ACIL ALLEN

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Report to NSW Ministry of Health

Medicines, Poisons and Therapeutic Goods Regulation 2023

Regulatory Impact Statement

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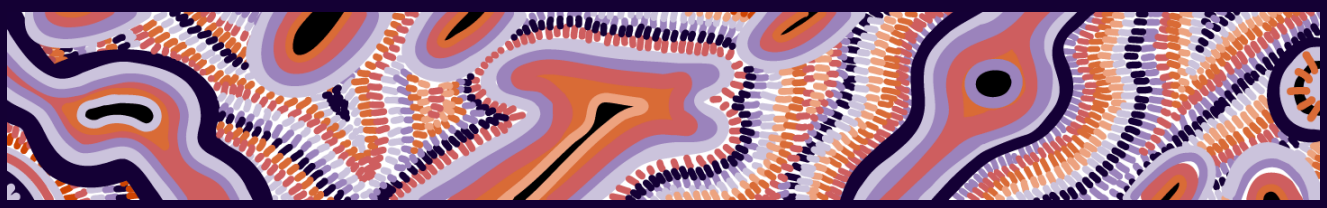


Goomup, by Jarni McGuire

Contents

Contents

Figures

Tables

Contents

Boxes

Glossary

AHPRA	Australian Health Practitioner Regulation Agency
AIHW	Australian Institute of Health and Welfare
AMS	Authority Management System
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARTG	Australian Register of Therapeutic Goods
DMTA	Drug Misuse and Trafficking Act 1985
GP	General Practitioner
GMP	Good Manufacturing Practice
ICD	International Classification of Diseases
ICU	Intensive Care Unit
MPTG	Medicines, Poisons and Therapeutic Goods
MPTGA	Medicines, Poisons and Therapeutic Goods Act 2022
MPTGR	Medicines, Poisons and Therapeutic Goods Regulation [DRAFT, for consultation]
NDRI	National Drug Research Institute
NSW	New South Wales
ODT	Opioid Dependence Treatment
OMEDD	Oral Morphine Equivalent Daily Dose
OTAC	Opioid Treatment Accreditation Course
OTP	Opioid Treatment Program
PSA	Pharmaceutical Society of Australia
PBS	Pharmaceutical Benefits Scheme

PBAC	Pharmaceutical Benefits Advisory Committee
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PTGA	*Poisons and Therapeutic Goods Act 1966*
PTGR	*Poisons and Therapeutic Goods Regulation 2008*
RIS	Regulatory Impact Statement
RBM	Regulatory Burden Measurement (Framework)
TGA	Therapeutic Goods Administration

Executive summary

Medicines, poisons (chemicals), and therapeutic goods (MPTGs) are essential to people's lives. However, they can also pose a risk to the health and safety of individuals when used inappropriately. To protect public health and safety, these substances and goods are regulated both at the Commonwealth and state/territory levels. Broadly:

- Commonwealth laws regulate:
  - how medicines and poisons legitimately come to be in Australia. For example, the Commonwealth licences: the cultivation of narcotic plants and the production and manufacture of narcotic drugs from narcotic plants for medicinal purposes or for research, the manufacture of medicines and other therapeutic goods, and the importation of such goods
  - the quality, safety or efficacy of medicines through registration or listing, or otherwise through approval, authorisation or exemption from registration or listing.

  In addition, in the interest of national uniformity regarding the control of medicines and poisons, the Commonwealth also provides a National Poisons Standard, established under the *Therapeutic Goods Act 1989* (Cth). The National Poisons Standard lists substances with similar risks under specific schedules. Each Schedule contains a list of substances that share similar risks, for which control measures are recommended to reduce the risks. In the interest of public health and safety, substances identified in these schedules can have restrictions placed upon their supply to minimise the misuse and abuse of such substances.[1] States and territories, including NSW, have generally adopted the Schedules and applied the recommended controls for each Schedule, subject to variations.
- In NSW, MPTGs are regulated by the *Poisons and Therapeutic Goods Act 1966* (PTGA) and the *Poisons and Therapeutic Goods Regulation 2008* (PTGR). The PTGA and PTGR mainly regulate:
  - the supply within, and from, NSW of medicines and poisons, being substances listed in the Schedules (scheduled substances)
  - activities such as the issuing of prescriptions, storage, labelling, packaging, record keeping, disposal, administration, and use of scheduled substances
  - who have access to scheduled substances to reduce opportunities for misuse, including their diversion to the illicit supply chain.

After a review of the PTGA and PTGR by the NSW Ministry of Health (the Ministry), the new *Medicines, Poisons and Therapeutic Goods Act 2022* (the MPTG Act) passed Parliament in November 2022. On commencement, the Act will update and modernise the PTGA and make a

[1] Australian Government 2023, *Explanatory statement – Therapeutic Goods Act 1989*. Federal register of legislation. Accessed March 2023: https://www.legislation.gov.au/Details/F2023L00067/Explanatory%20Statement/Text

range of changes to the existing legislative framework governing scheduled substances and therapeutic goods.

The draft *Medicines, Poisons and Therapeutic Goods Regulation 2023* (the MPTG Regulation) would support the operation of the MPTG Act. The PTGA and the PTGR will be repealed when the new MPTG Act and its regulation commence.

The MPTG Act sets out the framework to regulate activities involving scheduled substances and certain therapeutic goods. The objectives of the MPTG Act are to:

a) regulate activities involving scheduled substances and other prescribed therapeutic goods to protect public health and safety
b) use the Commonwealth Poisons Standard as the basis for classifying and regulating certain substances
c) complement the Commonwealth laws that regulate therapeutic goods, including by providing for certain Commonwealth laws to apply as a law of NSW in relation to the activities of persons who are not corporations
d) authorise certain activities involving scheduled substances and other prescribed therapeutic goods, including when the activities are prohibited under another law
e) provide for effective administration and enforcement mechanisms in relation to scheduled substances and other prescribed therapeutic goods.

The Medicines, Poisons and Therapeutic Goods Regulation 2023

The proposed MPTG Regulation would support the MPTG Act by making provisions relating to:

— wholesale supply of medicines/poisons
— obtaining a wholesale supply of medicines/poisons
— non-wholesale supply of medicines/poisons
— issuing prescriptions for medicines
— administration of medicines
— specific controls relating to higher-risk substances (such as for certain prescription-only medication and drugs of addiction), substances used for cosmetic purposes, and substances that are subject to additional controls and for which the prescribing/dispensing is 'monitored' on SafeScript NSW
— records of supply
— cleanliness requirements (including preparation and handling of substances)
— storage, packaging and labelling of medicines/poisons.

The *Subordinate Legalisation Act 1989* requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation before a principal statutory rule is made.[2] ACIL Allen has been engaged by the Ministry to prepare the RIS for the MPTG Regulation.

Objectives sought to be achieved by the Draft MPTG Regulation

The objective of the MPTG Regulation is to support the purpose of the MPTG Act and minimise the risks to the public and patient safety related to misuse and abuse of medicines and poisons and the risk of diversion of high-risk substances to the illegal supply chain.

[2] Parliamentary Counsel's Office 2018, *Information Sheet on the Staged Repeal of Statutory Rules*, https://www.pco.nsw.gov.au/corporate/Staged_repeal_of_statutory_rules_information.pdf, accessed 8 June 2023.

Overall, the key objectives of the MPTG Regulation can be seen as to:

— provide regulatory support and administrative detail for the operation of the MPTG Act

— protect public health and safety through the provision of a framework for adequate monitoring and control of activities involving scheduled substances and other prescribed therapeutic goods.

Options considered

The following options have been considered in this RIS:

— ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the PTGR sunset and not replace it with a new Regulation.

— ***Option 1*** — this option entails remaking the PTGR without any changes to align with the new MPTG Act (the *status quo* option).

— ***Option 2*** — this option entails making the proposed MPTG Regulation.

The key changes in the draft MPTG Regulation (compared to the status quo – the PTGR) relate to:

— more regular periodical inventory of stock of drugs of addiction

— wholesale supply of medicines and poisons in the absence of a wholesaler licence in a wider range of circumstances

— licensing of retail supply and wholesale supply of certain Schedule 7 substances

— restrictions on administration of Schedule 2, 3, 4 and 8 substances

— compliance standards for the Opioid Treatment Program

— approval to administer/prescribe/supply Schedule 8 substances (as distinct from the current authority requirements), with approval requirements more targeted to risk

— approval to administer/prescribe/supply certain Schedule 4 substances (as distinct from the current authority requirements) with approval requirements aligning more closely with Commonwealth recommendations, and compounding authority required under certain circumstances

— specific approval number requirements for prescriptions for certain Schedule 4 and 8 substances

— new compounding controls on products required to be sterile and authority requirements for a dentist, veterinary practitioner or medical practitioner who seeks to compound a Schedule 8 or Schedule 4D substance for non-topical use

— new restrictions to emergency use provisions

— clarifying the powers developed in the MPTG Act, including to specify which offences would be subject to on-the-spot fines / penalty infringement notices

— increased retail and wholesale supply licence fees, fees applying to an obtain licence, new fees applying to retail supply and wholesale supply of certain Schedule 7 substances, and fees applying to amend an existing licence.

These proposed changes are summarised in Table ES 1 and discussed in more detail in Chapter 5 (note that from here onwards, scheduled substances may be denoted with and 'S' and the schedule number – i.e. S8 denotes Schedule 8 substances).

Table ES 1 Summary of key regulatory changes contained in the draft MPTG Regulation

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
1. Periodical inventory of stock of drugs of addiction (Schedule 8 substances)	The PTGR requires people authorised to be in possession of a drug of addiction (Schedule 8 substance) to keep a drug register which sets out the stock they hold of those substances. In addition, Clause 118 of the PTGR requires that the person responsible for keeping this drug register to do an inventory of that stock twice per year in March and September.	The MPTG Regulation would increase the number of times that an inventory of stock of drugs of addiction must be taken to every month.	The purpose of this change is to reduce the risk of diversion of these substances, as there are many instances in which these substances are lost, stolen, and diverted for personal use or trafficking purposes. The change would also help to identify losses more quickly, which would assist in investigating diversion. Since the original requirements for 6 monthly checks in the PTGR (which go back over 40 years), there have been significant increases in the prescribing and dispensing of Schedule 8 substances. A community pharmacy may manage thousands of Schedule 8 movements in a six-month period. This means that being able to ascertain missing drugs in the register over a six-month period becomes problematic. There are now over 2,000 lost/stolen drug reports received by the Ministry each year.
2. Wholesale supply of medicines/poisons	**Wholesale supply** Currently under the PTGR, generally only holders of wholesaler's licences are authorised to wholesale supply[3] a scheduled substance and wholesalers can only supply to a person who is able to obtain the substances under the PTGA/PTGR. Pharmacies are only allowed to wholesale supply in a very limited number of circumstances, which include: – Wholesale supply to a master of a vessel if the vessel is about to go on a voyage and needs it to supply to someone in the vessel.	**Wholesale supply** It is proposed that the draft MPTG Regulation includes changes to the circumstances in which a person/entity can wholesale supply medicines / poisons in the absence of a wholesaler's licence. In particular, the draft Regulation allows pharmacies to wholesale supply in the following circumstances (which are not included under the existing framework), in addition to the circumstances already allowed under the PTGR: – where there is a change in ownership or in relation to the bankruptcy, liquidation or external administration of the pharmacy (S2, S3, S4, S8)[4]	The proposed changes in the MPTG Regulation recognise contemporary business processes and clinically safe practices. Allowing supply of certain scheduled substances between community pharmacies where there is an owner in common would facilitate business practices.

[3] Supply by wholesale means supply for the purposes of resupply.

[4] Under the Health Practitioner Regulation National Law:
- A person can't carry on a pharmacy business unless (amongst other requirements) all holders of a financial interest in the pharmacy business are registered pharmacists.
- A pharmacist must not own or have a financial interest in more than 5 pharmacy businesses in NSW.

Given this, it is not expected that wholesaling would occur between any more than five pharmacy businesses.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
	– Wholesale supply to an authorised practitioner for the purposes of an emergency supply or emergency supply by a veterinary practitioner. – Wholesale supply of limited substances to a first aider for first aid treatment. – Wholesale supply to a nurse/midwife immuniser for vaccine administration in the pharmacy premises. – Wholesale supply of a specific substance to another pharmacy for a specific patient who needs it. **Clinical samples** Currently, a manufacturer or wholesaler, or their agent, engaged in the manufacture or wholesale of any poison or restricted substance for therapeutic use can supply free samples provided such distribution occurs in a manner approved by the Secretary and to a person authorised to receive the substance (such as a medical practitioner).	– where the substance is within 6 months of expiry and not reasonably likely to be used by the pharmacy (S2, S3, S4 but not S4D or S8) – where the pharmacy has the exact ownership structure as the other pharmacy (S2, S3, S4 but not S4D or S8) – where it is to a private health facility or public health entity for a specific patient who needs it (or the return of such stock to the original supplying pharmacy from the receiving pharmacy) – to first aiders (specified additional first aid medication to that already provided for in the PTGR) – to masters of vessels and racing yachts, subject to specific threshold requirements being met. **Clinical samples** The following changes are proposed to samples: – Samples of Schedule 8 and Schedule 4D substances would not be authorised. – Any supply of samples of Schedule 2, 3, or 4 (not 4D) substances must only occur where the supply is otherwise authorised under the Act (such as from a licensed wholesaler to a medical/nurse practitioner) and the supplier receives a written request in the approved form from the health practitioner. These changes would apply to health practitioners and veterinary practitioners (i.e., both health practitioners and veterinarians would be required to fill out a written order in an approved form to receive samples).	The purpose of this change is to recognise the higher risk profile of S4Ds and S8s, including for diversion of these substances for personal use or trafficking purposes. The proposed change also seeks to ensure the integrity/transparency of the supply chain, including by requiring health/vet practitioner orders for supply of samples of Schedule 2, 3, or 4 (not 4D) from wholesalers.

	Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
3.	Retail supply and wholesale supply of Schedule 7 substances listed in Appendix J of the National Poisons Standard	The PTGR prohibits the supply of a Schedule 7 substance without authorisation, but not if the supply is by wholesale. Parallel to the PTGR authorising requirements, the wholesale licencing obligations in the PTGA are hinged to substances being used for therapeutic use. Schedule 7 substances are not used therapeutically, which means the supply by wholesale of Schedule 7 substances can occur without a licence in NSW, provided any relevant PTGR requirements are complied with (such as an authorisation). .	The draft MPTG Regulation includes a new requirement for persons/entities to be licenced if they seek to retail supply substances that are listed in Schedule 7 Appendix J of the National Poisons Standard (these are dangerous poisons such as cyanide and arsenic). The draft MPTG Regulation also clarifies that the requirement for a licence to wholesale supply a Schedule 7 substance in the Act only applies if the substance is listed in Appendix J of the National Poisons Standard. A person is not subject to the relevant wholesale and non-wholesale offences if the supply is to a person, or for resupply to a person, who is already authorised to possess or use the substance under the *Pesticides Act 1999*.	A Schedule 7 substance is a substance with a high potential for causing harm at low exposure and therefore, its availability, possession, storage, and use needs to be proportionately regulated. There is scope to strengthen the current regulation of Schedule 7 substances and to more closely align with the recommendations in the National Poisons Standard. The NSW Coroner has previously highlighted concerns about the current controls in relation to Schedule 7 substances such as cyanide, arsenic and strychnine. Further, the NSW Ministry of Health's A/g Chief Pharmacist has previously given evidence at two coronial proceedings in relation to diversion of cyanide which was ultimately used for suicide. The A/g Chief Pharmacist gave evidence in proceedings that NSW would be considering how to mitigate risks with Schedule 7 substances, including in relation to closer alignment with the National Poisons Standard recommendations.
4.	Restrictions on administration of schedule 2, 3, 4 and 8 substances	The PTGA does not expressly include administration in the definition of supply; however, in some provisions of the PTGR, it is implied that administration is considered supply. The PTGR does however expressly regulate administration of Schedule 4 and 8 substances in certain settings, such as hospitals, managed correctional centres and private health facilities, and administration of certain high-risk substances (such as Schedule 4D substances).	The MPTG Regulation restricts the circumstances in which a person can administer[5] a Schedule 2, 3, 4, and 8 substances to another person. While the old framework included restrictions in relation to non-wholesale supply of medicines (which could sometimes be read to include a restriction on administration) the draft Regulation creates explicit prohibition and new offences that applies more uniformly across scheduled substances, which are subject to exceptions (for example for health	The administration of certain medicines can be performed by a variety of people, including medical practitioners, nurse practitioners, nurses, paramedics, dentists, first aid officers and carers. Administration to other persons also occurs in a variety of different circumstances and settings, for example in hospitals, a GP clinic, workplaces, and in homes. Due to the variety of people who need to be able to administer medicines, and the different circumstances in which administration may occur, the draft MPTG

[5] Administer is defined in Schedule 3 of the Medicines, Poisons and Therapeutic Goods Act 2022 to mean: administer, in relation to therapeutic goods—

(a) means—

(i) to introduce into, or apply to, the body of a human or animal by any means a dose of the goods, or

(ii) to give a dose of the goods to a human to be taken immediately, but not to give a dose to be taken at a later time, and

(b) does not include a prescribed thing.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
		practitioners and carers who administer medicines). Under the draft MPTG Regulation, there would be a blanket offence for administering a Schedule 2, 3, 4, and 8 substance to another person (subject to carve-outs for certain persons) that is not limited to certain settings and which applies to Schedule 2, 3, 4 and 8 substances. There would be specific record keeping requirements for administration in settings such as hospitals, residential care facilities, private health facilities, opioid treatment clinics, and managed correctional centres. Additional details of the proposed restrictions and carve-outs for administration of Schedule 2, 3, 4 and 8 substances are included in Table 5.3 in Chapter 5.	Regulation creates consistent parameters around lawful administration of scheduled substances, with additional record keeping requirements applying in certain settings (such as a hospital, private health facility, managed correctional centre, residential care facility and opioid treatment clinic).
5. Compliance standards for Opioid Treatment Program	The NSW OTP provides opioid replacement therapy for people who are dependent on opioids such as heroin, morphine and oxycodone. It gives people the chance to manage their illicit or problematic use of opioids and reduce the harms that come about from such use. There are different types of drug treatments available and assessment by an authorised doctor or nurse practitioner is required to determine which treatment is the most suitable. Under the current regulatory framework: – The PTGA requires medical practitioners and nurse practitioners to obtain authorisation from the Health Secretary prior to prescribing or supplying any Schedule 8 medicine to a "drug dependent person". This means that the prescribing or supply of Opioid Dependence Treatment (ODT) to any drug dependent person under the NSW OTP must be assessed by the Health Secretary for appropriateness. – A further current control, to minimise congregation of OTP patients near pharmacies, Clause 92(1) of	Rather than requiring an approval/authorisation, the MPTG Act now provides that the OTP scheme will be moving to registration scheme, under which a medical practitioner or nurse practitioner seeking to prescribe/supply/administer ODT to a patient does not need an approval/authorisation, and only needs to register in relation to that patient. In addition, pharmacies must also register under the OTP scheme in order to be able to dispense under the program. Consistent with the existing practice that occurs via policy guidelines, this will allow a pharmacy to register as a dosing point and in turn allow medical practitioners and nurse practitioners to identify pharmacy dosing points that their patients can attend to receive their ODT dose. Registration by a doctor or nurse practitioner to supply/prescribe/administer ODT to a patient would not be required in certain situations, including: – where the administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds a registration, by:	The broad goal of opioid dependence treatment is to reduce harm due to non-medical use of opioids. To achieve this broad goal, the OTP takes a patient centred approach. This involves using treatment programs that incorporate ODT, such as methadone and buprenorphine treatment, which can lead to psychological stability, improved control over drug use, and eventual abstinence from opioid drugs. The registration scheme seeks to increase transparency of supply under the OTP without creating barriers to access via an approval process. Regulatory control and patient safety would be maintained through the use of regulatory tools such as Real Time Prescription Monitoring (SafeScript NSW) and the Authority Management System (AMS, under development). The Authority Management System would be accessible to the practitioners seeking to register to prescribe, supply, or administer ODT for their patient. The regime would ensure only one medical practitioner or nurse practitioner is providing care to an individual patient, and that the patient only receives one treatment dose, whether this is by oral

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
	the PTGR limits retail pharmacies to dosing 65 patients per day. This cap was instituted to address perceived amenity concerns. The reason an authority is required is to ensure there is only one practitioner prescribing/supplying to a patient. Only a medical practitioner/nurse practitioner may prescribe/supply ODT because these are Schedule 8 medicines (and this is the recommended control for this category under the Poisons Standard).	– a practitioner on the same premises (including a correctional centre) as the practitioner holding the approval, or – by a practitioner nominated by the practitioner who is registered; or – where the administration/supply/or prescription is to initiate or continue treatment to an inpatient or emergency department presentee in a public hospital (other than a public OTP clinic) or a private health facility; or – where the administration/supply/or prescription is for the purpose of continuing treatment of an OTP patient in the 21 days after their release from a correctional centre. The draft MPTG Regulation would remove the 65-patient cap for retail pharmacies, and instead require pharmacies to comply with enforceable OTP standards. Separate enforceable OTP standards would also apply to medical practitioners and nurse practitioners prescribing/supplying/administering ODT to a patient. The enforceable OTP standards, which are currently being developed, are anticipated to require pharmacies to develop and comply with an amenity plan if they seek to dose more than 80 OTP patients per day (excluding patients who are not daily-dosing with OTP treatment, e.g., depot buprenorphine). Additional details of the proposed compliance standards are provided in Section 5.3.5 in Chapter 5.	administration per day, or by long-acting depot injection. The cap of 65 daily patients for pharmacies was legislated in the context of a model of care that required patients to attend daily for supervised doses of methadone. There were some community concerns about the impact of large numbers of patients congregating in the retail area of a pharmacy. The proposed removal of the dosing cap for pharmacies reflects the availability of new opioid agonist medications with improved safety profiles that are more suitable for unsupervised dosing. With fewer patients needing to attend pharmacies daily to receive treatment, concerns about congregation of large numbers of people may no longer be relevant.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
6. Circumstances where a practitioner would require an approval to administer/prescribe/supply a Schedule 8 substance	The current regulatory framework creates sub-classes of Schedule 8 substances. The current controls for these sub-classes in the PTGA/PTGR framework are set out below. – *Type A Drugs of Addiction*— a medical practitioner or nurse practitioner requires authority to supply or prescribe a Type A drug of addiction. – *Type B Drugs of Addiction* — a medical practitioner or nurse practitioner requires authority to supply or prescribe if it will result in the patient having >2 months continuous supply/prescription of a Type B drug of addiction. – *Type C Drugs of Addiction* — a medical practitioner or nurse practitioner requires authority to supply or prescribe if it is to a patient who is drug dependant. – *Unregistered Type C Drugs of Addiction* — only a medical practitioner can issue a prescription for, or supply, for the purposes of a clinical trial, and must hold an authority to do so. The PTGA and PTGR create specific obligations in relation to prescription and supply of Schedule 8 substances for OTP. OTP applies to buprenorphine and methadone (which are both Type B Drugs of Addiction).	Sections 68 and 69 of the MPTG Act set out that a practitioner is required to hold an approval to administer/supply/prescribe Schedule 8 substances (and other prescribed substances) in the circumstances set out in the MPTG Regulation. In general, the draft MPTG Regulation would require that an approval is sought by a medical practitioner or nurse practitioner (and in certain cases, by a vet) in the following circumstances (the proposed controls are often similar to the controls under the PTGA and the PTGR, but there have been some adjustments, including new controls to better address risk. Additional details of the proposed controls and their rationale are included in Table 5.6 in Chapter 5. – Supplying/prescribing/administering any Schedule 8 substance (i.e., a drug of addiction) to a patient who has substance dependence, unless an exemption applies (for example, for palliative care). – Supplying/prescribing/administering specified stimulant Schedule 8 substances (dexamfetamine, lisdexamfetamine, methylphenidate) unless an exemption applies (for example, certain specialties of medical practitioner do not need to have an approval). – Supplying/prescribing/administering, N,*α*-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and psilocybine unless an exemption applies. – Supplying/prescribing/administering any Schedule 8 in an injectable or intranasal preparation, alprazolam, flunitrazepam, methadone for > 3 months unless exempted. – Supplying/prescribing/administering fentanyl, hydromorphone, morphine, or oxycodone in a dose > 100mg Oral Morphine Equivalent Daily Dose (OMEDD) unless exempted.	Schedule 8 substances are drugs of addiction that should be available for therapeutic use but require restriction on manufacture, supply, distribution, possession and use with an aim to reduce abuse, misuse and physical or psychological dependence. In 2022, the Ministry held workshops with a number of stakeholders to scope views on necessary controls in relation to the administration, prescription and supply of certain Schedule 8 substances in high-risk circumstances. The key controls proposed to be included in the MPTG Regulation reflect the results of this consultation process.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
		OTP methadone and buprenorphine will move from authority to registration. The prescribing, supply and administration of methadone or buprenorphine for the purposes of the OTP is recognised as appropriate medical treatment, therefore seeking approval is not required. However, controls should be in place to ensure the patient only receives one dose per day (i.e., to avoid double dosing, thereby minimising diversion and optimising treatment). The registration scheme seeks to ensure this by minimising risk and increasing the transparency of prescribing and, significantly, supply and administration under the OTP scheme, without creating barriers to access via an approval process.	
7. Circumstances where a practitioner would require: – an approval to administer/prescribe/supply a Schedule 4 substance; or – an authority to compound/manufacture a Schedule 4 substance.	Currently, approval to prescribe, supply or administer Schedule 4 substances is only required for certain substances that the National Poisons Standard recommends should be restricted to particular specialties. There are currently no controls under the NSW framework for dentists/veterinary practitioners/medical practitioners who compound Schedule 4 substances. Similarly, the Commonwealth framework creates carve-outs for these practitioners, in that they do not need to hold a Commonwealth manufacturer's licence to compound these substances (see additional discussion of compounding below under regulation area 9).	The draft Regulation would require that an approval to administer/prescribe/supply a Schedule 4 substance is sought in the following circumstances: – Supplying/prescribing/administering any compounded substance listed in Schedule 4 Appendix D that is for non-topical use. – Supplying/prescribing/administering certain Schedule 4 (prescription only) medicines, such as acitretin, unless the prescriber is in a specific specialty (such as dermatology). These would be called 'Nominated Schedule 4 substances', and certain specialties would be exempt from the requirement to hold an approval (for example, a Dermatologist would not require an approval to prescribe, supply or administer acitretin). In addition: – An *authority* would be required for dentists/veterinary practitioners/medical practitioners who seek to manufacture (compound) Schedule 4 Appendix D that is for non-topical use. This authority would be *in addition to the approval*	The list of Nominated Schedule 4 substances has been adjusted to more closely reflect the recommendations of the National Poisons Standard and the approach taken in other jurisdictions. The regulation now clearly recognises the specialities for whom an approval is not required (rather than this recognition being by external instrument). Noting the increased risks posed by Schedule 4D substances for non-topical use, including of diversion for personal use or trafficking purposes, the draft Regulation would require: – *approval* to prescribe, supply or administer compounded Schedule 4D substances for non-topical use – an *authority* to manufacture (compound) Schedule 4D substances for non-topical use if the practitioner is a dentist, veterinary practitioner or medical practitioner.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
		to administer/prescribe/supply these substances noted above. – The number of nominated Schedule 4 substances would increase (i.e., there would be more nominated Schedule 4 substances than are currently listed at Clause 37 of the PTGR). Additional details on the proposed changes to the list of Schedule 4 restricted substances are included in Table 5.8 in Chapter 5.	
8. Circumstances where an approval number would be required on a prescription for certain Schedule 4 and 8 substances	Prescribers and pharmacists have obligations around the form of prescription and supply on prescription for some of these substances. For example, a pharmacist is not able to dispense a prescription for a Type A drug of addiction unless the prescription has the authority reference number for that substance. Similarly, a pharmacist cannot dispense a prescription for certain Schedule 4 substances (such as acitretin) unless the doctor has obtained authority to issue that prescription.	The MPTG Regulation includes additional circumstances where a prescription must include an approval number. Approval numbers will be required if the substance is: – a compounded Schedule 8 substance – a specified stimulant (methylphenidate, lisdexamfetamine or dexamfetamine) – N,*α*-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and psilocybine – a nominated Schedule 4 substance (such as acitretine) – a compounded Schedule 4D for non-topical use. The intent is that a prescriber would need to include the approval number on a prescription when they prescribe the above substances (or write 'Approval exempt' if a relevant exemption from the requirement to get approval applies); and given a pharmacist can only dispense a prescription if it is in the correct form, the pharmacist would need to confirm that the prescription includes the above approval number (pharmacists would be subject to a penalty for dispensing prescriptions for the above substances on which the doctor has not included the approval number). Additional details on these proposed changes are included in Section 5.3.7 and 5.3.8 in in Chapter 5.	These changes aim to reduce abuse, misuse and dependence of these substances by ensuring integrity of the supply chain and ensuring that prescriptions for certain high-risk substances are only dispensed when the prescriber has been approved to prescribe that substance.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
9. Compounding controls	The manufacture of therapeutic goods in Australia generally requires a TGA manufacturing licence, however, a manufacturing licence from the TGA is not required if 'medicines are compounded only on a prescription or order for, or on request by a particular person, for therapeutic application to that person, or on a request from an authorised prescriber for use in their surgical/clinic/treatment room for an individual named patient'[6]. A manufacturing licence from the TGA is required if a pharmacist intends to compound biologicals, or compound medicines in a pharmacy and supply these by wholesale, for example to other pharmacies. In this case, if the compounded medicine is not for supply to an individual named patient (e.g., by way of a prescription or order), it would also need to be included in the ARTG.[7] Due to the non-wholesale supply licence exemption, compounded medicines are not subject to evaluation for quality, safety and efficacy by the TGA. Furthermore, while licensable manufacturers of compounded medicines have to meet the TGA's *Compounded medicines and good manufacturing practice (GMP), Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products*[8] (referred to as the 'TGA GMP Guide'), this guide is not required to be adopted by pharmacists performing compounding for individual patients.	The MPTG Regulation would require: – Compliance with the TGA GMP Guide when compounding sterile compounded preparations. A sterile compounded preparation is defined in the MPTG Act as: *a compound of substances, whether or not containing scheduled substances, that is required to be kept sterile, and includes a preparation in —* *(a) parenteral dosage form, other than an intradermal or subcutaneous injection of an allergen extract, and* *(b) ophthalmic dosage form.* – That a dentist, veterinary practitioner or medical practitioner who seek to manufacture (compound) a Schedule 8 or Schedule 4D substance for non-topical use obtains authorisation from the Secretary to do so, or be subject to an exemption. This would mitigate risks in relation to goods manufactured/compounded by persons operating under a Commonwealth exemption and without oversight by the Commonwealth.	Compounded medicines play an important role in meeting the healthcare needs of the NSW community when commercial preparations are unavailable or individualised dosing is required (for instance, compounding is often needed for paediatric patients). However, compounded products can pose serious health and safety risks, in particular those medicines required to be sterile, such as injectables and eyedrops. Compounded medicines pose additional risks to patients because: – pharmacy compounding has significantly less rigorous regulatory oversight than that required for medicines that have been registered on the ARTG by a TGA-licensed manufacturer – pharmacy-compounded products: – are not clinically evaluated for quality, safety or efficacy – are not tested to assess consistent product quality or stability (setting of expiry dates) – compounding products in the absence of good manufacturing practice regulations increases the potential for preparation errors – compounded products may provide an access route for medicines where use is currently experimental and more clinical trial evidence is needed to support use. Given these risks, it is important to ensure that poor practices are appropriately regulated.

