themselves or for a family member, from committing an offence against section 35 or section 36 of the MPTG Act. However, even if the medicine obtained is for personal use, if the medicine is not supplied by someone authorised to do so, obtaining or possessing the medicine may still constitute an offence.

Chapter 7 Manufacturing medicines

Section 33 of the MPTG Act contains an offence for manufacturing a regulated substance without authorisation to do so. This Chapter, in conjunction with Schedule 1 of this Regulation, assigns authority to manufacture to certain specified health related occupations.

Section 380 Authorisation under sch 1 to manufacture medicines - Act, s 33 (b)

Pursuant to this section, persons mentioned in column 2 of Schedule 1 of this Regulation may be authorised to manufacture a medicine. If manufacturing a medicine is amongst the authorised dealings for the person listed in column 3 of Schedule 1 in relation to that person, and if the manufacture is consistent with any listed restriction for the manufacturing, then the person is duly authorised. A person who manufactures a medicine who is not assigned the authority to manufacture by Schedule 1 may have breached section 33 of the MPTG Act. Similarly, a person who is authorised to manufacture by Schedule 1, but does not comply with a restriction to which the authorisation is subject may also have breached section 33 of the MPTG Act.

Chapter 8 Discarding medicines

This Chapter governs the discarding, and thereby disposal, of medicines. It details what constitutes the proper disposal of a medicine, but also addresses the discarding of residues of medicines by persons who have administered the medicine for their own use.

Section 390 Discarding controlled medicines – Act, s 34 (1) (a)

The disposal of a controlled medicine may only be handled by a select category of persons, referred to within the MPTG legislation as prescribed discarding witnesses. Under section 545 of this Regulation, a prescribed discarding witness includes, amongst others, persons as doctors, nurses, pharmacists, dentists and medicines and poisons inspectors.

This section establishes that a controlled medicine must only be disposed of by a prescribed discarding witness and in the presence of another prescribed discarding witness. However, an exception to this rule exists in circumstances where a controlled medicine has been administered by a person who is both authorised to administer and a prescribed discarding witness. In this limited set of circumstances, if another prescribed discarding witness is not reasonably available then the person administering the medicine may discard the residue in the presence of an ordinary person. It is important to note that this exception is limited to the discarding of the residue of a controlled medicine.

For example, if a controlled medicine has just been administered to a patient by a doctor, the doctor may discard the residue of the medicine with the patient as the witness, without the need for another doctor or a nurse to be present. However, if a pharmacist were disposing of old or damaged stock of a controlled medicine that pharmacist will require another prescribed discarding witness to verify the disposal of the medicines.

The discarding of a medicine under this section is taken to have been properly and validly performed if the medicine is destroyed so that it is unable to be used. The disposal of seized substances is more onerous and tightly controlled than this section, and is governed by Division 11.4 of the *Drugs of Dependence Act 1989*.

Chapter 9 Other medicines authorisations

This Chapter provides for a number of specific and limited authorisations in regard to medicines for a range of persons not addressed in other Chapters.

Part 9.1 Authorisations for delivery people and commercial disposal operators

Part 9.1 gives authorisations to delivery people and commercial disposal operators so that the handling of medicines by such persons in the ordinary course of their employment is authorised and lawful under the MPTG legislation.

Part 9.2 Emergency supply and administration of adrenaline and salbutamol

Part 9.2 contains one section; section 410. That provision authorises the supply and administration of adrenaline or salbutamol in emergencies.

Through the operation of section 410, if a person is in urgent need of salbutamol another person may lawfully supply salbutamol in a metered inhaler to the person requiring assistance. If the person in need of assistance cannot administer the salbutamol themselves, or will require assistance to administer the salbutamol, a person may administer the salbutamol to the ailing person or supply the salbutamol to a third person who will administer the salbutamol to the ailing person. In each instance the salbutamol delivered through the use of a metered inhaler.

The same section enables a person to supply adrenaline to a person in need of assistance. The provision also operates to permit a person to administer adrenaline directly to the person needing assistance through the use of a single use automatic injector that delivers no more than 0.3 miligrams of adrenaline, or to supply adrenaline to a third person who will administer adrenaline directly to the person needing assistance, also through the use of a single use automatic injector.

Part 9.3 Medicines authorisations for corrections functions

Part 9.3 gives authorisations for persons working within corrections facilities, and ensures such persons do not breach the MPTG legislation through the ordinary course of their employment.

Part 9.4 Authorisations for medicines research and education program purposes other than controlled medicines

The provisions in Part 9.4 give authorisations for medicines, other than controlled medicines, for research and education program purposes. The provisions in this Part enable scientifically qualified persons employed at a recognised research institution to handle medicines without contravening the MPTG legislation. For controlled medicines, Research and education programs will require a licence under Chapter 14.

A scientifically qualified person is, according to the dictionary in this Regulation, a dentist, doctor, pharmacist or veterinary surgeon, excluding trainees and interns. A person who has been awarded a doctorate for scientific studies is also considered a scientifically qualified person.

Section 20(5) of the MPTG Act lists recognised research institutions, which include the University of Canberra, the ANU, the Canberra Hospital, the CSIRO, or any other entity prescribed by this Regulation.

Part 9.5 Authorisations under medicines licences

Division 9.5.1 Controlled medicines research and education program licence authorisations

The governance structure for the issuing of controlled medicines research and education programs licences is contained in Part 14.2 of this Regulation. This Division establishes what is authorised by a licence issued under Part 14.2. Section 440 authorises a licence-holder to obtain and possess a controlled medicine at the premises to which the licence relates, as well as to supply the controlled medicine to anyone taking part in the program for the purposes of the program. Furthermore, the program supervisor and anyone taking part in the program is authorised to deal with the medicines stated on the licence, provided the dealing is in accordance with the terms of the licence.

Controlled medicines research and education programs at the Canberra Hospital are also authorised to issue written requisitions for the controlled medicines, whereas programs at other locations are authorised to issue a purchase order for the controlled medicine.

Controlled medicines research and education programs at the Canberra Hospital are under the authorisation condition that a controlled medicine is obtained under a requisition that complies with sections 55 and 56 of this Regulation. Programs at other locations are subject to the condition that the medicine is purchased on a complying purchase order. For a medicine a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 62.

Division 9.5.2 First-aid kit licence authorisations

The governance structure for the issuing of first-aid kit licences is contained in Part 14.3 of this Regulation. This Division establishes what is authorised by a licence issued under Part 14.3. Section 450(2) authorises a licence-holder to issue purchase orders, and obtain on a purchase order, medicines deemed to be *authorised medicines* under subsection 1. The authorisation to obtain a medicine under this Division is subject to the condition that the medicine is purchased on a complying purchase order. For a medicine a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 62.

In this section, *authorised medicines* are medicines identified in the licence for the first-aid kit as well as pharmacy medicines and pharmacist only medicines for the first-aid kit.

The licence-holder is also authorised to possess authorised medicines as part of the first-aid kit where it is for the emergency treatment of a person's medical condition. The licence-holder is also authorised to administer the authorised medicines if they reasonably believe that this is necessary for the emergency treatment of the person's medical condition.

Division 9.5.3 Wholesalers licence authorisations

The governance structure for the issuing of wholesalers licences is contained in Part 14.4 of this Regulation. This Division establishes what is authorised by a licence issued under Part 14.4. Section 460 authorises a licence-holder to do a variety of things from the premises stated on the licence, including issue purchase orders for medicines stated on the licence, obtain those medicines on a purchase order for the purposes of sale by wholesale, and to possess at the premises the licensed medicines.

Of particular importance for a wholesalers licence, the Division authorises the sale of medicines by wholesale, from the premises stated on the licence, to a person that is authorised to issue a purchase order for the medicine. Furthermore, the licence-holder is authorised to sell by wholesale to a person in another jurisdiction, including overseas, provided that person is lawfully able to obtain the medicine by wholesale.

It should be noted that the authorisations under this Division apply to all wholesaler's licences, unless a licence expressly states that a particular type of dealing is not authorised. In effect, this means that the terms of an issued licence can overrule or contradict the authorisations in this Division. For example, a licence could be issued that states the licensee is not authorised to supply by wholesale to a person in another country. Supply by wholesale to a person in another country will also be prevented if the medicine to which the licence relates is a prohibited export under the Commonwealth *Customs Act 1901*. In such circumstances the authorisation to supply to a person in another country does not apply.

The authorisation to obtain a medicine under this Division is also subject to the condition that the medicine is purchased on a complying purchase order. For a medicine a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 62. Additionally, a medicine may only be sold under a wholesaler's licence on a complying purchase order.

It is also a condition on the authorisation that the licence-holder, and all employees and agents of the licence-holder, comply the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use, and the Medicines Australia Code of Conduct (eg the latter, mentioned in section 460(e), applies to the supply of sample packs).

Division 9.5.4 Opioid dependency treatment licence authorisations

The governance structure for the issuing of opioid dependency treatment licences is contained in Part 14.5 of this Regulation. This Division establishes what is authorised by a licence issued under Part 14.5. The only medicines to which an opioid dependency treatment licence relates are buprenorphine and methadone for the treatment of a person's drug dependency.

Section 470 authorises a licence-holder, and any other pharmacist at the pharmacy to which the licence relates, to issue purchase orders, obtain on a purchase order, possess, and dispense or administer in accordance with a prescription. It is also permissible to supply to a nurse at the licensed pharmacy for administration under the supervision of a pharmacist.

The authorisation to obtain a medicine under this Division is subject to the condition that the buprenorphine or methadone is purchased on a complying purchase order. For a medicine a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 62.

It is also a condition on the authorisation that a person to whom buprenorphine or methadone is administered sign a written acknowledgement that reflects the approved name or brand name of the medicine administered, the date it was administered, and the form, strength and quantity of the medicine administered.

Division 9.5.5 Pharmacy medicines rural communities licences

The governance structure for the issuing of pharmacy medicines rural communities licences is contained in Part 14.6 of this Regulation. This Division establishes what is authorised by a licence issued under Part 14.6. Section 480 authorises a licence-holder to issue purchase orders for pharmacy medicines stated on the licence, obtain those medicines on a purchase order, and to possess at the retail premises and sell by retail those same medicines.

This Division also authorises an employee of the licence-holder to possess the medicines at the retail premises and sell by retail the medicines. This recognises the commercial practicalities as it should not be expected that the licence-holder will be present at the place of business at all times on each occasion that the business is trading.

It should be noted that the wording of the authorisation only permits medicines stated on the licence to be sold to customers attending the business premises. This thereby prevents sales over the internet or by mail order under the licence. This is further reinforced by an authorisation condition to the same effect.

The authorisation to obtain a medicine under this Division is subject to the condition that the medicine is purchased on a complying purchase order. For a medicine a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 62.

It is also a condition on the authorisation that pharmacy medicines to which the licence relates are sold in manufacturer's packs and are labelled either in accordance with section 502 of this Regulation or pursuant to an approval under section 193 of the MPTG Act.

Chapter 10 Packaging and labelling of medicines generally

General requirements for the packaging and labelling of medicines are set out within Chapter 10.

Section 500 When pharmacy medicines and pharmacist only medicines to be supplied in manufacturer's packs - Act, s 59 (1) (c) (i) and (2) (c) (i)

This provision establishes that a health professional, or an employee acting under their direction, must only supply a pharmacy medicine or pharmacist only medicine in a whole manufacturer's pack. For this section, supply does not include dispensing. The meaning of a *manufacturer's pack* is provided in the dictionary in this Regulation.

This requirement does not apply to pharmacists and intern pharmacists at a hospital, and prescribers supplying a medicine during a consultation. For the purposes of this section these persons are not treated as health professionals.

Section 600(e) of this Regulation enables a licence to be issued to a person who is not a pharmacist to sell, by retail, pharmacy medicines. Such licences were primarily contemplated to avoid disadvantaging rural communities that are without a local pharmacist by providing another mechanism whereby pharmacist only medicines could be made available for retail sale to the community. Accordingly, such licences are referred to as a pharmacy medicines rural communities licence. Under section 500(3), a pharmacy medicines rural licence-holder, and employees acting under their direction, can only sell pharmacy medicines in a whole manufacturers pack.

Section 501 Packaging of supplied manufacturer's packs of medicines - Act, s 59 (1) (c) (i) and (2) (c) (i)

The packaging requirements of a manufacturer's pack of a medicine is set out in this section. Manufacturer's pack can be packaged in accordance with paragraphs 21 through to 27 of the SUSDP. Manufacturer's pack may also be packaged in a container approved under section 193 of the MPTG or in a container in which the medicine may be sold under a corresponding law.

Section 502 Labelling of supplied manufacturer's packs of medicines - Act, s 60 (1) (c) (i) and (2) (c) (i)

A manufacturer's pack of a supplied medicine must, under this section, be labelled in accordance with paragraphs 3 through to 19 of the SUSDP, section 193 of the MPTG Act or a corresponding law. However, under this section supply of a medicine is not extended to include dispensing of a medicine or supplying a medicine on a requisition or standing order.