[6] Pharmacy Board of Australia 2020, *Frequently asked questions for pharmacists on the compounding of medicines,* June, https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD15%2F16634&dbid=AP&chksum=gMF1UYEc8RzLm0y41TbNqw%3D%3D, Accessed 20 June 2023.

[7] Ibid.

[8] The purpose of the TGA GMP Guide is to clarify the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products PE-009 requirements for the manufacture of extemporaneously compounded medicines.

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
10. Restrictions to emergency use provisions	The Pharmaceutical Benefits Scheme (PBS) allows certain pharmaceutical benefits to be provided to medical practitioners and nurse practitioners without charge, who in turn can supply or administer them free to patients for emergency use (this is colloquially referred to as 'doctor's bag supplies'). Clause 46 and Clause 97 of the PTGR provide the legislative mechanism facilitating a doctor's bag order, and more broadly, an order by an authorised practitioner (including a veterinary practitioner), being supplied by a pharmacist in NSW for emergency use. – Clause 46 currently allows for currently allows for order for emergency use in respect of **any** Schedule 4 substances (both for health and veterinarian practitioners). – Clause 97 currently allows for orders for emergency use: – for health practitioners for Schedule 8 substances (excluding unregistered Schedule 8) – for veterinary practitioners for **any** Schedule 8 substances.	Under the MPTG Regulation: – A health practitioner would only be able to obtain a substance for emergency use that is registered on the ARTG (i.e., compounded medication and non-registered medication would be excluded). – A veterinary practitioner would only be able to obtain a substance for emergency supply that is registered on the ARTG or the Australian Pesticides and Veterinary Medicines Authority (APVMA). This proposed change would mean that a doctor/veterinary would not be able to rely on the emergency use provisions to obtain Schedule 4 or Schedule 8 substances that are unregistered with the ARTG or APVMA. A doctor or veterinary seeking to obtain these supplies from a pharmacist for a patient would need to issue a prescription for an individual patient, and the pharmacist could then compound and dispense the unregistered Schedule 4/8 substance to the patient. For Schedule 4 and Schedule 8 substances that are registered with the ARTG/APVMA there would be no change to current practice.	The aims of the proposed changes are twofold: – To reduce risks to patient safety by recognising that unregistered medicines have not been assessed for quality, safety and efficacy unlike ARTG-registered medicines. Registered medicines are thoroughly evaluated and are subject to ongoing monitoring, including via Commonwealth adverse event reporting. – To address the risks related to compounded veterinary medicines. The current regulatory framework enables pharmacists to prepare large batches of compounded medicines for animal use without Commonwealth or state oversight. This approach aligns with the position of the Veterinary Practitioner's Board, which does not support supply to veterinarians by wholesale of compounded medicine for emergency use.
11. Licence fees	This proposed change entails: – increasing existing fees collected under the PTGR for retail and wholesale supply licence applications and renewals for Schedule 2, 3, 4 and 8 substances – creating new fees for: – wholesale licences for Schedule 9 and 7J substances – retail licences for Schedule 7J substances – amendments to licences – obtaining a licence.[9]		The rationale for the proposed changes to licence fees is as follows. – The current licence fees are out of step with other states/territories. – The Ministry notes that the fees collected under the current framework are not commensurate with the time involved for authorised officers to undertake the significant work involved in assessment of applications and renewals of

[9] The concept of 'obtaining a licence' is new and was introduced with the MPTG Act. It allows an entity to apply for a licence to receive/obtain a wholesale supply of stocks of medicines. Previously, under the PTGR framework, entities such as paramedic companies applied for a wholesaler licence and then wholesale supplied those medicines to their employee paramedics. The MPTG Act recognises that providing stock to employees is not really wholesale supply. In the paramedic company example, the company only needs to obtain the wholesale supply of stock, which is then administered/supplied by employees in the course of the practice of their profession. Under the new framework, entities such as paramedic companies would be applying for an obtain licence, rather than a wholesaler's licence.

<table>
<tr><th>Regulation area</th><th>Current situation</th><th>Proposed change</th><th>Purpose/rationale of the proposed amendment</th></tr>
<tr><td></td><td>The table below outlines the proposed changes to retail and wholesale supply licences' fees under the MPTG Regulation, compared to the current PTGR.
<table>
<tr><th>Licence type</th><th>Current license fees (last changed in 2013)</th><th>Proposed license fees for application and annual renewal (MTPGA 2022 and MPTGR 2023)</th></tr>
<tr><td colspan="3">Wholesale licences</td></tr>
<tr><td>Application fee for wholesaler licence involving Schedule 7Js</td><td rowspan="2">NA (no current fee for a wholesaler licence or authority)</td><td>$770
Amendment fee = 385</td></tr>
<tr><td>Annual renewal fee for wholesaler licence involving Schedule 7s</td><td>$330
Amendment fee = $165</td></tr>
<tr><td>Application fee for obtain licence involving Schedule 7s</td><td rowspan="2">NA (no current fee for obtain licence)</td><td>$330
Amendment fee = $165</td></tr>
<tr><td>Annual renewal fee for obtain licence involving Schedule 7s</td><td>$330
Amendment fee = $165</td></tr>
<tr><td>Application fee for wholesaler licence or obtain licence involving Schedule 8s and Schedule 9s</td><td>– S8 wholesaler licence - $356
– S8 obtain licence - No current fee for S8 obtain licence, however many of the entities which previously sought a wholesaler licence, would now seek an obtain licence
– S9 wholesaler licence - NA (no current fee for a wholesaler or obtain licence or an authority)
No current amendment fee for any licence</td><td>$2,930
Amendment fee = $1,465</td></tr>
<tr><td>Annual renewal fee for wholesaler licence or obtain licence involving Schedule 8s and Schedule 9s</td><td>– S8 wholesaler licence - $356
– S8 obtain licence - No current fee for S8 obtain licence, however many of the entities which previously sought a</td><td>$2,520
Amendment fee = $1,260</td></tr>
</table></td><td></td><td>licences. The proposed fees are a result of cost-recovery work undertaken by relevant areas of the Ministry to quantify the costs associated with administration of the scheme.</td></tr>
</table>

Regulation area	Current situation	Proposed change	Purpose/rationale of the proposed amendment
	wholesaler licence, would now seek an obtain licence – S9 wholesaler licence - NA (no current fee for a wholesaler or obtain licence or an authority) No current amendment fee		
	Application fee for wholesale or obtain licence involving Schedule 2s, Schedule 3s, and Schedule 4s	– $533 No current amendment fee	$1,650 Amendment fee = $825	
	Annual renewal fee for wholesale or obtain licence involving Schedule 2s, Schedule 3s, and Schedule 4s	– $533 No current amendment fee	$1,250 Amendment fee = $625	
	Retail licences		
	Application fee for Schedule 2 retail licence and Schedule 7J retail licence	– S2 — $90 – S7J - NA (no current fee for a retail licence for an S7J) No current amendment fee	$330 Amendment fee = $165	
	Annual renewal fee for Schedule 2 retail licence and Schedule 7J retail licence	– S2 — $90 – S7J - NA (no current fee for a retail licence for an S7J) No current amendment fee	$330 Amendment fee = $165	

Source: NSW Ministry of Health and ACIL Allen.

Assessment of options

The following sections summarise the assessment of impacts of the regulatory options outlined above. The first section assesses the expected impacts of the Base Case (i.e., of letting the PTGR sunset and not replacing it with the new Regulation) and the second section assesses the impacts of the proposed Draft MPTG Regulation (Option 2) against the status quo, i.e., remaking the PTGR (Option 1).

The costs and benefits associated with the alternative options have been analysed in this RIS mostly qualitatively. This is because the benefits and costs associated with the alternative options are not amenable to easy quantification due to:

— limited data available to comprehensively demonstrate the effectiveness of the MPTG Regulation

— the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the MPTG Regulation in a robust way.

In addition, in preparing this RIS, selected stakeholder consultations were conducted with a number of organisations. Where relevant, key comments made by stakeholders have been included in the discussion. These views need to be further tested during the public consultation period before a decision is made about making the MPTG Regulation.

Impacts of letting the PTGR sunset and not replacing it (the Base Case)

The likely general implications of letting the Regulation sunset are that:

— the Act would be unable to fully operate in the absence of legislative detail

— there would be no mechanism for a number of stakeholders to be able to wholesale supply, obtain wholesale supply or non-wholesale supply of medicines, resulting in a break in the supply chain of medicines across NSW, and an interruption to patient care

— there would not be restrictions/controls on the administration of medication (unlike the existing framework, the MPTG Act provides that supply does not include administration and generally does not regulate the administration of medication but focuses instead on controlling wholesale supply or supply)

— the health practitioners allowed to (non-wholesale) supply or prescribe medicines would be limited to those specifically authorised under the Act. Practitioners not specifically authorised under the Act (but authorised under the proposed Regulation) would not be able to supply, prescribe or administer medicines (e.g., pharmacists would not be able to administer vaccines, and nurses supplying medicines to patients under the direction of a doctor would not be carved-out from the supply offence provisions)

— medication prescription criteria would be absent

— patient medication labelling obligations would not exist

— obligations regarding cleanliness and handling of substances in certain settings would not exist

— healthcare and clinical tools, such as SafeScript NSW, which supports practitioners who prescribe and supply high risk medicines to patients, would no longer have a lawful basis

— there would be no controls regarding storage, disposal and destruction of high risk scheduled medicines

— mechanisms to authorise persons to undertake research with high-risk substances would be more limited.

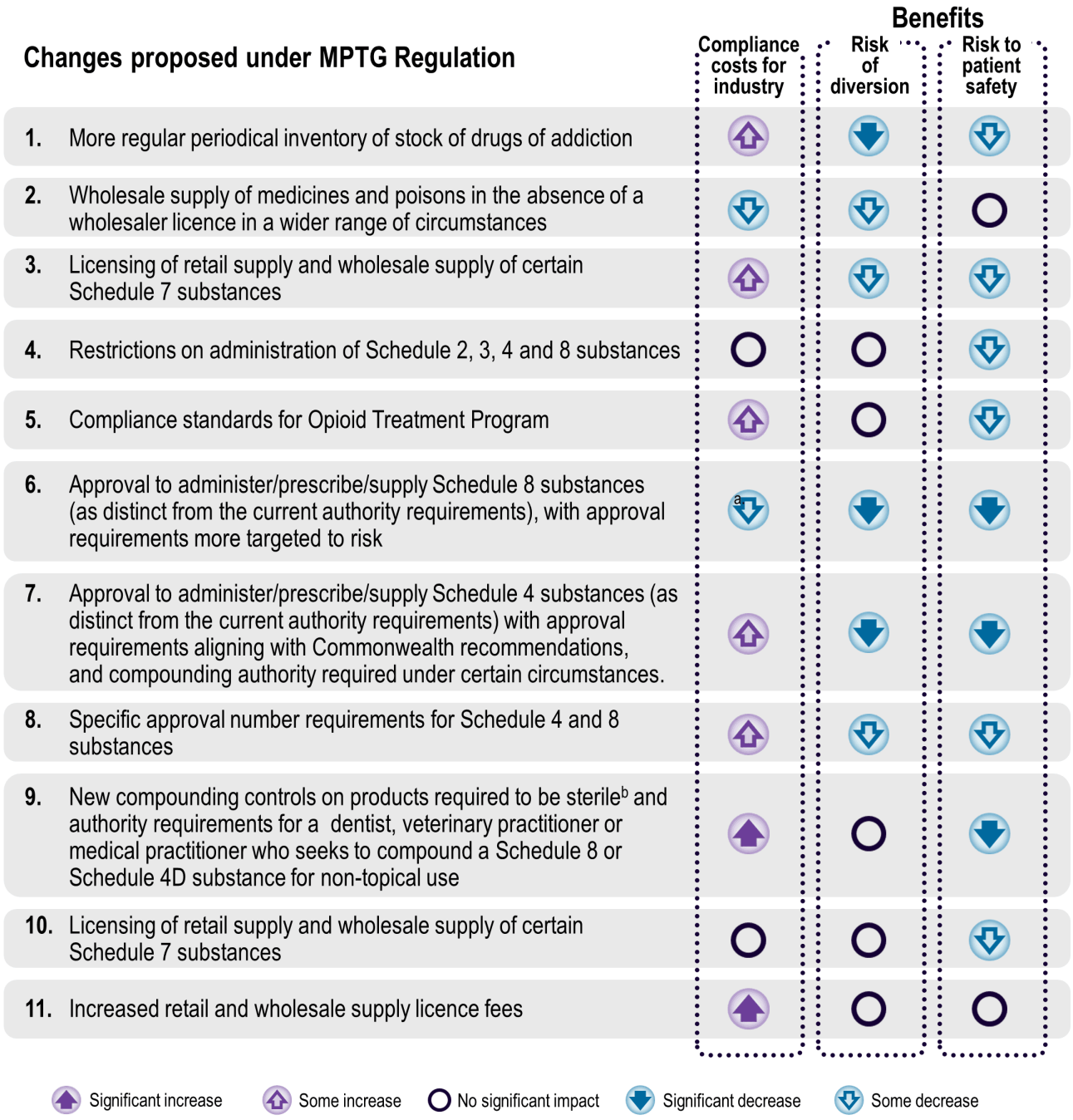
Overall, letting the PTGR sunset and not replacing it with a new Regulation is not considered appropriate as the risks and costs associated with eliminating legislative detail in relation to permitted wholesale supply and the obtaining, administration, prescribing, supply, handling, storage, labelling, disposal and destruction of certain medicines are considered to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

It is noted that all stakeholders consulted for the RIS agreed that letting the Regulation sunset is not an appropriate option as the Regulation is central to the operation of the Act and maintaining adequate standards for patient and public safety.

Impacts of the proposed MPTG Regulation (compared to the status quo)

As discussed before, the benefits and costs associated with the alternative options are not amenable to easy quantification. However, Figure ES 1 provides a summary of the relative nature of the benefits and costs of the key changes proposed under Option 2 across the eleven areas outlined before, with respect to Option 1 (i.e., the *status quo*).

Figure ES 1 Summary of potential relative impacts of the proposed Draft Regulation across key areas of change (relative to the status quo)



[a] Based on regulatory impact of change on medical practitioners and nurse practitioners but excludes regulatory impact on veterinary practitioners, who will now require an approval to prescribe, supply or administer compounded Schedule 8 substances. The Ministry do not currently collect data to quantify this change for veterinary practitioners.

[b] Not including approval requirements for compounded Schedule 4D and Schedule 8 substances.

Source: ACIL Allen.

In summary, in relation to the proposed MPTG Regulation across its main areas of change (with respect to the PTGR):

1. There is limited evidence to measure the impact that increased supervision of stocks of drugs of addiction would have on diversion, however the Ministry reports many instances of stock lost or not accounted for. By being able to more clearly ascertain when the stocks of these substances go missing, the proposed change would assist in investigating and regulating

diversion of these high-risk substances and by doing so, reduce risks to patient safety. Given the well-known risks posed by misuse and abuse of these substances and the likely modest additional costs of compliance imposed by these changes (which are detailed in Section 6.2.1), it is considered that the proposed **more frequent inventory requirements** are appropriate based on the precautionary principle.