Additionally, a label featuring the pharmacy's name, business address and phone number must be affixed to a manufacturer's packs of a pharmacist only medicine sold by retail at a community pharmacy. Similarly, a label featuring the licence-holder's name, business address and phone number must be affixed to a manufacturer's packs of a pharmacy medicine sold by a pharmacy medicines rural communities licence-holder.

Such labels ensure the contact details of the supplier are readily accessible should the person taking the medicine, or someone else assisting that person, have any questions or concerns about the medicine. This case be critically important should an adverse reaction or misadventure associated with the medicine occur.

Chapter 11 Storage of medicines

The correct, safe and appropriate storage of medicines is the focus of Chapter 11 of this regulation. The Chapter is divided into four Parts, the first containing only meanings of terms used throughout the Chapter, and the second Part setting out general storage requirements for medicines. Additional storage requirements for medicines, other than controlled medicines, are within Part 3 whereas specific storage requirement for controlled medicines are in the fourth Part.

Part 11.1 Preliminary

Section 510 Meaning of *prescribed person* – ch 11

This provision sets out who is, for the purposes of Chapter 11, a prescribed person. Included are certain health professionals such as doctors, dentists and podiatrists. However, the listed persons also extends to persons in charge of correctional centres, and to persons in charge of a residential aged care facility, or a disability care facility, where such a facility is without a pharmacy.

A controlled medicines research and education program licence-holder is also considered a prescribed person. Controlled medicines research and education program licences are the subject of Part 14.2 of this Regulation.

Section 511 Meaning of *key* – ch 11

Within Chapter 11, in addition to its ordinary meaning, a *key* includes an electronic swipe card or an electronic proximity device. This is a reflection on increasing prevalence in the community of such technology.

Part 11.2 Storage requirements for medicines generally

Section 515 Storage of medicines generally – Act, s 61 (b) and (c)

Section 515 operates to impose a duty upon a prescribed person to ensure that a medicine in the person's possession is stored within the storage temperature range for the medicine recommended by the manufacturer of the medicine. Certain medicines may become ineffective or possibly even harmful if they exceed or fall below a particular temperature range. The section also requires the prescribed person to ensure compliance with any other environmental condition that is necessary to preserve the stability and therapeutic quality of a medicine in the person's possession. Such a condition could be a simple as keep out sunlight or storage in a dry location. Nevertheless, as failure to observe such a condition could possibly make the medicine harmful or reduce the medicine's therapeutic quality, it is critical that such conditions are observed.

Where the prescribed person is a person listed in section 510(i), the duty to ensure the medicine is stored as required by section 515(1) does not apply if that person does not have control over the disposition of the medicine. This recognises that for the persons listed in section 510(i), although they are in charge of a particular facility or workplace, there may be medicines present for which they have no control.

Part 11.3 Additional storage requirements for medicines other than controlled medicines

Section 520 Storage of medicines other than controlled medicines in community pharmacies – Act, s 61 (b) and (c)

This provision imposes an obligations upon the pharmacist responsible for the management of a community pharmacy in regard to the storage of pharmacy medicines, under subsection 1, and pharmacist only medicines under subsection 2.

The first subsection requires the pharmacist to ensure that pharmacy medicines for retail sale are stored within 4 metres of, and within sight of, the pharmacy's dispensary. The practical application of this requirement will vary for each pharmacy subject to the pharmacy's overall size, and the size of the dispensary at the pharmacy.

The requirement that the medicine be stored within sight of the dispensary should not be interpreted narrowly. It would be commercially impractical to expect that all medicines would be stored in such a way as to be in sight of all areas of the dispensary at all times. It is to be expected, and permissible, for medicines to be stored on a shelf that is visible from one side of the dispensary but not the other. Similarly, there will be medicines that from time to time are not within sight of the dispensary, temporarily, because of the presence of an obstruction, most probably a customer. However, area of a pharmacy that are never visible from the dispensary, or are usually out of sight of the dispensary, should not be used to store a pharmacy medicine. Such areas of floor space are best utilised for products not regulated by the MPTG legislation.

Pharmacy medicines that are not for retail sale, which may include stock in storage that will eventually become available for retail sale, must be stored in such a manner as to restrict public access to the medicines.

Stricter storage requirements for pharmacist only medicines and prescription medicines are imposed by the second subsection. Such medicines must be stored in a part of the pharmacy premises to which the public does not have access. Additionally, such medicines must be stored so that only a pharmacist, or a person under the direct supervision of a pharmacist, has access to the medicine. It should be noted that a pharmacist does not include an intern pharmacist, thereby meaning that an intern pharmacist should only access such medicines when under the direct supervision of a pharmacist.

Section 521 Storage of medicines other than controlled medicines by other people – Act, s 61 (b) and (c)

Under this provision a prescribed person as defined by section 510 must ensure that medicines in their possession, other than controlled medicines, are stored so that public access to the medicine is restricted. The only category of prescribed persons exempted from this requirement is pharmacists responsible for the management of a community pharmacy, who are subject to the storage requirements imposed by section 520.

Where the prescribed person is a person listed in section 510(i), the duty to ensure the medicine is stored as required by section 515(1) does not apply if that person does not have control over the disposition of the medicine. This recognises that for the persons listed in section 510(i), although they are in charge of a particular facility or workplace, there may be medicines present for which they have no control.

Section 522 Storage of pharmacy medicines by pharmacy medicines rural communities licence-holders – Act, s 61 (b) and (c)

Section 600(e) of this Regulation enables a licence to be issued to a person who is not a pharmacist to sell, by retail, pharmacy medicines. Such licences were primarily contemplated to avoid disadvantaging rural communities that are without a local pharmacist by providing another mechanism whereby pharmacist only medicines could be made available for retail sale to the community. Accordingly, such licences are referred to as a pharmacy medicines rural communities licence.

An obligation is imposed by this provision on the holder of a pharmacy medicines rural communities licence to store a pharmacy medicine, for retail sale, in such a way as to ensure public access to the medicine is restricted.

Part 11.4 Additional storage requirements for controlled medicines

Section 530 Meaning of *personal custody* – pt 11.4

In addition to its ordinary meaning, for Part 11.4 *personal custody* includes, by virtue of this section, keeping a key in a combination-operated key safe, provided the person keeps the combination confidential.

Where the prescribed person is a person listed in section 510(i), the duty to ensure the medicine is stored as required by section 515(1) does not apply if that person does not have control over the disposition of the medicine. This recognises that for the persons listed in section 510(i), although they are in charge of a particular facility or workplace, there may be medicines present for which they have no control.

Section 531 Storage of controlled medicines by wholesalers licence-holders – Act, s 61 (b) and (c)

Controlled medicines in the possession of a wholesalers licence-holder must, unless required for immediate supply, be stored in a vault. Furthermore, such a vault must meet or better the requirements for a vault set out in Schedule 5, section 5.8 of this Regulation, and be fitted with an alarm system.

These strict security requirements reflect the elevated security concern posed by the quantities of a controlled medicine that a wholesaler's licence-holder is likely to possess.

If the total quantity of controlled medicines held by the licence-holder at any time is not large enough to merit storage in a vault, the approval of the Chief Health Officer can be sought to instead store the controlled medicines in a safe or strong room. Should the Chief Health Officer give approval under this section, that approval must be given in writing.

If the Chief Health Officer approves the use of a safe, the safe must meet or better the requirements set out for a safe in Schedule 5, section 5.6 of this Regulation, and be fitted with an alarm system.

If the Chief Health Officer approves the use of a strong room, the strong room must meet or better the requirements set out for a strong room in Schedule 5, section 5.7 of this Regulation, and be fitted with an alarm system.

Section 532 Storage of controlled medicines for certain health-related occupations – Act, s 61 (b) and (c)

Controlled medicines in the possession of a designated person must be stored by designated persons in either a locked container that is securely attached to a building and prevents ready access to the container's contents, or is a locked drawer, cupboard, room or vehicle. If such a container is unlocked through the usage of a combination lock, the designated person must keep the combination confidential. Where such a container is unlocked using a key, which by virtue of section 511 includes an electronic swipe card or proximity card, the designated person must keep personal custody of the key.

If a designated person keeps the medicine in a drawer, cupboard, room or vehicle, the designated person must keep personal custody of the key that would enable access to the medicine. Once again, the operation of section 511 extends the meaning of key to include an electronic swipe card or proximity card.

The only situation in which these storage requirements do not apply is where the controlled medicine is being carried by the designated person in a first-aid kit that is locked, or unlocked because it is in immediate use. Even then, is mandatory that the designated person keep personal custody of the key to the first-aid kit.

In addition to its ordinary meaning, for Part 11.4 *personal custody* includes, by virtue of section 530, keeping a key in a combination-operated key safe, provided the person keeps the combination confidential.

In section 531, a designated person includes a dentist, doctor, or veterinary surgeon, save for such a person at an institution. As the definitions of a dentist, doctor and veterinary surgeon in this Regulation do not include trainees or interns, this section does not authorise a trainee or intern to have a controlled medicine in a first-aid kit.

A first-aid kit licence-holder is also a designated person under this section. First-aid kits licences are obtained under Division 9.5.2 of this Regulation, and enables the licence-holder to posses certain medicines and purchase medicines through a purchase order. Such a licence also allows, in certain situations and subject to certain conditions, the supply or even administering of medicines.

The third category of *designated persons* is ambulance officers employed by a State, Territory or the Commonwealth. As such, ambulance officers of private companies and not employed by a State, Territory or the Commonwealth are not *designated persons* under this section, and will only be regarded as designated person if they possess a first-aid kit licence.

Section 533 Storage of controlled medicines by certain other prescribed people – Act, s 61 (b) and (c)

Persons to which this section applies must ensure that controlled medicines are stored in a storage receptacle, which includes medicines cabinets, safes, strong rooms and vaults. Which ever storage receptacle is used, it must meet or better the requirements for that storage receptacle set out in Schedule 5 of this Regulation.

Furthermore, persons to which this section applies must keep the storage receptacle securely locked when not in immediate use. If such a storage receptacle is unlocked through the usage of a combination lock, the person must keep the combination confidential. Where such a container is unlocked using a key, which by virtue of section 511 includes an electronic swipe card or proximity card, the person must keep personal custody of the key.

Where the person to which this section applies is the chief pharmacist at an institution, the storage receptacle must also be fitted with an alarm system.

Section 533 applies to persons listed in section 510 as prescribed persons, unless excluded, if they are in possession of a controlled medicine, unless that possession is for the immediate administration of the controlled medicine.

Persons excluded from the application of this section are dentists, doctors and veterinary surgeons at an institution in recognition that others, such as the person in charge of a ward, carry the responsibility for storage under this section. In situations where the controlled medicine is dispensed in a dose administration aid, possession of the controlled medicine by the person in charge of a residential aged care or residential disability care facility are also excluded, as too are the persons in charge of a correctional centre or CYP detention place. In this regulation a CYP detention place is a detention place under the ACT *Children and Young People Act 2008*.

Section 533 also does not apply to a prescribed person listed in section 510(i) if the person does not have control over the disposition of the medicine.

Chapter 12 Controlled medicines registers

Section 540 Keeping of controlled medicines registers by certain people – Act, s 48 (a) and s 50 (1) (b) and (2) (b)

Within this provision is Table 540 that lists, in column 2, prescribed persons who must keep a controlled medicines register for all controlled medicines in their possession. Column 3 of the same table specifies where the register is to be kept.

Section 540 also contains several exceptions to the requirement to keep a controlled medicines register for a controlled medicine in the person's possession. The first exception is for a controlled medicine in a first-aid kit. This is because section 541 addresses the keeping of controlled medicines registers for first-aid kit holders.

The remaining exceptions relate to a controlled medicine dispensed in a dose administration aid, and apply to persons in charge of residential aged care facilities, residential disability care facilities, correction centres and detention places under the *Children and Young People Act 2008*.

Table 540 does not include pharmacists. Instead, subsection 4 of the provision requires a pharmacist responsible for the management of a community pharmacy at which controlled medicines are kept to keep a controlled medicines register. Inclusion of pharmacists in Table 540 is not necessary as section 48 of the MPTG Act already requires a controlled medicines register to be kept for a community pharmacy.

Section 541 Keeping of controlled medicines registers by first-aid kit holders – Act, s 48 (a) and s 50 (1) (b) and (2) (b)

In this Regulation, a bag or container of medicines and other medical supplies kept by a person for the purposes of health care or emergency treatment is a first-aid kit.

Some first-aid kits possessed by dentists, doctors, veterinary surgeons, or ambulance officers employed by a State, Territory or the Commonwealth, include controlled medicines. Where this is the case, this provision requires that a controlled medicines register be kept with the first-aid kit.

It is also possible to obtain a first-aid kit licence under Division 9.5.2 of this Regulation. A first-aid kit licence enables the licence-holder to posses certain medicines and purchase medicines through a purchase order. Such a licence also allows, in certain situation and subject to certain conditions, the supply or even administering of medicines. If a first-aid kit possessed by a first-aid kit licence-holder contains controlled medicine, the licence-holder also is required by this section to keep a controlled medicines register with the first-aid kit.