2. To the extent that the proposed changes to the **circumstances when wholesale supply can occur without a licence** facilitates business practices and reduce compliance costs for pharmacies without increasing risks of diversion, the change is expected to be overall beneficial.
3. Overall, it is considered that the benefits from reduced risks of substance misuse stemming from the **increased requirements for wholesale supply of Schedule 7J substances** are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.
4. The proposed **changes to the administration** would increase clarity and consistency about the lawful administration of scheduled substances, and potentially reduce the risk of inappropriate or unsafe practices when treating patients. Accordingly, these changes are expected to be beneficial.
5. Given that the proposed **exemptions to the registration to prescribe/ supply for the OTP** would result in cost/time efficiencies for practitioners and the Ministry, increased efficiency of care and reductions of barriers to access to ODT; and the proposed **OTP standards** would maintain patient safety by mitigating risks in treatment, while imposing additional compliance costs to only a fairly low number of pharmacies dosing over 80 patients (which would require an approved amenity plan in place), the proposed change is expected to be overall beneficial.
6. The proposed changes to the circumstances in which a practitioner is required to hold an **approval to administer/supply/prescribe Schedule 8 substances** would decrease risks of misuse and abuse of these substances and reduce overall compliance costs for practitioners. Given this, the changes are expected to be beneficial.
7. Overall, it is considered that the benefits from reduced risks of substance misuse stemming from the **new and tightened controls of specific Schedule 4 substances** are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.
8. To the extent that the proposed prescription **approval number requirements** increase patient safety without substantial increases in compliance costs for prescribers and pharmacists, then the proposed change would be overall beneficial.
9. The proposed changes to the **controls of sterile compounded substances** which pharmacies are currently able to manufacture without a TGA licence are likely to increase the costs of regulatory compliance for pharmacies and the NSW Government. In addition, the **new authority requirements for dentists/veterinary practitioners/medical practitioners who seek to compound a Schedule 8 or a Schedule 4D substance for non-topical use** are likely to increase the costs of regulatory compliance for these practitioners and the NSW Government. However, given the potentially catastrophic consequences of worst-case safety/quality incidents related to compounded substances (which include illness, disability and death) and the lack of rigorous oversight of this sector, the proposed change is expected to be overall beneficial.
10. The proposed **exclusions from emergency use provisions** of Schedule 4 substances not registered on the ARTG or, for veterinary practitioner emergency supply, substances not registered on the ARTG/APVMA and Schedule 8 substances that are unregistered with the APVMA for veterinarians are not anticipated to increase the cost of regulatory compliance for doctors/veterinary practitioners as unregistered/compounded products are not subject to PBS subsidies. However, the changes may result in an increase in the costs of administering and

enforcing the regulation for the NSW Government. To the extent that reductions in the risks to patient safety from the proposed new restrictions more than offset the additional costs to the NSW Government, the proposed change is expected to be overall beneficial.

11. The proposed amendments to **licence fees** would represent a significant increase in the regulatory charges for suppliers, but would better reflect the costs of the regulatory activities by the Ministry, increase the level of cost recovery and increase allocative efficiency.

Notably, a key 'unintended' benefit from the proposed update of the Regulation (and the Act) highlighted by most stakeholders consulted for this RIS is the additional/better compliance with already existing requirements and obligations related to scheduled substances that would be achieved as a 'byproduct' of the process of educating people about the new requirements. Indeed, it was noted by several stakeholders that the practitioners' and pharmacists' knowledge of some of the current requirements is quite limited.

Conclusion

The Act and the Draft MPTG Regulation are intended to protect public health and safety through the provision of a framework for adequate monitoring and control of activities involving scheduled substances and other prescribed therapeutic goods.

Letting the PTGR sunset when the new MPTG Act commences and not replacing it with a new Regulation is not considered appropriate as the Act would be unable to fully operate in the absence of legislative detail, would result in a break in the supply chain of medicines across NSW (and an interruption to patient care), and would increase the risks to patient safety (due to substance misuse or abuse) and the risks to the health and safety of the public due to increased risks of diversion of dangerous substances. The costs associated with these increased risks are likely to significantly outweigh any potential benefits to government and industry related to reduced compliance and administrative costs.

In relation to the key eleven changes proposed for the Draft MPTG Regulation, overall, it is considered that these proposed changes achieve the right balance between reducing the risks to patient safety (due to substance misuse or abuse) and the risk of diversion of dangerous substances, and the additional red tape/compliance costs associated with the Regulation.

However, the Ministry would like to hear submission on whether the proposed changes in the MPTG Regulation are appropriate before a final decision is made regarding pursuing the proposed changes.

Next steps

Interested stakeholders are encouraged to consider aspects of the assessment contained within this RIS and the Draft MPTG Regulation. Key issues on which stakeholder views are sought include the following:

- Are there any costs and benefits of the Draft MPTG Regulation that have not yet been considered, and how material are these impacts?
- Are there any risks or unintended consequences of the Draft MPTG Regulation that have not yet been considered?
- Are there any additional amendments which could have a net positive impact on the proposed MPTG Regulation?
- Could the results of the proposed MPTG Regulation be achieved through any alternative options?
- Are there any clauses in the MPTG Regulation which require clarification?

Consistent with the *Subordinate Legislation Act 1998*, the Draft MPTG Regulation and this RIS will be open for public consultation for a period of at least 21 days, until 22 December 2023.

Submissions about the Draft MPTG Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 2030
ST LEONARDS NSW 1590

Submissions may also be made via email to MOH-MPTG-Submissions@health.nsw.gov.au.

Submissions must be received by 22 December 2023.

Individuals and organisations should be aware that generally any submissions received will be publicly available under the *Government Information (Public Access) Act 2009* and may be published. The Ministry, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

1 Introduction

1.1 Policy background and context

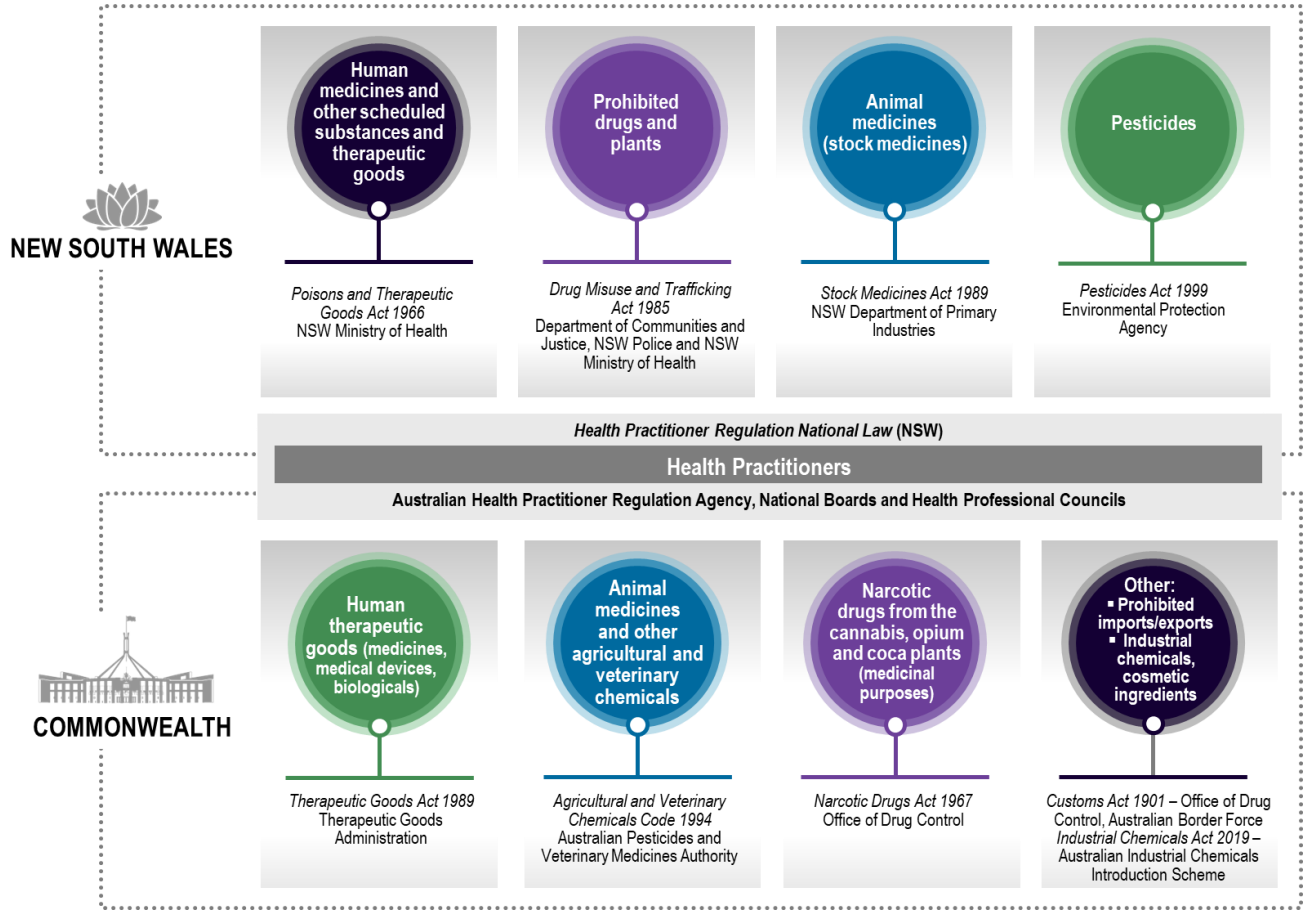
Medicines, poisons (chemicals), and therapeutic goods (MPTGs) are essential to people's lives. However, they can also pose a risk to the health and safety of individuals when used inappropriately. To protect public health and safety, these substances and goods are extensively regulated both at the Commonwealth and state/territory levels. The control of these substances and goods is largely achieved through the various legislation depicted in Figure 1.1. Broadly:

- Commonwealth laws regulate:
  - how MPTGs legitimately comes to be in Australia. For example, the Commonwealth licences: the cultivation of narcotic plants and the production and manufacture of narcotic drugs from narcotic plants for medicinal purposes or for research, the manufacture of medicines and other therapeutic goods, and the importation of such goods
  - the quality, safety or efficacy of MPTGs through registration or listing, or otherwise through approval, authorisation or exemption from registration or listing.

  In addition, in the interest of national uniformity regarding the control of medicines and poisons, the Commonwealth also provides a National Poisons Standard, established under the *Therapeutic Goods Act 1989* (Cth). The National Poisons Standard lists substances with similar risks under specific schedules. Each Schedule contains a list of substances that share similar risks, for which control measures are recommended to reduce the risks. In the interest of public health and safety, substances identified in these schedules can have restrictions placed upon their supply in order to minimise the misuse and abuse of such substances.[10] States and territories, including NSW, have generally adopted the Schedules and applied the recommended controls for each Schedule, subject to variations. A table of the Schedules of the National Poisons Standard (herein referred to as the Schedules) can be found in Appendix A.
- In NSW, MPTGs are regulated by the *Poisons and Therapeutic Goods Act 1966* (PTGA) and the *Poisons and Therapeutic Goods Regulation 2008* (PTGR). The PTGA and PTGR mainly regulate:
  - the supply within, and from, NSW of medicines and poisons, being substances listed in the Schedules (scheduled substances)
  - activities such as the issuing of prescriptions, storage, labelling, packaging, record keeping, disposal, administration, and use of scheduled substances
  - who have access to scheduled substances to reduce opportunities for misuse, including their diversion to the illicit supply chain and inappropriate and dangerous use.

[10] Australian Government 2023, *Explanatory statement – Therapeutic Goods Act 1989*. Federal register of legislation. Accessed March 2023: https://www.legislation.gov.au/Details/F2023L00067/Explanatory%20Statement/Text

Figure 1.1 Key NSW and Commonwealth regulatory regimes for medicines, poisons and therapeutic goods



Source: NSW Ministry of Health 2022, Consultation Draft: Medicines, Poisons and Therapeutic Goods Bill 2022, Discussion Paper

After a review of the PTGA and PTGR by the Ministry, the new *Medicines, Poisons and Therapeutic Goods Act 2022* (the MPTG Act) passed Parliament in November 2022 (additional details about this review are provided in Box 1.1). On commencement, the Act will update and modernise the PTGA and make a range of changes to the existing legislative framework governing scheduled substances and therapeutic goods.

The draft *Medicines, Poisons and Therapeutic Goods Regulation 2023* (the MPTG Regulation) would support the operation of the MPTG Act. The PTGA and the PTGR will be repealed when the new MPTG Act and its regulation commence.

The MPTG Act sets out the framework to regulate activities involving scheduled substances and certain therapeutic goods. The objectives of the MPTG Act are to:

a) regulate activities involving scheduled substances and other prescribed therapeutic goods to protect public health and safety
b) use the National Poisons Standard as the basis for classifying and regulating certain substances
c) complement the Commonwealth laws that regulate therapeutic goods, including by providing for certain Commonwealth laws to apply as a law of NSW in relation to the activities of persons who are not corporations
d) authorise certain activities involving scheduled substances and other prescribed therapeutic goods, including when the activities are prohibited under another law
e) provide for effective administration and enforcement mechanisms in relation to scheduled substances and other prescribed therapeutic goods.

Box 1.1 Review of the PTGA and PTGR and the new MPTG Act

Review of the PTGA and PTGR

In 2022, the Ministry undertook a review of the PTGA and PTGR to ensure that the framework regulating medicines, poisons, and therapeutic goods in NSW is contemporary, robust, safe, and efficient. As part of this review, the Ministry prepared the Exposure Draft *Medicines, Poisons and Therapeutic Goods Bill 2022* (Draft MPTG Bill) for public consultation and a discussion paper seeking submissions on the Draft MPTG Bill. In addition to this public consultation process, the NSW Ministry of Health also held targeted meetings with impacted professional groups and government stakeholders to ensure the proposed reforms to the regulatory framework were appropriate.

As part of the legislative review and discussion paper process, the Ministry identified a number of changes to the regulatory environment that warranted reform. These include:

- changes in recognised safe business practices regarding wholesale supply
- updates on the Commonwealth's National Poisons Standard
- identified loopholes in the current regulatory framework
- areas where restrictions could be relaxed (e.g., the requirements for authorisation for administering, prescribing, or supplying Schedule 8 medicines under the Opioid Treatment Program (OTP)
- recognition of increased risk of diversion, misuse or abuse of particular substances.

Over 80 submissions were received on the Draft MPTG Bill and discussion paper, including from the NSW Nurses and Midwives' Association, the Australian Medical Association, the Medical Services Committee, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, industry groups, healthcare regulators and members of the community. The submissions and feedback received through this consultation process informed the development of the new MPTG Act.

The new Medicines, Poisons and Therapeutic Goods Act 2022

The main changes in the MPTG Act are the following.

- updated and modernised language
- inclusion of mechanisms to more clearly recognise contemporary healthcare models
- new emergency provisions to allow for a swift, transparent and flexible response when needed in emergencies
- updated penalties to better reflect the seriousness of offences and modern enforcement tools (e.g., on-the-spot fines and compliance notices)
- simplified interaction with other legislation that regulates scheduled substances
- the Act automatically adopts the classification of medicines and poisons in the schedules of the National Poisons Standard to promote national uniformity, but allows regulations to make variations to the schedules should there be unique or intrinsic issues that arise in NSW in relation to a particular medicine or poison.