As the definitions of a dentist, doctor and veterinary surgeon in this Regulation do not include trainees or interns, this section does not authorise a trainee or intern to have a controlled medicine in a first-aid kit. Similarly, ambulance officers of private companies and not employed by a State, Territory or the Commonwealth are not authorised by virtue of their employment to have a first-aid kit containing a controlled medicine. To lawfully have a controlled medicine in a first-aid kit, any of these persons would need to possess a first-aid kit licence authorising possession of a controlled medicine.

Section 542 Form of controlled medicines registers – Act, s 49 (1) (b) and (2) (b)

Under this section, each page in a controlled medicines register must relate to a single form and strength of a controlled medicine. This means that if a single controlled medicine were possessed, but in different sized ampoules, each ampoule size requires its own page in the register.

Where a controlled medicines register is kept electronically, which is permissible, a separate record must be used for each form and strength of controlled medicine kept.

Section 543 Making entries in controlled medicines registers – Act, s 51 (1) (b)

Under section 51 of the MPTG Act a person who must keep a register for a regulated substance commits an offence unless that person ensures that the details prescribed by this Regulation are recorded.

In regard to a controlled medicine, the details required to be record under section 51 of the MPTG Act are listed in this provision. Amongst the details for dealing with a controlled medicine that must be recorded are the nature of the dealing itself, the date of the dealing, and the form, strength and quantity of the medicine dealt with, and the quantity of the medicine held following the dealing.

Details to be recorded under section 540(1)(d) and (e) apply only if the dealing is supplying the medicine. The details to be recorded under section 540(1)(f) apply if the dealing is supplying the medicine on prescription. If the dealing is supplying the medicine on a requisition, paragraph (g) of section 540(1) applies, and if the dealing is supplying the medicine on a purchase order, it is paragraph (h) that applies.

It is should also be noted that if section 53 of the MPTG Act applies to the dealing being recorded in the register, paragraph (i) states that the name of the person to whom the medicine is administered must also be recorded. The only situations in which paragraph (i) does not apply is where the controlled medicine is dispensed in a dose administration aid for a patient at a residential aged care facility or residential disability care facility, or a detainee at a correction centre or a CYP detention place. In this regulation a CYP detention place is a detention place under the ACT *Children and Young People Act 2008*.

Generally, the section requires that a dealing with a controlled medicine be entered in the controlled medicines register that a person is required to keep under this Chapter. However, with institutions it is possible for there to be numerous controlled medicines registers, particularly if the institution has a pharmacy and a number of wards. As such, this section provides that if the dealing happens in a pharmacy at an institution the dealing be entered into the controlled medicines register at the pharmacy. Whereas, if the dealing happens in a ward at an institution the dealing must be recorded in the controlled medicines register at the ward.

There may also be situations where a person must keep a controlled medicines register for a first-aid kit and another controlled medicines register. Subsection 3(c) confirms that if the dealing with a controlled medicines related to the first-aid kit must be recorded in the register for the first-aid kit, and all other dealings will be recorded in the other register to be kept by the person.

Section 544 Prescribed witnesses for administration of controlled medicines – Act, s 53 (a) and (b)

Section 544 lists persons who are prescribed as witnesses in relation to the administering of a controlled medicine. Essentially, this provision enables a dentist, a doctor, a midwife, a nurse, a nurse practitioner, or a pharmacist to be a prescribed witness to the administering of a controlled medicine.

An intern doctor, or an enrolled nurse registered under the *Health Professionals Act 2004* in the specialist area of medications, may also be prescribed witness to the administering of a controlled medicine, unless the administering is being performed by an intern doctor.

Section 545 Prescribed witnesses for discarding of controlled medicines – Act, s 54 (a) and (b)

Section 545(1) lists persons who are prescribed as witnesses in relation to the discarding of a controlled medicine. However, section 545 also expressly excludes a person from being a prescribed witness in relation to the discarding of a controlled medicine if the person is related to, employed by, or a close friend of the person discarding the controlled medicine.
Such persons are, by virtue of their relationship with the person discarding the controlled medicine, potentially able to be influenced by, or exert influence over, the person discarding the controlled medicine. Accordingly, their suitability as a prescribed witness is thereby diminished. For the same reason the supervisor of the person discarding the controlled medicine cannot be a prescribed witness, nor can a person supervised by the person discarding the controlled medicine.

Section 546 Changes to entries in controlled medicines registers – Act, s 55 (2) (b)

Section 542 confirms that a controlled medicines register may be kept in hardcopy form or electronically, and addresses the form in which a controlled medicines register must be kept.

Understandably, from time to time situations may arise in which an entry in a controlled medicines register needs to be changed, more often than not in order to correct an entry. Changes to an entry in a controlled medicines register is permissible, provided the requirements of this section are followed.

Subsection 1 relates to changes to an entry in a paper-based controlled medicines register. The subsection permits the person who made the entry to change the entry by signing and dating a marginal note or footnote that gives the amendment details and the date the amendment is made.

If the entry to be changed relates to the administering of a controlled medicine, the amendment must be witnessed by a person listed in section 544, and the witness must also sign the amendment to evidence that they witnessed the change. It is not required that the person prescribed under section 544 that witnessed the administering of the medicine be the same witness to the amendment of the controlled medicines register. However, where it is possible it is preferable.

Similarly, if the entry to be changed relates to the discarding of a controlled medicine, the amendment must be witnessed by a person listed in section 545, and the witness must also sign the amendment to evidence that they witnessed the change. Again, it is not required that the person prescribed under section 545 that witnessed the discarding of the medicine be the same witness to the amendment of the controlled medicines register, but it is still desirable where possible.

Subsection 2 of the provision relates to changes to an entry in an electronic controlled medicines register. Changes can be made by attaching or linking, by electronic means, a document featuring the person's signature, the date the details of the amendment. Where the entry relates to the administering of a controlled medicine, a prescribed witness under section 544 must also sign the document to be attached or linked. Should the entry relate to the discarding of a controlled medicine, the additional signature to be included is that of a prescribed witness under section 545. Just as it is with a paper-based register, the witness to the amendment need not be the original witness identified in the entry, but where possible it is desirable.

Chapter 13 Controlled medicines and appendix D medicines approvals for human use

The medicines of most serious concern within the SUSDP, and therefore the most tightly regulated by the MPTG legislation, are controlled medicines and appendix D medicines. Controlled medicines under the MPTG legislation are substances to which Schedule 8 of the SUSDP apply and these medicines warrant additional restrictions to reduce the likelihood of their misuse or dependence.

Approvals for human use of these two types of medicines is the subject matter of Chapter 13. The Chapter is divided into two Parts. Part 1 being approvals for controlled medicines, and Part 2 being approvals for appendix D medicines. Part 1 is further divided into four divisions, addressing standing controlled medicines approvals, controlled medicines approvals by the Chief Health Officer, endorsements to treat drug-dependency, and preliminary matters.

Part 13.1 Controlled medicines approvals

Division 13.1.1 Preliminary

Preliminary matters for Chapter 13 are contained within this Division. Section 550 establishes the meaning of *controlled medicines approval* for the purposes of this Regulation, whereas section 551 assigns a meaning to *designated prescriber* that applies to Part 13.1 only.

Division 13.1.2 Standing controlled medicines approvals

Under this Division a designated prescriber, as defined in Division 13.1.1, has a standing approval to prescribe a controlled medicine for one of their patients where that patient is an in-patient at a hospital.

A designated prescriber also has a standing approval to prescribe a controlled medicine for one of their patients, provided that the prescriber believes on reasonable grounds that the patient is not drug-dependent and that the patient has not been prescribed a controlled medicine within the preceding two month period. It is also a condition of that standing approval that if the controlled medicine is prescribed, it is for no more than 2 months.

This Division also gives a standing approval to doctors working at a correctional centre, CYP detention place, a hospital or an opioid dependency treatment centre operated by the Territory. This standing approval, which extends to intern doctors acting under the direct supervision of a doctor, enables the prescription of buprenorphine or methadone for a patient at the institution that the doctor works. Such a prescription must be in accordance with the opioid dependency treatment guidelines, and requires the doctor to apply.

This standing approval is effectively an interim approval for the treatment of outpatients and others, as an application under section 560 of this Regulation must be made within 72 hours of the buprenorphine or methadone first being prescribed.

Division 13.1.3 Chief health officer controlled medicines approvals

Through Division 13.1.3 applications may be made to the Chief Health Officer for approval to prescribe a controlled medicine. Section 561 determines the requirements of an application for approval to prescribe a controlled medicine, whereas section 562 specifies the decisions on an application that the Chief Health Officer can make. The Division permits the Chief Health Officer to impose restrictions on an approval given, and a period for which an approval will apply.

Should the Chief Health Officer think further information is needed to decide the application, the applicant can be asked for that information. If this occurs, the applicant must give the requested information to the Chief Health Officer, who is not obliged to make a decision on the application until the requested information is received.

Section 567 allows the Chief Health Officer to amend or revoke an approval that they have given. The amendment or revocation may be made on the Chief Health Officer's own initiative, and without consultation with the Medicines Advisory Committee. Should the Chief Health Officer amend or revoke an approval, a written notice must be given to the approval-holder, and this decision may also be reviewed by the Medicines Advisory Committee.
It should also be noted that the Medicines Advisory Committee may also direct the Chief Health Officer to amend or revoke an approval, irrespective of whether the approval was given at the direction of the Medicines Advisory Committee.

Whatever the decision of the Chief Health Officer, a written notice of the decision must be provided to the doctor no later than 7 days after the decision is made. If the approval is refused, or an unfavourable decision is made, the doctor has the right to seek a review of the decision, and the written notice of the decision should explain that right.

The Division assigns to the Medicines Advisory Committee the responsibility for reviewing a decision by the Chief Health Officer. The Medicines Advisory Committee is established under Part 15.2 of this Regulation.

Division 13.1.4 Endorsements to treat drug-dependency

This Division contains the framework under which the Chief Health Officer can give an endorsement to a doctor to treat drug-dependency. Within the Division, an endorsement is given by the Chief Health Officer under section 582 to the prescribing of buprenorphine or methadone to treat a person's drug-dependency. It must be noted that an endorsed doctor will also be required to have an approval to prescribe for an individual patient under Division 13.1.3.

Through the operation of this Division a doctor can apply to the Chief Health Officer, in writing, for an endorsement. In addition to the doctor's name, business address and telephone number, the doctor is required to give their qualifications and experience in treating drug-dependency. This information is critical as the Chief Health Officer cannot give an endorsement unless satisfied that the doctor possesses the necessary qualification and experience.

Should the Chief Health Officer think further information is needed to decide the application, the doctor can be asked for that information. If this occurs, the applicant must give the requested information to the Chief Health Officer, who is not obliged to make a decision on the application until the requested information is received.

Whatever the decision of the Chief Health Officer, a written notice of the decision must be provided to the doctor no later than 7 days after the decision is made. If the decision is to give the endorsement, it must include the doctor's name, details of any conditions to which the endorsement is subject, and an identifying number for the endorsement.

If the endorsement is refused, the doctor has the right to seek a review of the decision, and the written notice of the decision should explain that right.

The Division assigns to the Medicines Advisory Committee the responsibility for reviewing a decision by the Chief Health Officer to refuse an endorsement. The Medicines Advisory Committee is established under Part 15.2 of this Regulation.

A doctor seeking a review has 28 days from the receipt of the notice of the Chief Health Officer's decision to apply for a review. An application for review must comply with section 584(3). After considering an application the Medicines Advisory Committee must make a decision, which will either be to confirm the decision of the Chief Health Officer or to revoke the decision and give the endorsement.

Part 13.2 Appendix D medicines approvals

An authorisation under section 33 of this Regulation is subject to the condition that the prescriber have an approval under this Part, referred to as an appendix D medicines approval. Appendix D medicines approvals are made under either section 591 or 592 in this Part.

Through the joint application of section 591 and Schedule 3 of this Regulation certain specialist doctors have a standing approval, which is an enduring approval that always exists, in relation to certain appendix D medicines provided that particular conditions are met. For example, a specialist practising in a the specialist area of dermatology has a standing approval for a number of appendix D medicines listed column 3 in Part 3.2 of Schedule 3. However, column 4 in Part 3.2 of Schedule 3 imposes conditions 1 and 2 on the standing approval for some of those medicines, and conditions 1 and 4 for two of the medicines. What constitutes conditions 1, 2, 3 and 4 is detailed in Part 3.1 of Schedule 3.

If a doctor does not have a standing approval for an appendix D medicine, under section 592 the doctor may apply in writing to the Chief Health Officer for approval to prescribe an appendix D medicine. However, an application must still relate to a medicine and purpose listed column 3 in Part 3.2 of Schedule 3. For example, an approval can be sought to prescribe clozapine for human use. Applications must provide the name of the medicine, and the name, business address and telephone number of the doctor. Specialist doctors must also identify their area of speciality, whereas a doctor that is not a specialist must provide information about their qualifications and experience in relation to the medicine to which the application relates. Furthermore, if the Chief Health Officer requests any other information for the purposes of deciding on the application, that information is to be provided.

The Chief Health Officer must either approve or refuse the application, having regard to matters stated in section 593(3). Whatever the decision, written notice of the decision is to be provided within 7 days of the decision being made. If the decision is to grant an approval, the approval is subject to conditions stated in section 593(2), and the approval must be in a form that meets the requirements of section 594.