Source: ACIL Allen based on NSW Ministry of Health 2022, Consultation Draft: Medicines, Poisons and Therapeutic Goods Bill 2022 Discussion Paper; and Parliament of NSW 2022,Parliamentary Debates (Hansard), 19 October 2022, https://www.parliament.nsw.gov.au/bills/Pages/bill-details.aspx?pk=4030#:~:text=An%20Act%20to%20regulate%20activities,consequential%20amendments%20to%20other%20legislation

1.1.1 The Medicines, Poisons and Therapeutic Goods Regulation 2023

The proposed MPTG Regulation would support the MPTG Act by making provisions relating to:

- wholesale supply of medicines/poisons
- obtaining a wholesale supply of medicines/poisons
- non-wholesale supply of medicines/poisons
- issuing prescriptions for medicines
- administration of medicines
- specific controls relating to higher-risk substances (such as certain prescription-only medication and drugs of addiction), substances used for cosmetic purposes, and substances

that are subject to additional controls and for which the prescribing/dispensing is 'monitored' on SafeScript NSW (SafeScript, see Section 3.2.1 for more information)

- records of supply
- cleanliness requirements (including preparation and handling of substances)
- storage and labelling of medicines/poisons.

1.2 RIS requirements

The *Subordinate Legalisation Act 1989* requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation before a principal statutory rule is made.[11] ACIL Allen has been engaged by the Ministry to prepare the RIS for the MPTG Regulation.

The primary purpose of a RIS is to ensure that the costs and benefits of regulatory proposals are fully examined so that affected stakeholders can be satisfied that the benefits of the regulation exceed the costs. To achieve these ends, the *Subordinate Legislation Act 1989* requires a RIS to contain certain information including:

- an analysis of the nature and extent of the problem sought to be addressed by the regulation and establishing the need for regulation
- a statement of the objectives sought to be achieved by the regulation
- the identification of the alternative options by which those objectives can be achieved
- an assessment of the costs and benefits of the impacts of the alternative options
- an assessment as to which of the alternative options involves the greatest net benefit or the least net cost to the community
- a statement of the consultation program to be undertaken.

In addition to the *Subordinate Legislation Act 1989*, the introduction of regulations in NSW is also governed by Better Regulation Principles. The principles (outlined in Box 1.1) are a best practice guide for policy development and regulatory design process and must be followed in the development of every regulatory proposal.

In light of this, the chapters in this report are structured around the RIS content requirements and the application of the Better Regulation Principles.

[11] Parliamentary Counsel's Office 2018, *Information Sheet on the Staged Repeal of Statutory Rules*, https://www.pco.nsw.gov.au/corporate/Staged_repeal_of_statutory_rules_information.pdf, accessed 8 June 2023.

Box 1.2 The Better Regulation Principles

- **Principle 1:** The need for government action should be established. government action should only occur where it is in the public interest, that is, where the benefits outweigh the costs.
- **Principle 2:** The objective of government action should be clear.
- **Principle 3:** The impact of government action should be properly understood, by considering the costs and benefits (using all available data) of a range of options, including non-regulatory options**.**
- **Principle 4:** Government action should be effective and proportional.
- **Principle 5:** Consultation with business, and the community, should inform regulatory development.
- **Principle 6:** The simplification, repeal, reform, modernisation or consolidation of existing regulation should be considered.
- **Principle 7:** Regulation should be periodically reviewed, and if necessary reformed, to ensure its continued efficiency and effectiveness.

Source: NSW Treasury 2019, NSW Government Guide to Better Regulation, tpp19-01.

1.2.1 Scope of the RIS

The evaluation of costs and benefits of the alternative options analysed in this RIS has been undertaken mostly on a qualitative basis. This is because the benefits and costs associated with the alternative options are not amenable to easy quantification due to:

- limited data available to comprehensively demonstrate the effectiveness of the MPTG Regulation
- the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the MPTG Regulation in a robust way.

1.3 Structure of this report

The remainder of this report is structured as follows:

- Chapter 2 provides background information about the problems which warrants regulation.
- Chapter 3 establishes the need for a government response to the problems identified in Chapter 2.
- Chapter 4 describes the objectives of the MPTG Regulation.
- Chapter 5 describes the options analysed as a part of this RIS.
- Chapter 6 analyses the impact of the options detailed in Chapter 5.
- Chapter 7 makes a conclusion based on the analysis in Chapter 6.

Nature and extent of the problem 2

The RIS requirements place a high hurdle on new or more stringent regulation, meaning that regulation should only be introduced, or amended, where there is an identified problem which the regulation would cost-effectively address. Demonstrating that the proposed regulation is required consists of two steps. First, it is necessary to identify that a problem exists. Second, the RIS should demonstrate that the problem is amenable to government intervention and that a regulatory response is appropriate. This chapter addresses the first requirement through outlining the nature and extent of the problem that the Regulation intends to address. Chapter 3 assesses the case for government intervention.

2.1 Misuse, abuse and illicit diversion of high-risk substances

The PTGR and the proposed MPTG Regulation make it possible for the Ministry to exercise control over potent substances listed in the Schedules of the National Poisons Standard (scheduled substances) on the basis of their particular level of risk. By imposing restrictions on the distribution, prescription and administration of these substances, the Regulation reduces the threat to the health and safety of the people of NSW posed by the misuse, abuse and illicit diversion of these substances.

The misuse, abuse and diversion of scheduled substances have a range of negative impacts on public health and safety, including:[12]

— health impacts such as disease, death, overdose and hospitalisation

— social impacts such as violence, crime and trauma

— economic impacts like the cost of healthcare and law enforcement.

Drug **misuse** (inappropriate use) involves the use of a pharmaceutical drug for non-medical purposes, including use in doses and frequencies beyond what is prescribed.[13] Misuse of drugs can lead to chronic health conditions or dependencies that severely affect a person's quality of life or even result in death. Substances that are often misused include Schedule 8 substances like fentanyl, oxycodone and other opioids. Misuse is not confined to heavily controlled substances, as minimally controlled substances listed under Schedule 2 can also be misused (for example overuse of paracetamol or ibuprofen to provide pain relief for chronic conditions).

Drug **abuse** involves consumption to satisfy an addiction; that is, excessive and habitual use of a drug for non-medical or recreational purposes. Examples include the use of prohibited or heavily restricted substances like opium, heroin, hallucinogens, cocaine, amphetamines and cannabis,

[12] Australian Institute of Health and Welfare 2022, *Illicit drug use*, Accessed March 2023: https://www.aihw.gov.au/reports/illicit-use-of-drugs/illicit-drug-use.

[13] Australian Institute of Health and Welfare 2017, *National drug strategy household survey 2016: detailed findings,* p. 78. Accessed March 2023: https://www.aihw.gov.au/reports/illicit-use-of-drugs/2016-ndshs-detailed/summary.

which include prescription drugs listed under Schedule 4 and Schedule 8. As with drug misuse, abuse is not confined to substances that are heavily controlled or prohibited—even substances generally considered relatively safe that are accessible through a prescription can be abused for this purpose. For example, many prescription drugs listed under Schedule 4, such as sedatives and stimulants can be abused for non-medical purposes, including to prevent withdrawal in the case of addiction.[14]

Diversion refers to obtaining and/or using controlled substances for purposes other than their intended medical purpose. Diversion occurs through illicit activities like theft, fraud (such as forgery or alteration of scripts by users or healthcare workers), doctor shopping (obtaining multiple scripts by visiting multiple physicians), self-administration by health professionals or sharing among friends and family,[15] and any other inappropriate prescribing or dispensing of controlled substances. Diversion can occur across the supply chain, necessitating restrictions on supply, distribution and administration of controlled substances.

Misuse, abuse and diversion of scheduled substances represents a major risk to public health and safety that generates significant social and economic costs associated with drug-related crime, violence, addiction and other forms of harm. Diverted substances may be used by people with dependencies or by others for recreational purposes, which can lead to overdose deaths, infections, injuries or chronic diseases. Furthermore, they can be used in the manufacture of illegal substances, leading to wider availability of such substances and associated criminal activities.

2.2 Extent of the problem

This section describes the frequency and severity of improper use of controlled substances in NSW and Australia as a whole. As mentioned before, the misuse, abuse and diversion of controlled substances generates negative impacts on the community of NSW in several ways, for example through costs associated with providing inpatient hospital care and criminal justice. Other tangible costs include those relating to traffic accidents and workplace disruptions. There are also intangible losses that accrue to society, mainly those associated with reduced quality of life and loss of life. Tangible and intangible costs can be quantified under certain assumptions to produce estimates of the full cost of misuse, abuse and diversion of controlled substances.

The availability of such quantitative estimates of the social and economic costs[16] of misuse, abuse and diversion of controlled substances in Australia is quite limited, but the most recent estimates indicate that they are considerable. The National Drug Research Institute (NDRI), for example, estimated that in 2015-16,, pharmaceutical opioid misuse and illicit opioid use generated $15.76 billion in tangible and intangible costs to society.[17] This estimate, along with other quantitative estimates produced by NDRI for certain other controlled substances are discussed in greater detail in Section 2.2.2 below.

[14] Mayo Clinic (n.d.). *Prescription drug abuse*. Accessed March 2023: https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/symptoms-causes/syc-20376813.

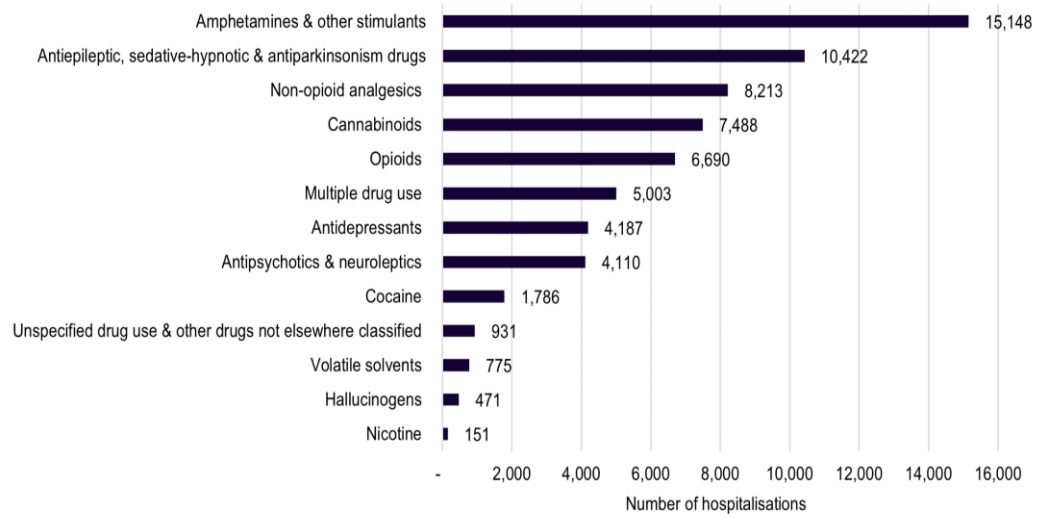
[15] Patterson E, Sullivan T & Ticehurst A 2018, Use and misuse of prescription drugs among police detainees. Trends & issues in crime and criminal justice no. 541. Canberra: *Australian Institute of Criminology*. https://www.aic.gov.au/publications/tandi/tandi541.

[16] That is, costs to society as a whole expressed in dollar terms.

[17] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16*, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University. Accessed March 2023: https://ndri.curtin.edu.au/publications-resources/project-reports-and-bulletins/social-and-economic-costs-of-substance-use.

Data relating to the prevalence of drug misuse and illicit drug use in NSW and Australian society as a whole, as well as impacts attributable or related to drug use (e.g., hospitalisations and deaths), is readily available and further highlights the extent of the problem. The misuse and abuse of drugs often leads to accidental deaths and injuries. Indeed, a large number of hospitalisations are attributable to misuse/abuse of pharmaceuticals and illicit substances. Figure 2.1 below shows the number of non-alcohol drug-related hospitalisations recorded across Australia between 2020 and 2021. The highest number of such hospitalisations was attributable to amphetamines and other stimulants (15,148), followed by antiepileptic, sedative-hypnotic and antiparkinsonism drugs (10,422), non-opioid analgesics (8,213), cannabinoids (7,488) and opioids (6,690).[18]

Figure 2.1 All non-alcohol drug-related hospitalisations in Australia by principal diagnosis, 2020–21



Source: Australian Institute of Health and Welfare 2022, Alcohol, tobacco and other drugs in Australia: data. Accessed March 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/data-tables.

Analysis of the National Mortality Database by the Australian Institute of Health and Welfare (AIHW) shows that in 2021 there were 1,704 drug-induced deaths in Australia, with a higher rate of drug-induced deaths in regional Australia than capital cities. Almost two-thirds (65%) of drug-induced deaths were considered accidental and 27% of deaths were considered intentional.[19] Further, the AIHW analysis notes that:

— opioids continue to be the most common drug class present in drug-induced deaths over the past decade (3.8 per 100,000 population in 2021). Opioids include the use of a number of drug types, including heroin, opiate-based analgesics (such as codeine and oxycodone) and synthetic opioid prescriptions (such as tramadol and fentanyl)

— benzodiazepines were the most common single drug type present in drug-induced deaths (2.9 per 100,000 population)

— over the past decade there has been a substantial rise in deaths involving psychostimulants. The rate has increased from 0.7 per 100,000 population (163 deaths) in 2012 to 1.8 (431 deaths) in 2021.

Children are at particularly high risk of hospitalisations and deaths from misuse and abuse of controlled substances. In 2020, there were 1,464 hospitalisations as a result of poisoning for

[18] Australian Institute of Health and Welfare 2022, *Alcohol, tobacco and other drugs in Australia*. Accessed March 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/impacts/health-impacts.

[19] Ibid.

children aged 0-4. This represents a crude hospitalisation rate that is more than double that of the population as a whole (95.3 per 100,000 people for this particular age group compared with 41.9 per 100,000 people for Australia overall).[20] Furthermore, injuries and poisoning are the primary cause of death in children aged 1-3, accounting for around 30% of deaths in this age group and remains a leading cause for all persons aged 0-16, accounting for 13.3% of deaths in 2020.[21]

Opioids

Opioids are particularly prone to misuse, abuse and diversion. The misuse and abuse of opioids, particularly pharmaceutical opioids, is a pressing issue in Australia. Indeed:

- The use of prescription opioids has increased considerably, with the number of prescriptions subsidised by the Pharmaceutical Benefits Scheme (PBS) increasing from 2.4 million in 1992 to 7 million in 2007,22 and from 13.2 million in 2012 to a peak of in 15.8 million in 2017. The number was 13.9 million by 2021.[23]
- In 2019, 8.3% of Australians aged 14 and over reported having misused prescription opioids as well as non-opioid analgesics, with 2.7% of Australians having done so in the previous 12 months.[24]

The NDRI notes that **in recent decades**, **the range and patterns of opioids used for extra-medical purposes** (which includes the misuse of pharmaceutical opioids and the illegal use of heroin) **have experienced considerable change**. Indeed, they note that **the use of pharmaceutical opioids exceeds the use of heroin**. According to the authors[25]:

- in 2016, in Australia, it was estimated that about 39,700 people had used illegal opioids (heroin or opium), about 715,000 had used pharmaceutical opioids for non-medical purposes and 3.1 million had used prescription opioids[26] as prescribed
- in 2017, 63% of opioid deaths in Australia were attributed exclusively to pharmaceutical opioids, 28% to illicit opioids and 8% to both illicit and pharmaceutical opioids (for people aged 15-64 years).

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[20] Australian Institute of Health and Welfare 2022, *Alcohol, tobacco and other drugs in Australia: data*. Accessed March 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/data-tables.

[21] HealthStats NSW 2021, *Deaths in children*. Accessed March 2023: https://www.healthstats.nsw.gov.au/#/indicator?name=-cat-kid-dth&location=NSW&view=Trend&measure=Percent&groups=Age%20(years),Cause%20of%20death&compare=Cause%20of%20death,Age%20(years)&filter=Cause%20of%20death,Injury%20and%20poisoning&filter=Age%20(years),0-16%20years.

[22] NPS MedicineWise 2014, *Pharmaceutical drug misuse in Australi*a. Accessed March 2023: https://www.nps.org.au/australian-prescriber/articles/pharmaceutical-drug-misuse-in-australia.

[23] Australian Institute of Health and Welfare 2022, *Alcohol, tobacco and other drugs in Australia: data*. Accessed March 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/data-tables.

[24] Australian Institute of Health and Welfare 2022, *Alcohol, tobacco and other drugs in Australia*. Accessed March 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/impacts/health-impacts.

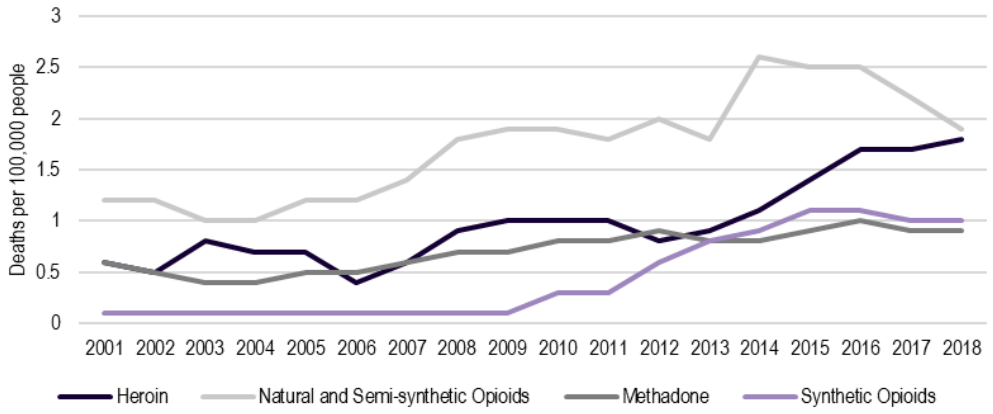
[25] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16*, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University. Accessed March 2023: https://ndri.curtin.edu.au/publications-resources/project-reports-and-bulletins/social-and-economic-costs-of-substance-use.

[26] Excludes private prescriptions and over-the-counter codeine products available at that time.

According to the AIHW, in 2021, a total of 962 opioid-induced deaths[27] were reported in Australia, representing 57% of all drug-induced deaths that occurred that year[28]. Furthermore, similar to the statistics quoted in the NDRI report, the latest data from the ABS shows that **more than 70% of opioid-induced deaths** (a total of 1,123 in 2018) **are attributable to pharmaceutical misuse and abuse**. [29]

Figure 2.2 breaks down opioid death rates by specific type. Natural and semi-synthetic opioids had the highest death rate at 1.9 per 100,000 in 2018 (down from a peak of 2.6 in 2014), but this has converged to match that of heroin (1.8), which has increased significantly over time. Synthetic opioids have emerged as the next deadliest type of opioid, with a crude rate of 1 per 100,000 people. Methadone, which is often used to treat heroin dependency, had a death rate of 0.9 per 100,000 people.[30]

Figure 2.2 Opioid-induced deaths per 100,000 people in Australia, by type, 2001-2018



Source: Australian Bureau of Statistics 2019, Opioid-induced deaths in Australia. Accessed March 2023: https://www.abs.gov.au/articles/opioid-induced-deaths-australia#-opioid-induced-deaths-over-time.

People who misuse or abuse opioids are at a greatly increased likelihood of experiencing or being the cause of accidental injuries.[31] Deaths in which opioids play a partially causal role are referred to as opioid-related[32].

[27] An opioid-induced death is defined as having an underlying cause of death directly attributed to one or more opioids, e.g., poisoning, overdose or toxicity.

[28] Australian Institute of Health and Welfare 2023, *Alcohol, tobacco & other drugs in Australia*, AIHW, Australian Government. Accessed 14 July 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/impacts/health-impacts#druginduceddeaths.

[29] Australian Bureau of Statistics 2019, *Opioid-induced deaths in Australia*. Accessed March 2023: https://www.abs.gov.au/articles/opioid-induced-deaths-australia#-opioid-induced-deaths-over-time.

[30] Ibid.

[31] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16*, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University. Accessed March 2023: https://ndri.curtin.edu.au/publications-resources/project-reports-and-bulletins/social-and-economic-costs-of-substance-use.

[32] An opioid-related death is when opioid use was found to be contributory to the death (indirectly, partially attributable), e.g., transport accidents, suicide, interpersonal violence and disease processes like bloodborne virus infections.

The NDRI estimate that around 122 premature deaths resulted from accidental injury attributable to opioids (prescription and illicit) in 2015-16.[33] People with an opioid dependence are at a greatly increased likelihood of experiencing or being the cause of accidental injuries.[34] The most common cause of premature death resulting from accidental injuries attributable to opioid misuse was road incidents (for example, pedestrian and cyclist injuries and motor vehicle road injuries) and falls.

2.2.2 The social and economic costs of illicit drug use

As mentioned before, there are myriad of costs to society associated with the misuse, abuse and diversion of dangerous controlled substances, including social costs like criminal and risky behaviours, driving under the influence, family, domestic and sexual violence, homicide and victimization,[35] and economic costs like lost productivity and increased expenditure on health and criminal justice (among other things).[36]

Quantitative estimates of such social and economic costs for NSW or even Australia overall are sparse, but the NDRI has produced estimates for a range of illicit drugs and misuse/abuse of controlled substances which can provide an indication of the magnitude of this problem. Of particular importance for this RIS are the NDRI's quantitative estimates of the social and economic costs of the extra-medical use of opioids, which includes the misuse of pharmaceutical opioids (use not as prescribed) and the illegal use of heroin (summarised in Figure 2.3 and Table 2.1). These estimates consider tangible costs like hospital care, workplace disruptions, policing, traffic and more, as well as intangible costs related to premature death.

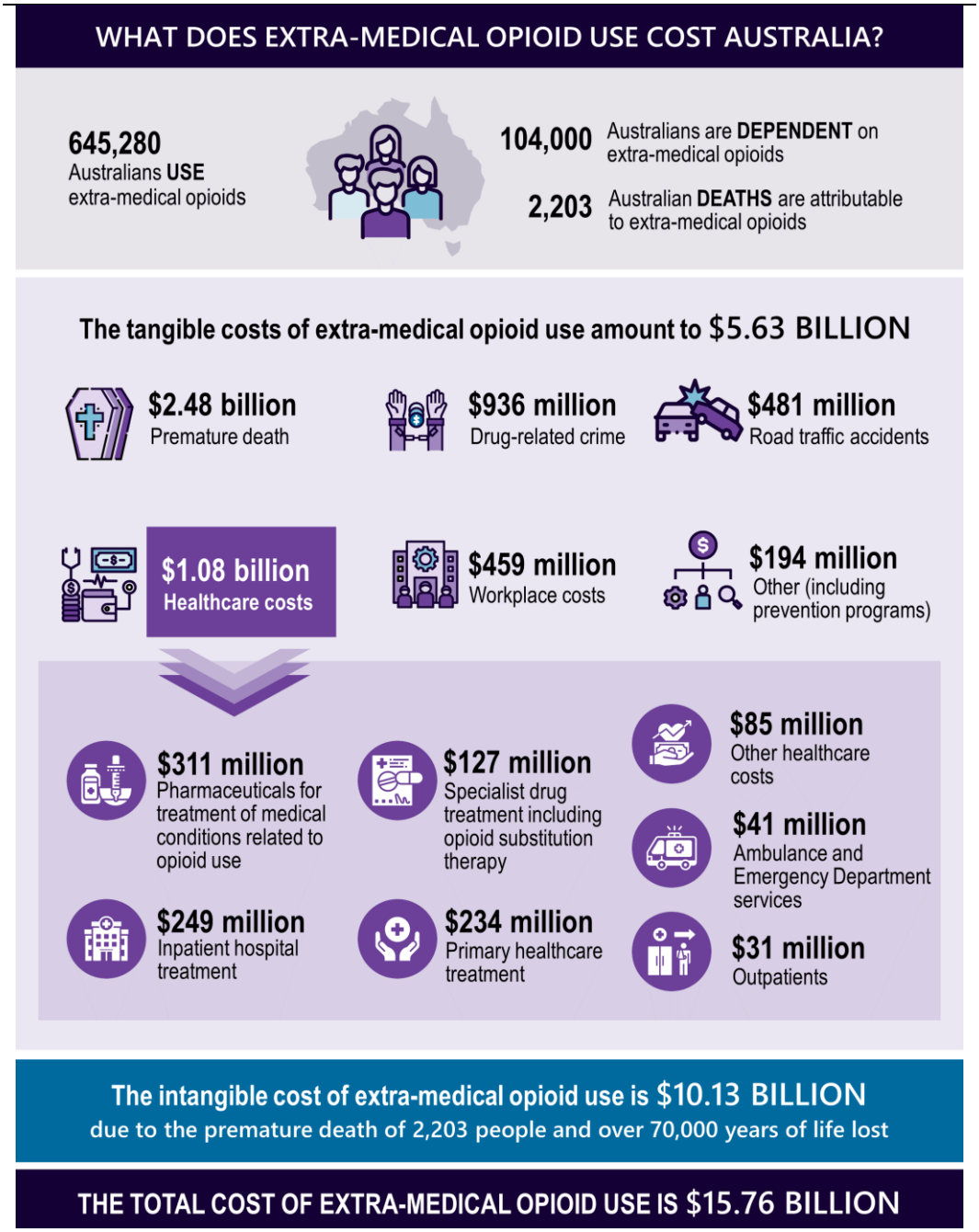
[33] This is the NDRI's central estimate of opioid attributable deaths. The NDRI uses a statistical method based on coronial data to estimate a range of opioid attributable deaths due to accidental injury. Using this method, it was estimated that in 2015-16 there were between 47.2 and 288.1 premature death from opioid attributable accidental injury, with the central estimate being 121.8 deaths.

[34] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16*, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University. Accessed March 2023: https://ndri.curtin.edu.au/publications-resources/project-reports-and-bulletins/social-and-economic-costs-of-substance-use.

[35] Australian Institute of Health and Welfare 2022, *Social impacts*. Accessed April 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/impacts/social-impacts.

[36] Australian Institute of Health and Welfare 2022, *Economic impacts*. Accessed April 2023: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/impacts/economic-impacts.

Figure 2.3 Cost of extra-medical opioid use to Australia in 2015-16



Note: extra-medical opioid use includes the use of any illegal opioids and the misuse of pharmaceutical opioids (use not as prescribed).

Source: Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University.

As shown in Table 2.1, the central estimates produced by the NDRI indicate that the total tangible costs of opioid misuse and illicit opioid use amounted to $5.6 billion in 2015-16. Intangible costs were estimated at $10.1 billion, for a total of $15.7 billion in combined costs to Australia. The costs may be as high as $44 billion under the high estimate, or as low as $9.8 billion in the lowest estimate.[37]

[37] Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. *Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in*

Tangible costs in the central scenario were primarily attributable to the tangible costs of premature death,[38] which made up about 46% of costs in this category. This was followed by criminal justice, hospital inpatient care and other healthcare, traffic accidents, other workplace costs and other costs.

The costs associated with premature death are the single largest contributors to total costs. Opioid-attributed deaths were found to have resulted in between 86,095 and 62,167.5 total years of life lost in 2015-16, with the central estimate being a loss of 70,961 years of life. This results in tangible costs of roughly $2.6 billion and intangible costs of more than $10 billion. The intangible costs are based on estimates of the value of a statistical life. The value of a statistical life year was calculated to be $286,553.

Table 2.1 Range of NDRI estimates of costs associated with misuse and illicit opioid use to Australia in 2015-16, $ million

Cost type	Central estimate	Lower estimate	Higher estimate
Tangible costs			
Gross costs of premature mortality	$2,624.0	$2,334.0	$3,133.3
Avoided healthcare costs	-$138.6	-$132.0	-$148.3
Hospital inpatient care	$249.3	$180.1	$366.8
Other health care	$829.5	$512.4	$1,215.4
Other workplace costs	$458.7	$173.7	$743.6
Criminal justice	$936.1	$565.0	$1,755.3
Traffic accidents	$480.6	$270.3	$692.0
Other costs	$194.0	$183.3	$204.6
Total tangible costs	**$5,633.5**	**$4,086.8**	**$7,962.8**
Intangible cost of premature mortality	$10,127.2	$5,668.3	$36,200.2
Total costs	**$15,760.7**	**$9,755.1**	**$44,163.0**

Source: Whetton, S., Tait, R.J., Chrzanowska, A., Donnelly, N., McEntee, A., Muhktar, A., Zahra, E., Campbell, G., Degenhardt, L., Dey, T., Abdul Halim, S., Hall, W., Makate, M., Norman, R., Peacock, A., Roche, A., Allsop, S., 2020. Quantifying the Social Costs of Pharmaceutical Opioid Misuse and Illicit Opioid Use to Australia in 2015/16*, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University. Accessed March 2023: https://ndri.curtin.edu.au/publications-resources/project-reports-and-bulletins/social-and-economic-costs-of-substance-use.*

2015/16, Tait, R.J., Allsop, S. (Eds.). ISBN 978-0-6487367-0-7, Perth, WA, National Drug Research Institute, Curtin University. Accessed March 2023: https://ndri.curtin.edu.au/publications-resources/project-reports-and-bulletins/social-and-economic-costs-of-substance-use.

[38] The tangible costs associated with premature mortality relate to reduced paid employment, costs accruing to employers as a result of workplace disruptions and lost household labour. These costs are partially offset by avoided healthcare costs, but such savings are minimal.

The case for government intervention 3

Establishing that a problem exists is not sufficient to justify government intervention. Rather, the case for action must be established on the basis of market failure, regulatory failure, or in order to achieve societal or environmental outcomes that would not be delivered by the market alone. Further, in building the case for government action, it is important to demonstrate that the problem could not be solved by the market itself or through alternative quasi or non-regulatory responses. [39]

This chapter explores the various types of market failure that are related to the use of medicines, poisons and therapeutic goods and whether there are non-legislative means for addressing them.

3.1 Market failure

Generally, a competitive market is the most efficient means of allocating resources across a society, ensuring that the goods and services demanded by consumers are produced efficiently and promoting innovation as well as consumer choice. A situation when a market fails to perform these functions is commonly known as market failure.

The presence of market failure implies that there is a potential for the government to improve outcomes for consumers, businesses, the economy and society as a whole. However, government action is not always warranted, and poorly designed regulations may create further inefficiencies or impose excessive or unnecessary administrative and compliance burdens on businesses, consumers and government.

Types of market failure include public goods, externalities, information asymmetries, bounded rationality and natural monopolies. In the case of medicines, poisons and therapeutic goods, the rationale for government intervention is most likely to be justified on the grounds of information asymmetries, bounded rationality and negative externalities. These are discussed in the following sections.

3.1.1 Information asymmetries

Information asymmetry can manifest is when consumers purchase/consume a good or service without fully being aware of the consequences of their decisions/actions. High sugar diets and obesity-related health issues are good examples, where the quantity of unhealthy food consumed by an individual may be more than would otherwise be if they were aware of the illnesses such diets are known to cause. In a healthcare setting, this might include the impact from consumption of a particular type or quantity of medication.