Chapter 14 Medicines licences

In many instances it is adequate for authorisation to handle certain types of medicines to be assigned by this regulation to categories of persons, subject to prescribed but broadly applying conditions. However, in other instances it is only appropriate to give authorisation to conduct certain activities to persons through the use of licences. This requires a person, be it an individual, company or institution, to apply for authorisation to perform the licensed activity, and thereby enabling the suitability of that person for that activity to be assessed. Licences also enable conditions to be imposed specific to the person, or the circumstances, and provide further enforcement methods in the event of improper use.

Licences for medicines are dealt with through Chapter 14 and it's six Parts. Controlled medicines research and education program licences are addressed within Part 2. Within the Part are sections regarding what must be included in an application for a controlled medicines research and education program licence, the restrictions imposed on such a licence, and additional information prescribed for such a licence.

First-aid kit licensees are addressed in the third Part of the Chapter. Like the previous Chapter, the Part is comprised of three sections addressing what must be included in an application for a first-aid kit licence, the restrictions imposed on such a licence, and additional information prescribed for such a licence.

The application of Part 4 is in regard to medicines wholesalers licences. Again, the Part consists of sections addressing what must be included in an application for a licence under the Part, the restrictions imposed on such a licence, and additional information prescribed for such a licence.

The focus of the remaining Parts is upon opioid dependency treatment licences and pharmacy medicines rural communities licences. pharmacy medicines rural communities licences is a licence issued to a person who is not a pharmacist to sell, by retail, pharmacy medicines. Such licences were primarily contemplated to avoid disadvantaging rural communities that are without a local pharmacist by providing another mechanism whereby pharmacist only medicines could be made available for retail sale to the community. Accordingly, such licences are referred to as a pharmacy medicines rural communities licence.

Part 14.1 Medicines licences generally

Section 600 Medicines licences that may be issued – Act, s 78 (2)

Section 78(2) of the MPTG provides that this Regulation may prescribe the types of licences that may be issued under the MPTG Act. This provision identifies the licences for medicines which may be issued under this Regulation, each of which are addressed in greater detail in the other Parts of this Chapter.

Part 14.2 Controlled medicines research and education program licences

Part 14.2 provides the governance structure for the issuing of licences for research or education programs proposing to involve controlled medicines. Section 605 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by a written approval of the proposed program from the person in charge of either the faculty or division of a recognised research institution at which the program would be conducted, or from the person in charge of the institution itself. Section 20(5) of the MPTG Act lists recognised research institutions, which include the University of Canberra, the ANU, the Canberra Hospital, the CSIRO, or any other entity prescribed by this Regulation.

Controlled medicines research and education program licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 606. A key consideration for the Chief Health Officer is whether the proposed program cannot be carried out without the use of the controlled medicine, and whether the program will be adequately supervised.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribe additional information to be included on a licence. For a controlled medicines research or education program licence that additional information is set out in section 607.

Part 14.3 First-aid kit licences

The governance structure for the issuing of first-aid kit licences is contained in this Part. Section 610 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by evidence that the applicant has successfully completed a course that qualifies the person to be registered as a nurse or employed as an ambulance paramedic. A letter of support from a doctor who will provide medical direction and support to the applicant is also required.

First-aid kit licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 611. A key consideration for the Chief Health Officer is whether the applicant and each person to be authorised by the licence has successfully completed a course that qualifies the person to be registered as a nurse or employed as an ambulance paramedic, and that the applicant provides, or will be providing, first-aid services to the community (eg at a workplace or under the *Emergencies Act 2004*). The Chief Health Officer must also be satisfied that the medicines to which the licence application relates are reasonably necessary to provide the first-aid services.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribed additional information to be included on a licence. For a first-aid kit licence that additional information is set out in section 612.

Part 14.4 Medicines wholesalers licences

This Part provides the governance structure for the issuing of licences for wholesale suppliers proposing to supply medicines. Section 615 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by a plan of the premises proposed to be used by the licensee that shows where the medicines are proposed to be stored and the location and nature of security devices at the premises.

Medicines wholesalers licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 616. A key consideration for the Chief Health Officer is the suitability and qualifications of the individual nominated to supervise the dealings to be authorised by the licence.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribed additional information to be included on a licence. For a medicines wholesalers licence section 617 requires that the licence also feature the name of the person approved under section 616(1) to supervise the dealings authorised by the licence.

Part 14.5 Opioid dependency treatment licences

Section 600(d) of this Regulation enables a licence to be issued for the treatment of opioid dependency with buprenorphine or methadone.

Section 620 Applications for opioid dependency treatment licences

Section 620 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application. Applications must be in writing, signed by the applicant, and specifying the applicant's full name and business address.

Section 621 Restriction on opioid dependency treatment licences - Act, s 85 (1) (a)

The Chief Health Officer issues opioid dependency treatment licences, but may only do so to a pharmacist at a community pharmacy. No other category of person may hold an opioid dependency treatment licence under this Regulation

Section 622 Witnessing not required for administration under opioid dependency treatment licence - Act, s 190 (1) (a)

This Regulation may, through the operation of section 190(1)(a) of the MPTG Act, exempt persons, regulated things, premises or even dealing with a regulated medicine, substance or therapeutic good. Section 190(2) provides that such an exemption can be conditional.

Division 4.2.2 of the MPTG Act contains offences relating to registers for regulated substances. Amongst those is section 53, which addresses the witnessing of administering of a medicine. The section requires a number of elements to be met, otherwise an offence is committed.

Section 622 exempts the administration of buprenorphine or methadone under an opioid dependency treatment licence from the requirement in section 53(e) of the MPTG Act, provided that the administration complies with section 471 of this Regulation. Section 471 contains authorisation conditions that apply to all opioid dependency treatment licences. Accordingly, compliance with section 471 is mandatory even without the application of section 622.

Part 14.6 Pharmacy medicines rural communities licences

Section 600(e) of this Regulation enables a licence to be issued to a person who is not a pharmacist to sell, by retail, pharmacy medicines. Such licences were primarily contemplated to avoid disadvantaging rural communities that are without a local pharmacist by providing another mechanism whereby pharmacist only medicines could be made available for retail sale to the community. Accordingly, such licences are referred to as a pharmacy medicines rural communities licence. This Division provides the governance structure for the issuing of such licences.

Section 625 Applications for pharmacy medicines rural communities licences

Section 625 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application. Applications must be in writing, and signed by the applicant. Furthermore, an application must include the applicant's full name, business address and telephone number. The pharmacy medicines that the applicant would propose to sell under the licence must also be included.

Section 626 Restrictions on issuing of pharmacy medicines rural communities licences - Act, s 85 (1) (a)

Pharmacy medicines rural communities licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 626. In order to qualify for a pharmacy medicines rural communities licence, the Chief Health Officer needs to be satisfied that the premises from which the medicines will be sold is more than 25 kilometres, using the shortest practical route, to the nearest community pharmacy.

The wording "by the shortest practical route" recognises geographical realities. It may be possible for a community pharmacy to be within a 25 kilometre radius of the applicant's business premises, but a trip to that pharmacy may be well in excess of 25 kilometres as certain obstacles may need to be navigated.

For example, it could be that a river or bay separates the applicant's business and the nearest community pharmacy. The community pharmacy may be only 20 kilometres away as the crow flies, but driving to that community pharmacy may be a trip exceeding 25 kilometres due to the trip around the bay or because of the location of the nearest bridge. In this example the route from one point the other by boat may be less than 25 kilometres. Nevertheless, the route by boat would not be considered to be "the shortest practical route" as travel by boat may not be possible at certain times of day or in certain conditions, and it may be a means of travel to which few people have access.

Additionally, the Chief Health Officer must be satisfied that the applicant is carrying on a business of selling goods by retail.

Chapter 15 Medicines – other provisions

Part 15.1 Opioid dependency treatment guidelines

This part contains a single section that enables the Minister to approve, by notifiable instrument, guidelines for the treatment of opioid dependency. If the Minister chooses to approve guidelines under this Part, the guidelines may make provision for the prescribing, administration, or both, of buprenorphine and methadone to drug-dependent people.

Part 15.2 Medicines advisory committee

Section 194 of the MPTG Act establishes the medicines advisory committee. Provisions about the medicines advisory committee, its membership and operations, are contained within this Part. The medicines advisory committee is comprised of 3 doctors, one of which will serve as committee chair. Of the doctors on the committee, section 635 requires the committee have a member with experience in the teaching or practice of psychiatry, and a member that was nominated by the ACT branch of the Australian Medical Association. It is possible for a single member to fulfil both of these requirements, and may even fulfil both of these requirements and be appointed as chair of the committee.

There are provisions within the Chapter pertaining to the conduct of committee meetings, voting, the necessary quorum for meetings and the disclosure of interests by members. Section 644 of this regulation also gives the Minister the power to end a member's appointment in given circumstances, such as bankruptcy, contravention of a law of the Territory and even misbehaviour.

Part 15.3 Other medicines provisions

Section 650 Advertising controlled medicines – Act, s 66 (3) (b)

Section 66 of the MPTG Act effectively prohibits advertising controlled medicines, and does so through offences in subsections (1) and (2). However, pursuant to subsection (3) of the same provision the offences in subsections (1) and (2) do apply to an advertisement prescribed under this regulation, or an advertisement by a pharmacist prescribed by this regulation.

Section 650 operates to prescribe a pricelist published by a pharmacist that includes a controlled medicine for the purposes of section 66(3)(b) of the MPTG Act, provided that the pricelist complies with the *Price Information Code of Practice* published by the Therapeutic Goods Administration.

Section 651 Advertising other medicines

Section 66 of the MPTG Act contains offences for advertising controlled medicines. This provision establishes offences for advertising of declared medicines. The offences in this provision are less serious than those in section 66 of the MPTG Act, and therefore carry a lessor maximum penalty. As that maximum penalty is 30 penalty units the offence in section 651 is appropriately located within this regulation rather than the MPTG Act.

Section 651 also advises that the offences within the provision do not apply in two circumstances. Similar to section 650, a pricelist published by a pharmacist that includes a declared medicine will not amount to an offence, provided that the pricelist complies with the *Price Information Code of Practice* published by the Therapeutic Goods Administration. The other exception is an advertisement for a declared medicine in a publication that is published primarily for dentists, doctors, pharmacists or veterinary surgeons.

Section 652 Prescribed institutions – Act, dict, def *institution*, par (b)

The definition of *institution* contained in the dictionary of the MPTG Act states that an institution:

> (a) means a hospital, residential aged care facility, residential disability care facility or other institution used for the accommodation, treatment and care of people suffering from mental or physical conditions; and
>
> (b) includes a body prescribed by regulation as an institution.

This section prescribes a correctional centre and a CYP detention place as an institution for the purposes of paragraph (b) of the MPTG Act's dictionary definition. A correctional centre has its ordinary meaning. However, for this regulation a CYP detention place is a detention place under the ACT *Children and Young People Act 2008*.

Chapter 16 Low and moderate harm poisons

The MPTG Act contains a number of offences for supplying improperly packaged or labelled regulated substances. What amounts to appropriate packaging and labelling for low and moderate harm poisons is the subject matter of this Chapter.

Part 16.1 Preliminary

Section 660 Meaning of *relevant law* – ch 16

For the purposes of this Chapter, a law of another Australian State or Territory, referred to in the MPTG legislation as a *corresponding law*, is a relevant law. Additionally, the Commonwealth *Agricultural and Veterinary Chemicals Act 1997* and the *Therapeutic Goods Act 1989* are also relevant laws for Chapter 16.

Part 16.2 Authorisation to supply low and moderate harm poisons

Section 661 Authorisation to supply low and moderate harm poisons – Act, s 26 (1) (b) and (2) (b)

Through section 661 all persons are authorised to supply a low or moderate harm poison. However, anyone who chooses to supply a low or moderate harm poison must comply with the conditions set out in section 662.

Section 662 Authorisation condition for supplying low and moderate harm poisons – Act, s 44 (1) and (2) (b)

Although anyone can, under section 661, supply a low or moderate harm poison, the poison must be supplied in manufacturer's packs. Furthermore, the manufacturer's pack must comply with section 665 of this Regulation or with an approval given under section 193 of the MPTG Act. The manufacturer's pack must also be labelled in accordance with either section 666 of this Regulation or an approval given under section 193 of the MPTG Act.

Part 16.3 Authorisation to manufacture low and moderate harm poisons

Section 663 Authorisation to manufacture low and moderate harm poisons – Act, s 33 (b)

If a person is authorised to manufacture a low or moderate harm poison under a relevant law, as defined by section 660, then that person is also authorised under this provision to manufacture the poison in the ACT.

Section 664 Authorisation condition for manufacturing low and moderate harm poisons – Act, s 44 (1) and (2) (b)

By virtue of this provision, if a relevant law as defined in section 660 imposes a condition on a person manufacturing a poison, then that condition is also a condition on an authorisation to manufacture a low or moderate harm poison under section 661.

Part 16.4 Packaging and labelling of low and moderate harm poisons

Section 665 Packaging of supplied manufacturer's packs of low and moderate harm poisons - Act, s 59 (1) (c) (i) and (2) (c) (i)

Under section 59 of the MPTG Act, a person authorised to supply a regulated substance risks committing an offence if the substance supplied is not appropriately labelled.

This section specifies that for the purposes of section 59 of the MPTG Act, a manufacturer's pack of a low or moderate harm poison is packaged correctly if it is packaged in one of three ways. The poison may also be packaged in accordance with an approval under section 193 of the MPTG Act, or in accordance with either the paragraphs 21 to 28 of the SUSDP. The third approved packaging method is the supply of the substance in a container in which the poison may be sold under a relevant law.

If the poison is camphor or naphthalene intended for domestic use, the container in which the poison is sold under a relevant law must also prevent the camphor or naphthalene from being removed from the packaging, or ingested. Both camphor and naphthalene are routinely used in domestic settings, and provided both are appropriately packaged they are safe for such usages.

It should be noted that an approval for non-standard packaging and labelling can be obtained under section 193 of the MPTG. Where this has occurred, the person to whom the approval has been granted does not need to comply with this section, provided that the terms of the approval are adhered to.

Section 666 Labelling of supplied manufacturer's packs of low and moderate harm poisons - Act, s 60 (1) (c) (i) and (2) (c) (i)

Under section 60 of the MPTG Act, a person authorised to supply a regulated substance risks committing an offence if the substance that is supplied is not appropriately labelled.

This section specifies that for the purposes of section 60 of the MPTG Act, a manufacturer's pack of a low or moderate harm poison is labelled correctly if it is labelled in accordance with either the paragraphs 3 to 19 of the SUSDP, a relevant law or an approval under section 193 of the MPTG Act.

It should be noted that an approval for non-standard packaging and labelling can be obtained under section 193 of the MPTG. Where this has occurred, the person to whom the approval has been granted does not need to comply with this section, provided that the terms of the approval are adhered to.

Chapter 17 Dangerous poisons authorisations

Part 17.1 Overview of dangerous poisons authorisations

Section 670 General overview of authorisations for dangerous poisons

This section reiterates that it is the MPTG Act that prohibits dealing with a dangerous poison without an authorisation, and section 20 of the MPTG Act sets out when a person is authorised to deal with a regulated substance.

Section 671 Overview of dangerous poisons authorisations under this regulation

Dangerous poisons authorisations under this Regulation are listed in this section.

Section 672 General overview of authorisation conditions for dangerous poisons

This section essentially reiterates that section 44 of the MPTG Act requires a person authorised to deal with a dangerous poison to comply with conditions to which the authorisation is subject. The section also draws the reader's attention to the fact that conditions on authorisations are additional to other restrictions that may be placed upon a person's authorisation under the MPTG legislation.

Part 17.2 Authorisations under dangerous poisons licences

Division 17.2.1 Dangerous poisons manufacturers licence authorisations

The governance structure for the issuing of dangerous poisons manufacturers licences is contained in Part 18.2 of this Regulation. This Division establishes what is authorised by a licence issued under Part 18.2.

Section 675 authorises a licence-holder to do a variety of things from the premises stated on the licence, including possess the dangerous poison for sale by wholesale and, not unexpectedly, manufacture the dangerous poison.

Of particular importance for a dangerous poisons manufacturer's licence, the Division authorises the sale of dangerous poisons by wholesale, from the premises stated on the licence, to a person that is authorised to issue a purchase order for the dangerous poison. Furthermore, the licence-holder is authorised to sell by wholesale to a person in another jurisdiction, including overseas, provided that person is lawfully able to obtain the dangerous poison by wholesale.

It should be noted that the authorisations under this Division apply to all the dangerous poisons manufacturer's licences, unless a licence expressly states that a particular type of dealing is not authorised. In effect, this means that the terms of an issued licence can overrule or contradict the authorisations in this Division.

For example, a licence could be issued that states the licensee is not authorised to supply by wholesale to a person in another country. Supply by wholesale to a person in another country will also be prevented if the dangerous poison to which the licence relates is a prohibited export under the Commonwealth *Customs Act 1901*. In such circumstances the authorisation to supply to a person in another country does not apply.

The authorisation to obtain a dangerous poison under this Division is subject to the condition that the dangerous poison is purchased on a complying purchase order. For a dangerous poison a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 721. Additionally, a dangerous poison may only be sold under a wholesaler's licence on a complying purchase order.

A further condition is that dangerous poisons are only to be supplied under this Division for non-household purposes. The condition means the dangerous poison may be supplied for garden purposes, provided the garden is a non-household garden.

As the condition applies to wholesalers, a dangerous poison may only be supplied to a person who has an authority to possess a dangerous poison, and that the supply conforms with section 720 of this Regulation.

A special condition also exists where the dangerous poison is a liquid containing paraquat. In such circumstances the poison must be coloured blue or green and must have an offensive smell. These visual and olfactory indicators are necessary to identify the danger associated with this particular poison.

Section 676(e) also contemplates that the licence-holder will receive a document from a buyer to whom a dangerous poison was supplied. This document, acknowledging receipt of the dangerous poison, should be provided within 7 days of the dangerous poison being delivered. Should this not occur, the licence-holder must, within 24 hours after the end of the 7 day period, advise the Chief Health Officer in writing.

There is also a requirement for certain records to be kept at the licence-holders business premises, or another location if approved in writing by the Chief Health Officer. Those records include the filled purchase order, the delivery acknowledgement, and a record that satisfies section 722 of this Regulation.

Division 17.2.2 Dangerous poisons - research and education program licence authorisations

This Division specifies the types of dealings for which a dangerous poisons research and education program licence-holder is authorised, as well as the conditions that apply to all such licences. Additionally, the program supervisor and anyone participating in the program are authorised to deal with the dangerous poison to which the licence relates, provided that the dealing occurs, for the purposes of the program, at the premises stated in the licence.

A dangerous poisons research and education program licence-holder is authorised to obtain dangerous poisons in accordance with the terms of their licence. It is a further condition on a licence-holder's authorisation that all dangerous poisons purchased under the licence are done so through a complying purchase order. For a dangerous poison a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 721.

Division 17.2.3 Dangerous poisons suppliers licence authorisations

The governance structure for the issuing of dangerous poisons suppliers licences is contained in Part 18.4 of this Regulation. This Division establishes what is authorised by a licence issued under Part 18.4.

Section 685 authorises a licence-holder to do a variety of things from the premises stated on the licence, including issuing purchase orders for a dangerous poison, obtaining a dangerous poison through a purchase order for sale, and possessing the dangerous poison for sale.

Of particular importance for a dangerous poisons suppliers licence, the Division authorises the sale of dangerous poisons on a purchase order, from the premises stated on the licence, to a person that is authorised to issue a purchase order for the dangerous poison. Furthermore, the licence-holder is authorised to sell a dangerous poison to a person in another jurisdiction, including overseas, provided that person is lawfully able to obtain the dangerous poison.

It should be noted that the authorisations under this Division apply to all supplier's licences, unless a licence expressly states that a particular type of dealing is not authorised. In effect, this means that the terms of an issued licence can overrule or contradict the authorisations in this Division. For example, a licence could be issued that states the licensee is not authorised to supply to a person in another country. Supply to a person in another country will also be prevented if the dangerous poison to which the licence relates is a prohibited export under the Commonwealth *Customs Act 1901*. In such circumstances the authorisation to supply to a person in another country does not apply.

It is a condition under section 686 of this Regulation that all dealings with a dangerous poison take place under the supervision of an individual approved under section 716(1).

All dangerous poisons sold under the licence must be sold under a purchase order that meets the requirements of section 720. However, if a dangerous poison is subject to condition 3 in appendix J of the SUSDP that poison must not be supplied to a person unless they are allowed to use that poison under condition 3 of appendix J.

A further condition is that dangerous poisons are only to be supplied under this Division for non-household purposes. The condition means the dangerous poison may be supplied for garden purposes, provided the garden is a non-household garden.

A special condition also exists where the dangerous poison is a liquid containing paraquat. In such circumstances the poison must be coloured blue or green and must have an offensive smell. These visual and olfactory indicators are necessary to identify the danger associated with this particular poison.

Section 686(e) also contemplates that the licence-holder will receive a document from a buyer to whom a dangerous poison was supplied. This document, acknowledging receipt of the dangerous poison, should be provided within 7 days of the dangerous poison being delivered. Should this not occur, the licence-holder must, within 24 hours after the end of the 7 day period, advise the Chief Health Officer in writing.

There is also a requirement for certain records to be kept at the licence-holders business premises, or another location if approved in writing by the Chief Health Officer. Those records include the filled purchase order, the delivery acknowledgement, and a record that satisfies section 722 of this Regulation.

Part 17.3 Other dangerous poisons authorisations

Division 17.3.1 Authorisations for manufacturing etc purposes

Section 690 in this Division directs that a person mentioned in column 2 in Schedule 4 of this Regulation is authorised for a relevant dealing with a dangerous poison mentioned in column 3 of Schedule 4. However, the authorisation is on the proviso that the poison is for the purpose mentioned in column 4 in Schedule 4 and the dealing is consistent with any condition or restriction mentioned in column 3. Furthermore, where the dealing is issuing a purchase order for the poison, the purchase order must comply with section 720 of this Regulation,

Under this Division, the types of dealings that are regarded as *relevant dealings* include the issuing of a purchase order, obtaining the poison, possessing the poison and discarding the poison.

Division 17.3.2 Authorisations for delivery people and commercial disposal operators

Division 17.3.2 gives authorisations to delivery people and commercial disposal operators so that the handling of medicines by such persons in the ordinary course of their employment is authorised and lawful under the MPTG legislation.

Division 17.3.3 Authorisations for dangerous poisons research and education programs by scientifically qualified people

The provisions in Division 17.3.3 give authorisations for dangerous poisons for research and education program purposes. The provisions in this Division enable scientifically qualified persons employed a recognised research institution to handle dangerous poisons without contravening the MPTG legislation.

A scientifically qualified person is, according to the dictionary in this Regulation, a dentist, doctor, pharmacist or veterinary surgeon, excluding trainees and interns. A person who has been awarded a doctorate for scientific studies is also considered a scientifically qualified person.

Section 20(5) of the MPTG Act lists recognised research institutions, which include the University of Canberra, the ANU, the Canberra Hospital, the CSIRO, or any other entity prescribed by this Regulation.

Chapter 18 Dangerous poisons licences

Part 18.1 Dangerous poisons licences generally

Section 700 Dangerous poisons licences that may be issued - Act, s 78 (2)

Section 78(2) of the MPTG provides that this Regulation may prescribe the types of licences that may be issued under the MPTG Act. This provision identifies the licences for dangerous poisons which may be issued under this Regulation, each of which are addressed in greater detail in the other Parts of this Chapter.

Part 18.2 Dangerous poisons manufacturers licences

This Part provides the governance structure for the issuing of manufacturers licences for dangerous poisons. Section 705 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by a plan of the premises proposed to be used by the licensee. The plan submitted must show the locations where dangerous poisons are proposed to be stored, irrespective of whether those poisons are those manufactured under the licence sought or are precursor dangerous poisons.

The plan must also reflect each part of the premises where a manufacturing process is proposed to be carried out and the nature of the process, as well as the location and nature of security devices at the premises.

Dangerous poisons manufacturers licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 706. A key consideration for the Chief Health Officer is the suitability and qualifications of the individual nominated to supervise the dealings to be authorised by the licence.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribed additional information to be included on a licence. For a dangerous poisons manufacturers licences section 707 requires that the licence also feature the name of the person approved under section 706(1) to supervise the dealings authorised by the licence.

Part 18.3 Dangerous poisons research and education program licences

This Part provides the governance structure for the issuing of licences for research or education programs proposing to involve dangerous poisons. Section 710 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by a written approval of the proposed program from the person in charge of either the faculty or division of a recognised research institution at which the program would be conducted, or from the person in charge of the institution itself. Section 20(5) of the MPTG Act lists recognised research institutions, which include the University of Canberra, the ANU, the Canberra Hospital, the CSIRO, or any other entity prescribed by this Regulation.

Dangerous poisons research and education program licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 711. A key consideration for the Chief Health Officer is whether the proposed program cannot be carried out without the use of the dangerous poison, and whether the program will be adequately supervised.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribed additional information to be included on a licence. For a dangerous poisons research or education program licence that additional information is set out in section 712.

Part 18.4 Dangerous poisons suppliers licences

This Part provides the governance structure for the issuing of dangerous poisons supplier licences. Section 715 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by a plan of the premises proposed to be used by the licensee that shows where the dangerous poisons are proposed to be stored and the location and nature of security devices at the premises.

Licences to supply dangerous poisons are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 716. A key consideration for the Chief Health Officer is the suitability and qualifications of the individual nominated to supervise the dealings to be authorised by the licence.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribed additional information to be included on a licence. For a dangerous poisons supplier licence section 717 requires that the licence also feature the name of the person approved under section 716(1) to supervise the dealings authorised by the licence.