The risk of misuse or abuse of scheduled substances is often not fully understood by prescribers and consumers. As a result of information asymmetries/failures, the market is unlikely to be efficient in this context.

[39] NSW Treasury 2019, *NSW Guide to Better Regulation*, TPP 19-01, January.

Information asymmetries occur at two levels, for consumers and health care professionals.

Users of scheduled substances may not be fully informed about the consequences of misuse or abuse of these substances on their own health. There are studies documenting the 'gap' in consumers' understanding of the likely impact of misuse or abuse of these substances on their health, despite there being almost universal recognition that some of these substances may have undesirable health implications if used inappropriately.

For example, recently the Therapeutic Goods Administration (TGA) commissioned ORIMA Research to investigate the awareness and understanding of opioids amongst both consumers and health care professionals.[40] ORIMA Research found that, overall, there is limited awareness and understanding of opioids amongst consumers. Furthermore, substantial proportions of consumers did not recognise their own medication(s) as being an opioid. Indeed:

- one in five current opioid consumers (18%) did not recognise the term 'opioids', and recognition was even lower amongst potential consumer and general public respondents
- only half of current opioid consumers (53%) were aware that they were taking an opioid medication, and even fewer (43%) correctly identified all of their current opioid medications as being opioids
- only around two-thirds of consumer respondents (68%) were aware that there were specific weaning/tapering strategies to reduce/stop opioid usage
- only around two-thirds of consumer respondents (68%) were aware that opioids had greater risks than basic over-the-counter medicines. In particular, there was limited awareness of the risk of dependence / addiction, including:
  - who was susceptible – around one-third of consumer respondents (32%) incorrectly believed that dependence was only a risk for certain people
  - how dependency develops – the qualitative research found that many participants held a misconception that dependency could only develop over longer periods of opioid usage (e.g., several months or years)
- only a few participants in the qualitative research were aware that unsafe and ineffective usage of prescription opioids was a problem in Australia.

Prescribers of scheduled substances can face information asymmetries where a patient goes 'doctor shopping' and obtains multiple prescriptions from different healthcare providers without the providers' knowledge of the other prescriptions. Furthermore, prescribers can have low awareness levels about the levels of safety, effectiveness and dependency amongst their patients using scheduled substances. For instance, in their opioid report to the TGA, ORIMA Research found relatively high rates of prescribers who indicated that they did not know what proportion of their patient base were using opioids safely and effectively, and what proportion were dependent (see Table 3.1).

In addition, while less common, health care professionals prescribing certain scheduled substances can have gaps in their knowledge about their safe use and/or disposal and of alternative (less risky) treatments (e.g., alternative treatments to treat pain instead of opioids). For instance, ORIMA Research found that:

- of eight survey questions relating to awareness and understanding of opioids, around two in five prescriber respondents[41] (39%) answered all correctly, and nine in ten (91%) answered more than half correctly

[40] ORIMA Research 2020, *A report on communications developmental research relating to opioid regulatory reforms*, July, https://www.tga.gov.au/sites/default/files/communication-developmental-research-prescription-opioids.pdf, accessed June 2023.

[41] The research surveyed 376 opioid prescribers.

- awareness of safe disposal methods for opioids and how opioid dependency develops was relatively limited:
  - only 79% of prescribers were aware that flushing opioids down the toilet or throwing them in the bin were not safe ways to dispose of opioids
  - only 81% correctly identifying that addiction is possible even when people follow prescription instructions
- the level of awareness and understanding of opioids varied amongst prescribers from certain demographics, in particular, ORIMA Research found that:
  - allied health care professional had considerably less awareness of opioids than prescriber participants
  - amongst prescribers, General Practitioners (GPs) and dentists had lower awareness of opioids than specialists (86% of GPs, 88% of dentists and 99% of specialists answered more than half survey questions correctly).

Table 3.1 Prescribers who 'don't know' about opioids safety, effectiveness and dependency amongst their patients

Prescriber	Using opioid medications *safely*	Using opioid medications that are *fully effective*	*Dependent/ addicted* to their opioid medication
Specialist	11%	15%	24%
GP	5%	7%	14%
Dentist	19%	28%	38%
Other doctor (e.g., registrars and residents)	15%	17%	27%
Nurse practitioner	6%	6%	16%

Source: ORIMA Research 2020, *A report on communications developmental research relating to opioid regulatory reforms*, July, https://www.tga.gov.au/sites/default/files/communication-developmental-research-prescription-opioids.pdf.

3.1.2 Bounded rationality

One of the core assumptions of efficient markets is that the players in that market make decisions and work towards outcomes that maximises their benefits. These benefits may be different for each person (representing the diversity of motivations and consumer preferences). However, some people make decisions with long-lasting consequences that are not well understood or considered at the time. This could be due to cognitive or emotional limitations, time pressures or a range of other factors. Economists describe this as bounded rationality. Put formally, bounded rationality describes the phenomenon of people making decisions that do not maximise their own utility function. Where this is the case, government can increase consumer welfare through regulation or structures to guide those decision.

One example includes the case of addiction. Consumers who are addicted to a substance may seek out or consume that substance in the moment, even if they know they will regret it. By restricting access to that substance, governments can mitigate the risks posed by that substance for that person and the public.

3.1.3 Negative externalities

Externalities are defined as costs and benefits of an activity that are experienced by people or organisations other than those directly involved in the activity. They exist when the welfare of some agent, or group of agents, is affected by the actions of another and this is not reflected in market prices. When the effects of one agent on another are not taken into account, market prices will not reflect the true marginal cost/benefit of the good or service traded. A common example is pollution,

where unless a producer is required to compensate society for the pollution they generate (by internalising the cost of mitigation/remediation in their production cost), they would produce more of that good than at the socially optimum level.

Negative externalities related to the medicines, poisons and therapeutic goods include:

- the cost of public healthcare for conditions/illnesses developed as a result of substance misuse
- the impact of substance misuse or abuse on the broader community, including:
  - social impacts such as violence, crime and trauma
  - economic impacts like law enforcement and social services.

Because these negative impacts are not reflected in the cost of medicines, more would be consumed than is socially optimal, in spite of the problems (social, environmental and economic) they pose.

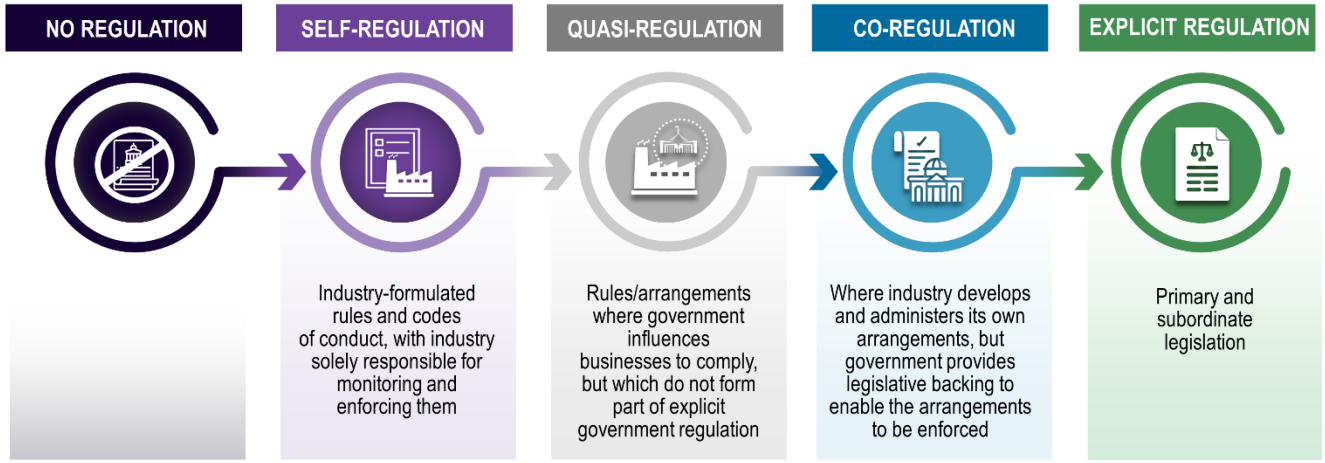
3.2 Can the problem be addressed by non-legislative means?

Having established a justification for government intervention arising from market failure, it is necessary to consider whether there are non-regulatory or quasi-regulatory responses the government could pursue, or whether the market may self-correct through its normal functioning.

3.2.1 Is there scope for self-regulation, quasi-regulation or co-regulation?

In a broad sense, regulation can be considered as a spectrum ranging from self-regulation (where there is little or no government involvement), through quasi-regulation and co-regulation (which refers to a range of rules, instruments or standards that government expects businesses to comply with), to explicit government regulation (see Figure 3.1).

Figure 3.1 Continuum of government intervention



Source: ACIL Allen based on Commonwealth of Australia 2007, Best Practice Regulation Handbook.

According to the *Australian Government Best Practice Regulation Handbook*[42], **self-regulation** is typically characterised by the industry formulating rules and codes of conduct. As noted by the Australian Treasury's Taskforce on Industry Self-regulation, self-regulation should be considered where:

- *there is no strong public interest concern, in particular, no major public health and safety concern;*
- *the problem is a low risk event, of low impact/significance, in other words the consequences of self-regulation failing to resolve a specific problem are small; and*
- *the problem can be fixed by the market itself, in other words there is an incentive for individuals and groups to develop and comply with self-regulatory arrangements (e.g. for industry survival, or to gain a market advantage).*

Taskforce on Industry Self-regulation 2020, Industry Self-Regulation in Consumer Markets, p. 43.

Quasi-regulation includes a wide range of rules and/or arrangements where governments influence businesses/industry to comply, but which do not form part of explicit government regulation.[43] Examples of quasi-regulation include accreditation schemes and codes of conduct/practice developed with government involvement. Box 3.1 outlines the circumstances in which self or quasi-regulation may be appropriate.

Quasi-regulation is likely to be successful when government is not convinced of the need to develop or mandate a code for the whole industry. Flexible, tailor-made solutions and less formal mechanisms bring cost advantages, and the industry is capable of engaging in a cohesive response.

Box 3.1 Checklists for assessment of self and quasi-regulation

Self-regulation should be considered where:

- there is no strong public interest concern, in particular, no major public health and safety concern
- the problem is a low-risk event, of low impact or significance
- the problem can be fixed by the market itself.

Quasi-regulation should be considered where:

- there is a public interest in some government involvement in addressing a community concern and the issue is unlikely to be addressed by self-regulation
- there is a need for an urgent, interim response to a problem in the short term, while a long-term regulatory solution is being developed
- government is not convinced of the need to develop or mandate a code for the whole industry
- there are cost advantages from flexible, tailor-made solutions and less formal mechanisms
- there are advantages in the government engaging in a collaborative approach with industry, with industry having substantial ownership of the scheme. For this to be successful, there needs to be:
  - a specific industry solution rather than regulation of general application
  - a cohesive industry with like-minded participants, motivated to achieve the goals
  - a viable industry association with the resources necessary to develop and/or enforce the scheme
  - effective sanctions or incentives to achieve the required level of compliance, with low scope for benefits being shared by non-participants
  - effective external pressure from industry itself (survival factors), or threat of consumer or government action.

As in the case of self-regulation, proposed approaches should not restrict competition.

Source: Commonwealth of Australia 2007, Best Practice Regulation Handbook.

[42] Commonwealth of Australia 2007, *Best Practice Regulation Handbook*.

[43] Commonwealth of Australia 2007, Best Practice Regulation Handbook.

Co-regulation typically refers to situations where industry develops and administers its own arrangements, but government provides legislative backing to enable the arrangements to be enforced.[44]

It is clear that in the case of medicines and poisons, several of the conditions for relying on self-regulation, quasi-regulation, or co-regulation are not met:

- the problems caused by misuse or abuse of medicines and poisons are of high impact/significance
- there is a strong public interest concern, in particular the significant concerns regarding harm to human health and community safety
- there are no market incentives for individuals, health professions and businesses to comply with self-regulatory arrangements
- there is no cohesive industry with like-minded participants motivated to achieve the same goals. The number of stakeholders involved in the manufacturing, wholesale supply, non-wholesale supply, prescription and administration of poisons and medicines is large and with diverse interests.

Use of clinical tools

A possible form of quasi-regulation is the use of clinical tools developed by government that provide real-time information about a patient's prescription history for certain high-risk medicines to prescribers and dispensers. An example of such a tool is SafeScript NSW.

SafeScript NSW is a database providing real-time information about a patient's prescription history for certain high-risk medicines to support clinical decision making and patient safety. The system was made available to certain prescribers and pharmacists in all NSW areas in May 2022.

Eligible prescribers (medical practitioners, nurse practitioners and dentists) and pharmacists registered with the Australian Health Practitioner Regulation Agency (AHPRA) are able to access SafeScript after they have registered for the system.

The use of SafeScript is not mandatory, but all practising relevant prescribers and pharmacists in NSW are encouraged to use the system to help reduce unsafe use of monitored medicines in the community.

While clinical tools like SafeScript are key complementary measures to any regulatory response to help minimise some of the compliance, monitoring and enforcing costs of legislation, by themselves, are unlikely to be effective in relation to public risks related to misuse and abuse of medicines and poisons.

3.2.2 Provision of information

A possible non-regulatory response by government to problems arising from information asymmetry could be to provide more information to consumers so that they are more informed. However, this approach is unlikely to be effective in relation to public risks related to misuse and abuse of medicines and poisons. While requiring manufacturers to disclosure information to consumers/users about the health risk associated with the goods and services they supply could form an important part of a regulatory response, information provision by government on its own is not sufficient to address the problem.

[44] Australian Law Reform Commission 2012, *Classification—Content Regulation and Convergent Media*, Final Report, February, https://www.alrc.gov.au/wp-content/uploads/2019/08/final_report_118_for_web.pdf, accessed 8 December 2022.

3.3 Summing up

The discussion in this and the previous chapter suggests that, in principle, there is a case for regulating the supply, prescription and administration of medicine, poisons and therapeutic goods on the basis that:

- There are existing market failures that endanger public health and safety and inhibit socially optimal production and consumption of controlled substances. These include information asymmetries, bounded rationality, and negative externalities.
- There is a lack of non-regulatory alternatives to correct for these market failures.
- Existing regulation needs to be updated to reflect changes to the regulatory environment, improved government and community understanding of risks, and changing business practices.

The case for regulation is qualitatively assessed in this RIS to determine whether the regulations, including changes to the status quo would be of net benefit to New South Wales in the following chapters.

4 Objectives of the proposed regulation

An important goal of a regulatory impact statement is to identify clearly the objective of the regulatory intervention.

The overall objective of the MPTG Regulation is to support the purpose of the MPTG Act and minimise risks to patient safety and the risk of diversion by making provisions relating to:

- wholesale supply of medicines/poisons
- obtaining a wholesale supply of medicines
- obtaining a wholesale supply of poisons (for example for use in manufacturing and industry)
- non-wholesale supply of medicines/poisons
- issuing prescriptions for medicines
- administration of medicines
- specific controls relating to higher-risk substances (such as drugs of addiction), substances used for cosmetic purposes, and substances that are subject to additional controls and for which the prescribing/dispensing is 'monitored' on SafeScript NSW
- records of supply
- cleanliness requirements (including preparation and handling of substances)
- storage and labelling of medicines/poisons.

Overall, the key objectives of the MPTG Regulation can be seen as to:

- provide legislative support and administrative detail for the operation of the MPTG Act
- protect public health and safety through the provision of a framework for adequate monitoring and control of activities involving scheduled substances and other prescribed therapeutic goods.