Chapter 19 Dangerous poisons – other provisions
Part 19.1 Dangerous poisons purchase orders
Section 720 Supplying dangerous poisons on purchase orders

The supply of a dangerous poison on a purchase order must meet certain requirements, which are set out in this section. Dangerous poisons to be supplied on a purchase order must be supplied in manufacturer's packs that are properly labelled in accordance with section 732, properly packaged in accordance with section 731, and are securely wrapped and packed. The provision imposes requirements in regard to the delivery of the dangerous poison, which differ depending on whether or not the supplier is delivering the poison in person. Which ever method is used, the poison can only be delivered to an adult, and that person must sign for the delivery.

Section 721 General requirements for dangerous poisons purchase orders - Act, s 38 (2) (c)

Purchase orders for dangerous poisons must, under this section, be signed by the person issuing the order. Furthermore, if the person issuing the purchase order amends the order at any stage, the person must record their initials and the date along side the amendment.

Subsection 2 specifies what information must be included in a purchase order for a dangerous poison, such as the form, strength and quantity of the dangerous poison supplied.

Section 722 Recording supply of dangerous poisons on purchase orders

Under this section, a person who supplies a dangerous poison to someone else on a purchase order is required to make a written record of the supply. The information required to be kept under this provision includes the date of the order, the date the order is supplied, and the form, strength and quantity of the dangerous poison supplied. For obvious reasons, the details of the person to whom the dangerous poison was supplied is also required to be recorded.

Through a comparison of the record made under this section with the purchase order to which the supply relates, discrepancies and variations should be identifiable. Identification of such variances and discrepancies may enable the identification of dangerous poisons being misused, redirected or unusual supply patterns. Therefore, the keeping of such records is invaluable from a regulatory perspective.

Under section 11 of the *Electronic Transactions Act 2001* records can be kept in an electronic format provided certain criteria can be met. Accordingly, a requirement to keep a written record is met if the record is kept in an electronic form.

Part 19.2 Wholesale supply of dangerous poisons under corresponding laws

Section 725 Conditions for wholesalers supplying dangerous poisons under corresponding laws – Act, s 20 (4) (c)

This provision imposes conditions upon all persons who supply, under authority assigned by a corresponding law, dangerous poisons by wholesale. Through this provision, dangerous poisons are only to be supplied for non-household purposes. The condition means the dangerous poison may be supplied for garden purposes, provided the garden is a non-household garden.

As the condition applies to wholesalers, a dangerous poison may only be supplied to a person who has an authority to possess a dangerous poison, and that the supply conforms with section 686 of this Regulation.

A special condition also exists where the dangerous poison is a liquid containing paraquat. In such circumstances the poison must be coloured blue or green and must have an offensive smell. These visual and olfactory indicators are necessary to identify the danger associated with this particular poison.

Part 19.3 Packaging and labelling of dangerous poisons

Section 730 Meaning of *relevant law* – pt 19.3

For the purposes of this Part, a law of another Australian State or Territory, referred to in the MPTG legislation as a *corresponding law*, is a relevant law. Additionally, the Commonwealth *Agricultural and Veterinary Chemicals Act 1997* and the *Therapeutic Goods Act 1989* are also relevant laws for this Part.

Section 731 Packaging of supplied manufacturer's packs of dangerous poisons - Act, s 59 (1) (c) (i) and (2) (c) (i)

The packaging requirements of a manufacturer's pack of a dangerous poison is set out in this section. Manufacturer's pack must be packaged in accordance with paragraphs 21 through to 27 of the SUSDP. Alternatively, a manufacturer's pack may be packaged in a container approved under section 193 of the MPTG or in a container in which the dangerous poison may be sold under a corresponding law.

Section 732 Labelling of supplied manufacturer's packs of dangerous poisons - Act, s 60 (1) (c) (i) and (2) (c) (i)

Under section 60 of the MPTG Act, a person authorised to supply a regulated substance risks committing an offence if the substance that is supplied is not appropriately labelled.

This section specifies that for the purposes of section 60 of the MPTG Act, a manufacturer's pack of a dangerous poison is labelled correctly if it is labelled in accordance with paragraphs 3 to 19 of the SUSDP or a relevant law.

It should be noted that an approval for non-standard packaging and labelling can be obtained under section 193 of the MPTG. Where this has occurred, the person to whom the approval has been granted does not need to comply with this section, provided that the terms of the approval are adhered to.

Part 19.4 Storage of dangerous poisons

Section 735 Storage of dangerous poisons - Act, s 61 (b) and (c)

Dangerous poisons must, under this provision, be stored in a part of the premises to which the public does not have access. Additionally, such dangerous poisons must be stored so that only a prescribed person, or a person under the direct supervision of a prescribed person, has access to the poison. Persons listed in column 2 of Table 740 who possess dangerous poisons are prescribed persons.

Part 19.5 Dangerous poisons registers

Section 740 Keeping of dangerous poisons registers by certain people – Act, s 48 (a) and s 50 (1) (b) and (2) (b)

Within this provision is Table 740 that lists, in column 2, prescribed persons who must keep a dangerous poisons register for all dangerous poisons in their possession. Column 3 of the same table specifies where the register is to be kept.

Section 741 Form of dangerous poisons registers – Act, s 49 (1) (b)

Under this section, each page in a dangerous poisons register must relate to a single form and strength of a dangerous poison. This means that if a single dangerous poison were possessed, but in different strength, each strength requires its own page in the register.

Where a dangerous poisons register is kept electronically, which is permissible, a separate record must be used for each form and strength of dangerous poison kept.

Section 742 Making entries in dangerous poisons registers – Act, s 51 (1) (b)

Under section 51 of the MPTG Act a person who must keep a register for a regulated substance commits an offence unless that person ensures that the details prescribed by this Regulation are recorded.

In regard to a dangerous poison, the details required to be recorded under section 51 of the MPTG Act are listed in this provision. Amongst the details for dealing with a dangerous poison that must be recorded are the nature of the dealing itself, the date of the dealing, and the form, strength and quantity of the poison dealt with, and the quantity of the poison held following the dealing.

Details to be recorded under section 742(1)(d) applies only if the dealing is receiving the poison. The details to be recorded under section 742(1)(e) applies if the dealing is supplying the poison.

This provision also makes it expressly clear that a dealing with a dangerous poison must be entered in the dangerous poisons register that a person is required to keep under this Chapter.

Section 743 Prescribed witnesses for discarding of dangerous poisons – Act, s 54 (a) and (b)

Adults are prescribed by section 743(1) as witnesses in relation to the disposal of a dangerous poison. However, section 743 also expressly excludes a person from being a prescribed witness in relation to the disposal of a dangerous poison if the person is related to, employed by, or a close friend of the person disposing of the poison. Such persons are, by virtue of their relationship with the person disposing of the dangerous poison, potentially able to be influenced by, or exert influence over, that person. Accordingly, their suitability as a prescribed witness is thereby diminished. For the same reason the supervisor of the person disposing of the dangerous poison cannot be a prescribed witness, nor can a person supervised by the person disposing of the dangerous poison.

Section 744 Changes to entries in dangerous poisons registers – Act, s 55 (2) (b)

Section 741 confirms that a dangerous poison register may be kept in hardcopy form or electronically, and addresses the form in which a dangerous poison register must be kept.

Understandably, from time to time situations may arise in which an entry in a dangerous poisons register needs to be changed, more often than not in order to correct an entry. Changes to an entry in a dangerous poisons register is permissible, provided the requirements of this section are followed.

Subsection 1 relates to changes to an entry in a paper-based dangerous poisons register. The subsection permits the person who made the entry to change the entry by signing and dating a marginal note or footnote that gives the amendment details and the date the amendment is made.

If the entry to be changed relates to the disposing of a dangerous poison, the amendment must be witnessed by a person listed in section 743, and the witness must also sign the amendment to evidence that they witnessed the change. It is not required that the person prescribed under section 743 that witnessed the disposal of the dangerous poison be the same witness to the amendment of the dangerous poisons register. However, where it is possible it is preferable.

Chapter 20 Paints

There are some paints that contain certain substances and poisons that can be highly toxic or dangerous, and thereby have the potential to be harmful if contacted directly or to contaminate food, water or even the surrounding environment. Nevertheless, some of these paints may still have special or specific, all be it limited, applications. This Chapter contains some sections that determine what usages certain paints can be used for, and some sections that instruct usages for which certain paints must not be used for. Each section within this Chapter links back to an offence contained within the MPTG Act.

Section 750 Manufacture, supply and use of paints containing white lead - Act, s 70 (1) (b), (2) (b) and (3) (b)

Section 70 of the MPTG Act contains offences for manufacturing, supplying or using paint containing white lead, also known as basic lead carbonate, unless that paint is manufactured, supplied or used in accordance with this regulation.

The only purpose permitted by this regulation for which paint containing white lead may be used is as a mirror backing, provided certain criteria are met. The first requirement is a limitation on the percentage of lead within the non-volatile content of the paint. Should the amount of lead exceed 15% of the non-volatile content, the paint does not comply with this section, and this therefore illegal and very unsafe.

Another requirement is that the paint is not applied more than 40 microns thick. This is also a requirement to minimise the danger that the applied paint may present. Should the applied paint be greater than 40 microns thick the paint does not comply with this section, and this therefore illegal and very unsafe. The final requirement is for the applied paint that contains the white lead to be further coated by a paint that does not contain lead. This requirement is intended to create a barrier between the lead-based paint that can be harmful and any person who may handle the mirror.

These requirements apply not just to persons using the paint to create the mirror, but to persons supplying the paint containing white lead. As such, if the supplier is not certain that the paint containing white lead will be used as a mirror backing, they must not supply the paint. Similarly, if the supplier suspects that the person to whom the paint is to be supplied cannot comply with the requirements of this section the paint must not be supplied.

Section 751 Manufacture, supply and use of paints for certain purposes - Act, s 71 (1) and (3)

Section 15 of the MPTG Act establishes what is the medicines and poisons standard, and the medicines and poisons standard defines what is a first schedule paint and what is a third schedule paint.

Section 71(1) of the MPTG Act contains an offence for manufacturing, supplying or using a first schedule paint in a manner prescribed by this regulation. Section 751(1) contains the usages of a first schedule paint that are prohibited through section 71(1) of the MPTG Act. Those usages include application to roofs or other surfaces that may be used for the collection or storage of potable water.
Also included is application to furniture and to fences, walls, posts, gates and to buildings, with the exception of a building that is used only for industrial purposes, for mining, or as an oil terminal. Application to premises used for the manufacture, processing, preparation, packing or serving of products for human or animal consumption is also prohibited. These prescribed applications reflect the danger of first schedule paints, and the high risk of contamination that first schedule paints pose.

Similarly, section 71(3) of the MPTG Act contains an offence for manufacturing, supplying or using a third schedule paint in a manner prescribed by this regulation. Section 751(2) contains the usages of a first schedule paint that are prohibited through section 71(3) of the MPTG Act. Those usages include application to roofs or other surfaces that may be used for the collection or storage of potable water. Also included is application to furniture and to buildings, fences, walls, posts, gates, bridges, pylons, pipelines, storage tanks or similar structures. Application to premises, equipment or utensils used for the manufacture, processing, preparation, packing or serving of products for human or animal consumption is also prohibited. These prescribed applications reflect just how dangerous schedule 3 paints are, and the extreme risk of contamination that third schedule paints present.

The elevation in maximum penalties from section 71(1) to section 71(3) of the MPTG Act is indicative of the escalating danger between first schedule paints and third schedule paints.

Both subsections in this provision apply to manufacture, supply and use. As such, it not just an offence to use a first schedule or third schedule paint on furniture, but is also an offence to supply or manufacture such paints for application to furniture. Accordingly, a manufacturer of a third schedule paint that represents that the third schedule paint is suitable for use on furniture will breach section 71(3) of the MPTG Act. Indeed, if the manufacturer does not indicate that the third schedule paint must not be applied to furniture they may even contravene section 71(3) of the MPTG Act.

Similarly, a person who supplies a first schedule paint to person knowing it will be applied to furniture will breach section 71(1) of the MPTG Act. However, the supplier may also have committed the offence under section 71(1) if the supplier is reckless as to how the paint will be applied, or even if the supplier fails to give warnings about improper applications of a first schedule paint.

Section 752 Manufacture, supply and use of paints for toys - Act, s 72 (b)

Due to several major recalls, the safety of paints used in toys has been the subject of much media and public attention in the years prior to the introduction of the MPTG legislation. The Australian and New Zealand Standard AS/NZS ISO 8124.3:2003 is a standard for safety requirements for Children's Toys. AS/NZS ISO 8124.3:2003 contains standards for children's toys in regard to general requirements, construction and, in Part 3, toxicological attributes, such as coating materials.

Accordingly, this provision permits a paint that complies with specifications for coating materials for toys contained in AS/NZS ISO 8124.3:2003 to be manufactured, supplied or used for application to toys. As the provision applies to the Standard in force from time to time, any amendment to the Standard is immediately applicable under this section.

The application of this section will have relevance to other ACT legislation. By virtue of this provision, a paint used on a toy that does not conform to AS/NZS ISO 8124.3:2003 also does not conform with this regulation, and thereby contravenes the offence contained in section 72 of the MPTG Act. By implication, a toy made with, or coated in a paint that does not conform with AS/NZS ISO 8124.3:2003 will most likely be regarded as manufactured in an unsafe manner, and may contravene the ACT Fair Trading legislation.

Section 753 Manufacture, supply and use of paints containing pesticides - Act, s 73 (b)

Under section 73 of the MPTG Act it is an offence to manufacture, supply or use a paint that contains a pesticide prescribed in this regulation. This section states the pesticides that are prescribed, and therefore effectively prohibited, by the MPTG Act. What constitutes a pesticide is, for the purposes of the MPTG legislation, set out in the SUSDP.

However, subsection 2 provides an exception to the general prohibition effected by section 73 of the MPTG Act. If a paint that contains a pesticide listed in section 753 of this regulation is for human therapeutic use, then subsection 1 of this provision, and therefore the offence in section 73 of the MPTG Act, do not apply.

Chapter 21 Prohibited and appendix C substances

The substances of most serious concern within the SUSDP, and therefore the most tightly regulated by the MPTG legislation, are prohibited substances and appendix C substances. Substances to which Schedule 9 of the SUSDP applies are generally illegal substances that are subject to abuse. For this reason such substances are prohibited substances under the MPTG legislation. Appendix C substances are substances that Appendix C of the SUSDP applies. The sale, supply and use of these substances are prohibited because of the degree of danger to health that they represent.

Part 21.1 Preliminary

Section 760 Meaning of prohibited substance – ch 21

For the purposes of Chapter 21 of this regulation, an appendix C substance is included in the meaning of prohibited substance. Appendix C substances and prohibited substances are defined in section 13 of the MPTG Act.

Section 761 Prohibited substances licences – Act, s 78 (2)

Section 78(2) of the MPTG provides that this Regulation may prescribe the types of licences that may be issued under the MPTG Act. Licences for a program of research or education relating to a prohibited substance may, through the operation of section 761, be issued.

Part 21.2 Prohibited substances research and education program licences

Division 21.2.1 Issue of prohibited substances research and education program licences

This Division provides the governance structure for the issuing of licences for research or education programs proposing to involve prohibited substance. Section 765 contains the details for the lodging of an application for such a licence and the information that must be provided to support the application.

Applications must be in writing, and signed by the applicant. Furthermore, an application must also be accompanied by a written approval of the proposed program from the person in charge of either the faculty or division of a recognised research institution at which the program would be conducted, or from the person in charge of the institution itself. Section 20(5) of the MPTG Act lists recognised research institutions, which include the University of Canberra, the ANU, the Canberra Hospital, the CSIRO, or any other entity prescribed by this Regulation.

Prohibited substances research and education program licences are issued by the Chief Health Officer, but only if the Chief Health Officer is satisfied as to the matters set out in section 766. A key consideration for the Chief Health Officer is whether the proposed program cannot be carried out without the use of the prohibited substance, and whether the program will be adequately supervised.

Section 88 of the MPTG Act sets out information that must be included in all types of licences issued under the MPTG legislation. Subsection 1(k) of that same section enables this Regulation to prescribed additional information to be included on a licence. For a prohibited substances research or education program licence that additional information is set out in section 767.

Division 21.2.2 Prohibited substances research and education program authorisations

This Division specifies the types of dealings for which a prohibited substances research and education program licence-holder is authorised, as well as the conditions that apply to all such licences. Additionally, the program supervisor and anyone participating in the program are authorised to deal with the prohibited substance to which the licence relates, provided that the dealing occurs at the premises stating in the licence.

A prohibited substances research and education program licence-holder is authorised to obtain prohibited substances in accordance with the terms of their licence. It is a further condition on a licence-holder's authorisation that all prohibited substances purchased under the licence are done so through a complying purchase order. For an Appendix C or prohibited substance a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 772.

Division 21.2.3 Other provisions - prohibited substances research and education program licences

Section 770 Approvals of dealings for prohibited substances research and education program licences – Act, s 20 (1) (c)

Under this provision, the Chief Health Officer can grant an approval to a person to deal with a prohibited substance for a research and education licence. The types of dealings that can approved under this provision are limited to obtaining the substance, possessing the substance, issuing a purchase order for the substance, and supplying the substance on a complying purchase order to the licence-holder.

For an Appendix C or prohibited substance a complying purchase order is, according to the dictionary in this Regulation, a purchase order pursuant to section 772.

An approval under this section must be in writing. Such an approval may also be conditional, or for a stated period or until a stated event transpires.

Section 771 Authorisation condition for approval-holders – Act, s 44 (1) (b) and (2) (b)

An approval-holder's authorisation under section 770 is subject the condition that filled purchase orders and records required under section 773 are kept. These records are to be kept for at two years from the date of supply, at the approval-holder's business premises.

The Chief Health Officer also has the power, under this provision, to give written approval for the records to be kept at an alternative location. This recognises commercial practicalities. For example, it may not be possible to keep the volume of records at the business premises.

Section 772 General requirements for prohibited substances purchase orders – Act, s 38 (2) (c)

Purchase orders for prohibited substances must, under this section, be signed by the person issuing the order. Furthermore, if the person issuing the purchase order amends the order at any stage, the person must record theirs initials and the date along side the amendment.

Subsection 2 specifies what information must be included in a purchase order for a prohibited substance, such as the form, strength and quantity of the prohibited substance supplied.

Section 773 Recording supply of prohibited substances on purchase orders

Under this section, a person who supplies a prohibited substance to someone else on a purchase order is required to make a written record of the supply. The information required to kept under this provision includes the date of the order, the date the order is supplied, and the form, strength and quantity of the prohibited substance supplied. For obvious reasons, the details of the person to whom the prohibited substance was supplied is also required to be recorded.

Through a comparison of the record made under this section with the purchase order to which the supply relates, discrepancies and variations should be identifiable. Identification of such variances and discrepancies may enable the identification of prohibited substances being misused, redirected or unusual supply patterns. Therefore, the keeping of such records is essential from a regulatory perspective.

Under section 11 of the *Electronic Transactions Act 2001* records can be kept in an electronic format provided certain criteria can be met. Accordingly, a requirement to keep a written record is met if the record is kept in an electronic form.

Section 774 Information for CHO about supplied prohibited substances research and education program licences – Act, s 31 (1) (a) (ii), (1) (b), (2) (a) (ii), (2) (b) and (4)

Section 774 applies if a person supplies a prohibited substance to a prohibited substances research and education program licence-holder. The section requires certain information to be given, in writing to the Chief Health Officer. The information includes the date of the supply, the name of the person to whom the substance was supplied, and the form, strength and quantity of the prohibited substance supplied. The information to be given to the CHO must be provided within 7 days of the end of the calendar month in which the supply took place.

This provision reflects the seriousness and level of public health concern associated with prohibited substances. The effect of the section is to enable the Chief Health Officer, through the information required to be provided, to monitor the details, such as quantities, of prohibited substances being used by a research and education program licence-holder.

Part 21.3 Prohibited substances registers

Section 775 Keeping prohibited substances registers by certain people – Act, s 48 (a) and s 50 (1) (b) and (2) (b)

Within this provision is Table 775 that lists, in column 2, prescribed persons who must keep a prohibited substance register for all prohibited substance in their possession. Column 3 of the same table specifies where the register is to be kept.

Section 776 Form of prohibited substances registers – Act, s 49 (1) (b)

Under this section, each page in a prohibited substances register must relate to a single form and strength of a prohibited substance. This means that if a single prohibited substance were possessed, but in different sizes, each size requires its own page in the register.

Where a prohibited substances register is kept electronically, which is permissible, a separate record must be used for each form and strength of prohibited substance kept.

Section 777 Making entries in prohibited substances registers – Act, s 51 (1) (b)

Under section 51 of the MPTG Act a person who must keep a register for a regulated substance commits an offence unless that person ensures that the details prescribed by this Regulation are recorded.

In regard to a prohibited substance, the details required to be record under section 51 of the MPTG Act are listed in this provision. Amongst the details for dealing with a prohibited substance that must be recorded are the nature of the dealing itself, the date of the dealing, and the form, strength and quantity of the substance dealt with, and the quantity of the substance held following the dealing.

Details to be recorded under section 777(1)(d) applies only if the dealing is receiving the substance. The details to be recorded under section 777(1)(e) applies if the dealing is supplying the substance.

This provision also makes it expressly clear that a dealing with a prohibited substance must be entered in the prohibited substance register that a person is required to keep under this Chapter.

Section 778 Prescribed witnesses for discarding of prohibited substances – Act, s 54 (a) and (b)

Section 778(1) lists persons who are prescribed as witnesses in relation to the disposal of a prohibited substance. However, section 778 also expressly excludes a person from being a prescribed witness in relation to the disposal of a prohibited substance if the person is related to, employed by, or a close friend of the person disposing of the prohibited substance. Such persons are, by virtue of their relationship with the person disposing of the prohibited substance, potentially able to be influenced by, or exert influence over, that person. Accordingly, their suitability as a prescribed witness is thereby diminished. For the same reason the supervisor of the person disposing of the prohibited substance cannot be a prescribed witness, nor can a person supervised by the person disposing of the prohibited substance.

Section 779 Changes to entries in prohibited substances registers – Act, s 55 (2) (b)

Section 776 confirms that a prohibited substances register may be kept in hardcopy form or electronically, and addresses the form in which a prohibited substances register must be kept.

Understandably, from time to time situations may arise in which an entry in a prohibited substances register needs to be changed, more often than not in order to correct an entry. Changes to an entry in a prohibited substances register is permissible, provided the requirements of this section are followed.

Subsection 1 relates to changes to an entry in a paper-based prohibited substances register. The subsection permits the person who made the entry to change the entry by signing and dating a marginal note or footnote that gives the amendment details and the date the amendment is made.

If the entry to be changed relates to the disposing of a prohibited substance, the amendment must be witnessed by a person listed in section 778, and the witness must also sign the amendment to evidence that they witnessed the change. It is not required that the person prescribed under section 778 that witnessed the disposal of the prohibited substance be the same witness to the amendment of the prohibited substances register. However, where it is possible it is preferable.

Chapter 22 Therapeutic goods

As the title of the legislation suggest, the MPTG Act and this Regulation cover therapeutic goods in addition to medicines and poisons. In many instances the ramifications of misuse, intentional or otherwise, or improper supply of a therapeutic good will not be as serious as those for a medicine or poison. Nevertheless, the misuse or improper supply of a therapeutic good may result in harm, so it is appropriate to regulate therapeutic goods through the MPTG legislation.

Section 800 Definitions – ch 22

For the purposes of this Chapter, corrective contact lenses, correct lenses for spectacles and plano lenses are optical devices. Plano lenses are non-corrective contact lenses. A definition of prescription specific to this Chapter is also included.

Section 801 Prescribed regulated therapeutic goods – Act, s 14, def *regulated therapeutic good*, par (b)

Section 14 of the Act defines what constitutes a regulated therapeutic good. The effect of paragraph (b) of that section is to include in the meaning of a regulated therapeutic good anything prescribed by this regulation. The purpose of section 801 is to prescribe optical devices for the purposes of section 14(b) of the MPTG Act. In this regard, the definition of an optical device under section 800 of this Chapter is applicable.

Section 802 Authorisation to supply optical devices – Act, s 74 (1) (b) and (2) (b)

Under section 74 of the MPTG Act it is an offence to supply a regulated therapeutic good to another person, or oneself, unless the person is authorised to supply the regulated therapeutic good under this regulation. What constitutes a regulated therapeutic good is defined in section 14 of the MPTG Act. Through the operation of section 800 of this regulation, optical devices are a regulated therapeutic good.

This provision gives optometrists and opticians authorisation to supply optical devices, on prescription issued by an optometrist or a doctor. The authorisation is limited to the extent necessary to practice, and if the optometrist or optician is employed, that the supply is within the scope of their employment.

Provided it is within the scope of their employment, section 802 also authorises an employee of an optometrist to sell and deliver optical devices being supplied by an authorised optometrist or optician.

Determining what is and what is not within the scope of employment will be determined based on any documented procedures and rules within a work place, a person's job description, and established practices within a workplace. Also relevant will be any orders or instructions, oral or written, issued to the employee. Some of these considerations may contradict others. For example, established practices within a workplace may not actually conform to documented procedures. In such circumstances, evaluating whether a person acted outside of the scope of their employment will require an assessment of what workplace rules and instructions prevail or dominate.

Section 803 Authorisation conditions for supplying optical devices – Act, s 75 (1) (b)

An optometrist's or optician's authorisation under section 802 of this regulation, as it applies to corrective contact lenses and corrective lenses for spectacles. is subject to conditions stated in section 803. This provision essentially operates to require that corrective lenses, be it for contacts or spectacles, are only supplied on a written prescription, and that the prescription is not more than a year old. A definition of prescription specific to the Chapter is contained in section 800.

Chapter 23 Notification and review of decisions

Chapter 9 of the Act, in conjunction with Schedule 1 of the MPTG Act, provides for the review of decisions under the MPTG Act by the Chief Health Officer . This Chapter of the Regulation provides for the review of decisions made under this Regulation.

Section 850 Meaning of *reviewable decision* – ch 23

Pursuant to this section, a decision of a kind listed in column 3 of Table 850, made by the Chief Health Officer pursuant to a section of this Regulation listed in column 2 of Table 850, is a reviewable decision. The entity that may apply for a review of the decision mentioned in column 3 of Table 850 is listed in column 4 of the same Table.

Section 851 Notice of reviewable decisions

Section 851 operates to require a person, when making a reviewable decision, to give a written notice of the decision to each entity listed in column 4 of Table 850.

Section 852 Applications for review

Section 852 makes it expressly clear that in addition to the entities listed in column 4 of Table 850, any other person who interests are affected by the decision may apply for a review of a reviewable decision.

Chapter 24 Miscellaneous

This Chapter contains some miscellaneous provisions, concerning such matters as authorisations for public employees and containers not to be used for human use.

Section 860 Authorisations for public employees – Act, s 26 (1) (b), (2) (b), s 35(1) (b), (2) (b) and s 36 (b)

Under section 860 a public employee may lawfully obtain a regulated substance and possess a regulated substance to the extent necessary for public employee to exercise a function that the person may have under the MPTG Act.

Similarly, to the extent necessary for a public employee to exercise a function under the MPTG Act, a public employee may supply a regulated substance or regulated therapeutic good to a law enforcement officer for law enforcement purposes.

The section also operates to lawfully permit a public employee to supply a regulated substance, or regulated therapeutic good, to another person for the purposes of discarding the regulated substance or regulated therapeutic good. However, the person to whom regulated substance or regulated therapeutic good is supplied must be authorised to obtain it. Again, the authority provided by this section is limited to the extent necessary for public employee to exercise a function that the person may have under the MPTG Act.

The *Legislation Act 2001* defines who is a public employee. In the majority of cases a public employee is a public servant. However, a public employee also includes a person employed by a territory instrumentality, a statutory office-holder, or a person employed by a statutory office-holder. Accordingly, it is through this provision that certain public servants are lawfully able to handle a regulated substance through the course of their employment.

Section 861 Other authorisations for public employees – Act, s 20 (1) (a), (2) (a) and s 74 (1) (b)

Section 861 operates to enable the Chief Health Officer to issue a permit to a public employee enabling that person to lawfully deal with a regulated substance or regulated therapeutic good, provided the dealing is in accordance with the permit. Such permits may identify the public employee by name, or by position held.

A permit issued by the Chief Health Officer must be in writing and contain a unique identifying number, the full name of the permit holder, and conditions to which the authorisation given by the permit is subject. The type, or types of regulated substance or regulated therapeutic goods authorised to be dealt with must also be stated on the permit, together with the types of dealings. An expiry term for the permit is also mandated.

The meaning of *deal* in regard to a regulated substance is defined by section 19 of the MPTG Act.

The *Legislation Act 2001* defines who is a public employee. In the majority of cases a public employee is a public servant. However, a public employee also includes a person employed by a territory instrumentality, a statutory office-holder, or a person employed by a statutory office-holder. Accordingly, it is through this provision that certain public servants are lawfully able to handle a regulated substance through the course of their employment.

Section 862 Certain containers not to be used for human-use substances – Act, s 63 (1) (b)

Section 63 of the MPTG Act contains an offence for supplying a human use substance in a container where that container is prescribed by this Regulation. This section instructs that containers of a kind mentioned in paragraphs 21, 22 or 23 of the SUSDP are prescribed for the purposes of section 63 of the MPTG Act. Accordingly, it is an offence to supply a human use substance in such a container.

Section 863 Displacement of Legislation Act, s 47 (6)

Through this provision, the normal operation of section 47(6) of the *Legislation Act 2001* is displaced in regard to Australian and New Zealand Standard AS/NZS ISO 8124.3:2003. Accordingly, AS/NZS ISO 8124.3:2003 does not need to be placed on the ACT Legislation Register as a notifiable instrument. This avoids issues around copyright infringement that might arise from the reproduction of the standard on the ACT Legislation Register.

Section 864 Amendments of Health Professionals Regulation 2004

This provision directs that consequential amendments to the Health Professionals Regulation 2004 are made as set out in Schedule 6 of this Regulation.

Chapter 30 Transitional

Given the complexity of reforming a number of Acts and regulations and the necessity of allowing licences and authorisations made under those Acts to continue until replaced by new licences and authorisations, transitional provisions have been included in the MPTG Act.

Part 14.3 (Transitional – licences and authorisations) of the MPTG Act provides that licences that were in force under the *Drugs of Dependence Act 1989*, the *Poisons Act 1933* and the *Poisons and Drugs Act 1978* immediately prior to the commencement of the MPTG Act are to be regarded as a licence under the MPTG Act as prescribed by this Regulation. This enables a smooth transition from the various pieces of legislation being repealed and replaced to the new legislation, and avoids the need for the reissue of a plethora of licences immediately upon the commencement of the new Act.

This Chapter contains transitional provisions that link back to Part 14.3 of the MPTG Act.

Section 1000 Definitions – ch 30

This provision simply specifies that within Chapter 30 of this Regulation a reference to DODA means the ACT *Drugs of Dependence Act 1989*, and a reference to the Poisons and Drugs Act means the ACT *Poisons and Drugs Act 1978*.

Section 1001 DODA wholesaler's licences – Act, s 520 (2)

Pursuant to this provision, a wholesaler's licence for a controlled medicine under the ACT *Drugs of Dependence Act 1989* will continue to operate under the MPTG legislation as if it were a medicines wholesalers licence.

Where an expiry date or term on the licence is stipulated, the licence will continue under the MPTG legislation for the same period. Where no expiry or term on the licence is stated, the licence will remain in force for a period of six months from the date of commencement of the MPTG Act. The MPTG clearly instructs that licences preserved by these transitional provisions continue to be subject to any condition to which the licence was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1002 Poison's Act licences – Act, s 520 (2)

Pursuant to this provision, a licence under the *Poisons Act 1933* will continue to operate under the MPTG legislation as if it were a licence to possess for sale and to sell the regulated substance stated on the licence under the *Poisons Act 1933*.

Where an expiry date or term on the licence is stipulated, the licence will continue under the MPTG legislation for the same period. Where no expiry or term on the licence is stated, the licence will remain in force for a period of six months from the date of commencement of the MPTG Act. The MPTG clearly instructs that licences preserved by these transitional provisions continue to be subject to any condition to which the licence was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1003 Poisons and Drugs Act licences – Act, s 520 (2)

A manufacturer's licence under the ACT *Poisons and Drugs Act 1978* for a dangerous poison will continue to operate under the MPTG legislation as if it were a dangerous poisons manufacturer's licence. Similarly, a vendor's licence under the ACT *Poisons and Drugs Act 1978* for a dangerous poison will continue to operate under the MPTG legislation as if it were a dangerous poisons supplier's licence.

Where an expiry date or term on the licence is stipulated, the licence will continue under the MPTG legislation for the same period. Where no expiry or term on the licence is stated, the licence will remain in force for a period of six months from the date of commencement of the MPTG Act. The MPTG clearly instructs that licences preserved by these transitional provisions continue to be subject to any condition to which the licence was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1004 DODA authorisations – Act, s 522 (2)

An authorisation for a controlled medicine under section 33 of the ACT *Drugs of Dependence Act 1989* will, by virtue of this section, be taken to be a controlled medicines research and education program licence for the same medicine, or medicines, under the MPTG legislation.

Where an expiry date or term on the authorisation issued under the ACT *Drugs of Dependence Act 1989* is stipulated, the new licence will continue under the MPTG legislation for the same period. Where no expiry or term on the authorisation is stated, the new licence will remain in force for a period of six months from the date of commencement of the MPTG Act. The MPTG clearly instructs that authorisations that become licences under the MPTG through these transitional provisions continue to be subject to any condition to which the authorisation was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1005 Poisons and Drugs Act authorisations – Act, s 522 (2)

An authorisation for a dangerous poison under section 26 of the ACT *Poisons and Drugs Act 1978* will, by virtue of this section, be taken to be a dangerous poison research and education program licence for the same poison, or poisons, under the MPTG legislation.

Where an expiry date or term on the authorisation issued under the ACT *Poisons and Drugs Act 1978* is stipulated, the new licence will continue under the MPTG legislation for the same period. Where no expiry or term on the authorisation is stated, the new licence will remain in force for a period of six months from the date of commencement of the MPTG Act.

The MPTG clearly instructs that authorisations that become licences under the MPTG through these transitional provisions continue to be subject to any condition to which the authorisation was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1006 Public Health (Prohibited Drugs) Act authorisations – Act, s 522 (2)

An authorisation under section 6A of the ACT *Public Health (Prohibited Drugs) Act 1957* will, by virtue of this section, be taken to be a prohibited substances research and education program licence for the same regulated substance, or substances, under the MPTG legislation.

Where an expiry date or term on the authorisation issued under the ACT *Public Health (Prohibited Drugs) Act 1957* is stipulated, the new licence will continue under the MPTG legislation for the same period. Where no expiry or term on the authorisation is stated, the new licence will remain in force for a period of six months from the date of commencement of the MPTG Act. The MPTG clearly instructs that authorisations that become licences under the MPTG through these transitional provisions continue to be subject to any condition to which the authorisation was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1007 DODA approvals to prescribe drugs of dependence – Act, s 531 (2)

An approval under section 69 of the *Drugs of Dependence Act 1989* will, by virtue of this section, be taken to be a controlled medicines approval under Division 13.1.3 of the MPTG Act for the controlled medicine to which the approval relates.

The new approval will continue under the MPTG legislation for the unexpired period of the original approval. The MPTG clearly instructs that the approval will continue to be subject to any condition to which the approval was subject immediately before the commencement of the MPTG legislation. Such conditions remain in force unless the condition ceases to have effect, or the condition is removed or varied under the MPTG Act.

Section 1008 Expiry – ch 30

Section 1008 provides that Chapter 30 expires on 31 March 2010. The purpose of this provision is to ensure that transitional provisions are not retained on the statute books for longer than is necessary.

Schedule 1 Medicines – health related occupations authorisations

It is through Schedule 1 that the various health-related occupations are assigned authorisation to deal with medicines.

There are 13 Parts to Schedule 1, each dealing with a different health-related occupation. These range from ambulance services and officers in Part 1.1, to doctors (Part 1.3) through to optometrists (Part 1.8) and finally to veterinary surgeons and their employees at Part 1.13. Even opioid dependence treatment centres operated by the Territory are addressed in the Schedule.

Under each Part the person authorised is listed in column 2, and what that person is authorised to do is specified in column 3.

Schedule 2 Optometry medicines

Part 1.8 of Schedule 1 of this Regulation sets out the authorisations relating to optometrists and employees of optometrists. Several of those authorisations are subject to conditions to which this Schedule relates.

Schedule 2 contains two tables; Table 2.1 and Table 2.2. Table 2.1 identifies general optometry medicines and the prescribed purposes for which those medicines may be used. Table 2.2 sets out restricted optometry medicines and the medicine groups into which those restricted optometry medicines fall.

Schedule 3 Designated appendix D medicines – standing approvals

The focus of Schedule 3 is standing approvals for designated Appendix D medicines. The Schedule consists of two Parts. Part 3.1 of the Schedule defines the four different approval conditions that are then placed upon certain specialist doctors by Part 3.2. Appendix D medicines are listed in the SUSDP.

Schedule 4 Dangerous poisons – manufacturing etc authorisations

Column 3 of Schedule 4 identifies a range of dangerous poisons. The people who may have a legitimate reason to access that dangerous poison are listed in column 2, and the prescribed purpose for which those persons may access the dangerous poison can be found in column 4. For example, there can be little argument that cyanides are a dangerous poison. However, cyanides are used in the manufacturing of gold jewellery and as such access to this dangerous poison is necessary for jewellers.

It is through this Schedule and section 690 of this Regulation that persons listed in column 2 of Schedule 4 are duly authorised to deal with the corresponding dangerous poison in column 3.

Schedule 5 Requirements for storage receptacles

Part 11.4 of this Regulation imposes additional requirements on certain persons in regard to the storage of controlled medicines, be it within medicine cabinets, safes, strong rooms and vaults.

This Schedule sets out requirements for the construction and installation of medicine cabinets, safes, strong rooms and vaults for persons who are required by Part 11.4 to keep controlled medicines safely and securely stored.

Schedule 5 is specific in regard to matters such as lock requirements for medicine cabinets, the thickness of the doors and body of medicine cabinets, and even the length of time in which a medicine vaults should be able to withstand attempts to enter it using tools, torches or explosives.

Schedule 6 Amendments of Health Professionals Regulation 2004

This Schedule sets out a number of consequential amendments to be made to the Health Professionals Regulation 2004, primarily to Schedules 5, 11 and 15. Amongst the changes is a new definition of *community pharmacy* to replace the definitions of *community pharmacy* and *institution* currently existing in the Health Professional Regulation 2004.

Dictionary

The Dictionary contains definitions of terms used throughout the Regulation. Definitions within the Dictionary include *bioequivalent, disability care, in-patient, trainee* and *young detainee*. Terms that frequently appear for which dictionary definitions are provided include *CYP detention place, first-aid kit, intern,* and *manufacturer's pack.*