5 Options considered

A RIS should identify and assess the policy options that could achieve the objectives of government action outlined in Chapter 4. The options that have been identified are the following.

- ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the PTGR sunset and not replace it with a new Regulation.
- ***Option 1*** — this option entails remaking the PTGR without any changes to align with the new MPTG Act (the *status quo* option).
- ***Option 2*** — this option entails making the proposed MPTG Regulation.

Each of these options are discussed in more detail in the sections below.

5.1 Base case: no Regulation

This option would entail letting the PTGR sunset when the new MPTG Act commences and not replacing it with a new Regulation.

In considering this option it is useful to outline a view of the likely general implications of such a regulatory change, as this provides a basis for assessing the range of potential costs and benefits under this scenario.

If the PTGR were discontinued and not replaced, the MPTG Act would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the MPTG Act operates. Under this scenario, some activities involving scheduled substances and other prescribed therapeutic goods would still be regulated under the Act, but:

- there would be no mechanism for a number of stakeholders to be able to wholesale supply, obtain wholesale supply or non-wholesale supply of medicines
- there would not be restrictions/controls on the administration of medication
- the health practitioners allowed to (non-wholesale) supply or prescribe medicines would be limited to those specifically authorised under the Act. Practitioners not specifically authorised under the Act (but authorised under the proposed Regulation) would not be able to supply, prescribe or administer medicines
- medication prescription criteria would be absent
- patient medication labelling obligations would not exist
- there would be no obligations regarding cleanliness and handling of substances
- healthcare and clinical tools, such as SafeScript NSW would no longer have a lawful basis
- there would be no controls regarding storage, disposal and destruction of high risk scheduled medicines

— mechanisms to authorise persons to undertake research with high-risk substances would be more limited

— penalty infringement notices (on-the-spot fines) would not be able to be issued, as the offences for which these are prescribed are set in the MPTG Regulation.

In the absence of the Regulation, and of prescriptive requirements for medicines and poisons, the Ministry would have no ability to restrict the administration, prescribing, and supply of certain medicines in certain circumstances and/or by certain people. This would result in an ineffective enforcement and compliance regime and increased risks to the health and safety of NSW residents.

5.2 Option 1: remaking the existing PTGR without changes (status quo)

This option entails remaking the PTGR without any changes, which means that:

— the requirements for the manufacturing, supply, prescribing and administration of medicines and poisons specified in the current PTGR would remain unchanged

— there would be major misalignment between the Regulations and the MPTG Act.

5.3 Option 2 — adopting the proposed MPTG Regulation

This option entails making the proposed MPTG Regulation. The key changes in the draft MPTG Regulation (compared to the status quo – the PTGR) are outlined in the sections below.

5.3.1 Periodical inventory of stock of drugs of addiction

The PTGR requires people authorised to be in possession of a drug of addiction (Schedule 8 substance) to keep a drug register which sets out the stock they hold of those substances. In addition, Clause 118 of the PTGR requires that the person responsible for keeping this drug register does an inventory of that stock twice per year in March and September.

Given the risk of diversion of these substances and the greatly increased volumes prescribed and dispensed (for instance, a pharmacy dosing 40 OTP patients 5 times per week alone could easily have 5,200 stock movements in a six-month period and OTP audits demonstrate many unaccountable losses of methadone, including many examples of large volumes not accounted for), the MPTG Regulation would increase the number of times that an inventory must be taken to every month. The change would help to identify loss more quickly, which would assist in investigating diversion.

5.3.2 Wholesale supply of medicines and poisons

Table 5.1 outlines the proposed changes for the wholesale supply of medicines and poisons under the MPTG Regulation, compared to the current PTGR (note that from here onwards, scheduled substances may be denoted with and ‘S’ and the schedule number – i.e., S8 denotes Schedule 8 substances).

The proposed changes in the MPTG Regulation recognise modern business and clinical safe practices by allowing supply of certain scheduled substances between community pharmacies where there is an owner in common would facilitate business practices.

The purpose of the proposed change to clinical samples is to recognise the higher risk profile of Schedule 4D and 8 substances, including for diversion of these substances for personal use or trafficking purposes. The proposed change also seeks to ensure the integrity/transparency of the supply chain, including by requiring health/vet practitioner orders for supply of samples of Schedule 2, 3, or 4 (not 4D) from wholesalers.

Table 5.1 Proposed change to wholesale supply of medicines and poisons under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
Wholesale supply Currently under the PTGR, generally only holders of wholesaler's licences are authorised to wholesale supply[45] a scheduled substance and wholesalers can only supply to a person who is able to obtain the substances under the PTGA/PTGR. Pharmacies are only allowed to wholesale supply in a very limited number of circumstances, which include: – Wholesale supply to a master of a vessel if the vessel is about to go on a voyage and needs it to supply to someone in the vessel. – Wholesale supply to a nurse/midwife immuniser for vaccine administration in the pharmacy premises, to a first aider in respect of a limited number of medicines, or to an authorised practitioner for an emergency 'doctor's bag'. – Wholesale supply a specific substance to another pharmacy for a specific patient who needs it. **Clinical samples** Currently, a manufacturer or wholesaler, or their agent, engaged in the manufacture or wholesale of any poison or restricted substance for therapeutic use can supply free samples provided such distribution occurs in a manner approved by the Secretary and to a person authorised to receive the substance (such as a medical practitioner).	**Wholesale supply** It is proposed that the draft MPTG Regulation includes changes to the circumstances in which a person/entity can wholesale supply medicines / poisons in the absence of a wholesaler's licence. In particular, the draft Regulation allows pharmacies to wholesale supply in the following circumstances (which are not included under the existing framework), in addition to the circumstances already allowed under the PTGR: – where there is a change in ownership or in relation to the bankruptcy, liquidation or external administration of the pharmacy (S2, S3, S4, S8)[46] – where the substance is within 6 months of expiry and not reasonably likely to be used by the pharmacy (S2, S3, S4 but not S4D or S8) – where the pharmacy has the exact ownership structure as the other pharmacy (S2, S3, S4 but not S4D or S8) – where it is to a private health facility or public health entity for a specific patient who needs it (or the return of such stock to the original supplying pharmacy from the receiving pharmacy) – to first aiders (specified additional first aid medication to that already provided for in the PTGR) – to masters of vessels and racing yachts, subject to specific threshold requirements being met. **Clinical samples** The following changes are proposed to samples: – Samples of Schedule 8 and Schedule 4D substances would not be authorised. – Any supply of samples of Schedule 2, 3, or 4 (not 4D) substances must only occur where the supply is otherwise authorised under the Act (such as from a licensed wholesaler to a medical/nurse practitioner) and the supplier receives a written request in the approved form from the health practitioner. These changes would apply to health practitioners and veterinary practitioners (i.e., both health practitioners and veterinarians would be required to fill out a written order in an approved form to receive samples).

Source: ACIL Allen and Ministry of Health.

5.3.3 Retail supply and wholesale supply of Schedule 7 substances

Table 5.2 outlines the proposed changes for the retail supply and wholesale supply of Schedule 7 substances listed in Appendix J of the National Poisons Standard under the MPTG Regulation, compared to the current PTGR.

[45] Supply by wholesale means supply for the purposes of resupply.

[46] Under the Health Practitioner Regulation National Law:
- A person can't carry on a pharmacy business unless (amongst other requirements) all holders of a financial interest in the pharmacy business are registered pharmacists.
- A pharmacist must not own or have a financial interest in more than 5 pharmacy businesses in NSW.

Given this, it is not expected that wholesaling would occur between any more than five pharmacy businesses.

The aim of this change is to strengthen the current regulation of Schedule 7 substances, including to address concerns highlighted by the NSW Coroner about the current controls in relation to Schedule 7 substances such as cyanide, arsenic and strychnine. In addition, the NSW Ministry of Health's A/g Chief Pharmacist has previously given evidence at two coronial proceedings in relation to diversion of cyanide which is ultimately used for suicide. The A/g Chief Pharmacist gave evidence in proceedings that NSW would be considering how to mitigate risks with Schedule 7 substances, including in relation to closer alignment with the National Poisons Standard recommendations.

Table 5.2 Proposed changes to the retail supply and wholesale supply of Schedule 7 substances under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
The PTGR prohibits the supply of a Schedule 7 substance without authorisation, but not if the supply is by wholesale. Parallel to the PTGR authorising requirements, the wholesale licencing obligations in the PTGA are hinged to substances being used for therapeutic use. Schedule 7 substances are not used therapeutically, which means the supply by wholesale of Schedule 7 substances can occur without a licence in NSW, provided any relevant PTGR requirements are complied with (such as an authorisation).	The draft MPTG Regulation includes a new requirement for persons/entities to be licenced if they seek to retail supply substances that are listed in Schedule 7 Appendix J of the National Poisons Standard (these are dangerous poisons such as cyanide and arsenic). These obligations apply in parallel to requiring the making and keeping of records creating greater transparency of the supply chain for these high-risk substances. The draft MPTG Regulation also clarifies that the requirement for a licence to wholesale supply a Schedule 7 substance in the Act only applies if the substance is listed in Appendix J of the National Poisons Standard. A person is not subject to the relevant wholesale and non-wholesale offences if the supply is to a person, or for resupply to a person, who is already authorised to possess or use the substance under the *Pesticides Act 1999*.

Source: ACIL Allen and NSW Ministry of Health.

5.3.4 Restrictions on administration of schedule 2, 3, 4 and 8 substances

Table 5.3 outlines the proposed changes to the administration of schedule 2, 3, 4 and 8 substances under the MPTG Regulation, compared to the current PTGR.

The administration of certain medicines can be performed by a variety of people, including medical practitioners, nurse practitioners, nurses, paramedics, dentists, first aid officers and carers. Administration to other persons also occurs in a variety of different circumstances and settings, for example in hospitals, a GP clinic, workplaces, and in homes.

Due to the variety of people who need to be able to administer medicines, and the different circumstances in which administration may occur, the draft MPTG Regulation creates consistent parameters around lawful administration of scheduled substances, with additional record keeping requirements applying in certain settings (such as a hospital, private health facility, managed correctional centre, residential care facility and opioid treatment clinic).

Table 5.3 Proposed changes to the administration of schedule 2, 3, 4 and 8 substances under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
The PTGA does not expressly include administration in the definition of supply; however, in some provisions of the PTGR, it is implied that administration is considered supply. The PTGR does however expressly regulate administration of Schedule 4, and 8 substances in certain settings, such as hospitals, managed correctional centres and private health facilities, and administration of certain high-risk substances (such as Schedule 4D substances).	The MPTG Regulation restricts the circumstances in which a person can administer[47] a Schedule 2, 3, 4, and 8 substance to another person. While the old framework included restrictions in relation to non-wholesale supply of medicines (which could sometimes be read to include a restriction on administration) the draft Regulation creates explicit prohibition and new offences that applies more uniformly across scheduled substances, which are subject to exceptions (for example for health practitioners and carers who administer medicines). Under the draft MPTG Regulation, there would be a blanket offence for administering a Schedule 2, 3, 4, and 8 substance to another person (subject to carve-outs for certain persons) that is not limited to certain settings and which applies to Schedule 2, 3, 4 and 8. There would be specific record keeping requirements for administration in settings such as hospitals, residential care facilities, private health facilities, opioid treatment clinics, and managed correctional centres. Details of the proposed restrictions and carve-outs for administration of schedule 2, 3, 4 and 8 substances are provided below. **Administration of Schedule 2 and 3 substances** The MPTG Regulation would provide that a person must not administer a Schedule 2 or 3 substance to a person unless the person: a) is a registered health practitioner acting in the lawful course of the registered health practitioner's practise, or b) is acting under the direction of a person in paragraph (a), or c) is the carer of the patient, to whom the substance has been lawfully supplied or dispensed, or d) is a person giving first aid to the patient, or e) is employed or engaged by the Ambulance Service of NSW and approved by the Health Secretary to administer the substance, for the treatment of a patient, or f) is a patient transport officer employed or engaged by the Royal Flying Doctor Service of Australia, or g) is employed or engaged at a school or childcare facility and the administration is to a child of medication supplied by the child's parent or guardian in accordance with the medication's label. **Administration of Schedule 4 and 8 substances** The MPTG Regulation would provide that a person must not administer a Schedule 4 or 8 substance to a person unless the person: a) is a medical practitioner, nurse practitioner, dentist, or endorsed nurse/midwife/optometrist/podiatrist b) is a person acting under the direction of a person in paragraph (a), or c) is a pharmacist administering the substance in accordance with a prescription lawfully issued for the patient, or d) is an optometrist, podiatrist, paramedic, dental hygienist, dental therapist, or oral health therapist who is acting in the lawful course of the registered health practitioner's practise and is authorised to obtain the substance under the Act, or e) is a carer of the patient, and the substance has been supplied by an authorised practitioner or dispensed on prescription for the patient, or f) is a first aider giving first aid to the patient; or

[47] Administer is defined in Schedule 3 of the Medicines, Poisons and Therapeutic Goods Act 2022 to mean: administer, in relation to therapeutic goods—
(a) means—
(i) to introduce into, or apply to, the body of a human or animal by any means a dose of the goods, or
(ii) to give a dose of the goods to a human to be taken immediately, but not to give a dose to be taken at a later time, and
(b) does not include a prescribed thing.

Current situation (under PTGR)	Proposed change under the MPTG Regulation
	g) is employed or engaged by the Ambulance Service of NSW and approved by the Health Secretary to administer the substance, for the treatment of a patient, or h) is employed or engaged at a school or childcare facility and the administration is to a child of medication supplied by the child's parent or guardian in accordance with the medication's label. **Administration of Schedule 2, 3, 4 and 8 substances — specific offence in a public health entity, private health facility, residential care facility, managed correctional centre or OTP clinic** The MPTG Regulation would provide that a person must not administer a Schedule 2, 3, 4 or 8 substance to a patient in a public health entity, private health facility, residential care facility, managed correctional centre or OTP clinic unless the person is acting under the direction of a medical practitioner, nurse practitioner, or endorsed midwife. The MPTG Regulation would set out specific record keeping obligations in relation to administration that occurs in these settings, which would align with the existing record keeping obligations at Clause 58/120 PTGR.

Source: ACIL Allen and NSW Ministry of Health.

5.3.5 Compliance standards for Opioid Treatment Program

Table 5.4 outlines the proposed changes to the OTP under the MPTG Regulation, compared to the current PTGR.

Notably, the change from approval to registration under the OTP scheme is a feature of the new MPTG Act (not the proposed MPTG Regulation). However, the MPTG Regulation requires compliance with published standards (OTP Standards) that:

— practitioners would have to comply when prescribing, supplying or administering opioids under the OTP scheme

— pharmacists who dispense under the OTP scheme would have to comply with

— OTP clinics must have in place to ensure safe and quality use of medicine.

Table 5.4 Proposed changes to the OTP registration under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
The NSW OTP provides opioid replacement therapy for people who are dependent on opioids such as heroin, morphine and oxycodone. It gives people the chance to manage their illicit or problematic use of opioids and reduce the harms that come about from such use. There are different types of drug treatments available and assessment by an authorised doctor or nurse practitioner is required to determine which treatment is the most suitable. Under the current regulatory framework: – The **PTGA** requires medical practitioners and nurse practitioners to obtain authorisation from the Health Secretary prior to administering, prescribing, or supplying any Schedule 8 medicine to a "drug dependent person". This means that the prescribing or supply of ODT to any drug dependent person under the NSW OTP must be assessed by the Health Secretary for appropriateness. – A further current control, to minimise congregation of OTP patients near pharmacies, Clause 92(1) of the **PTGR** limits retail pharmacies to dosing 65 patients per day. This cap was instituted to address perceived amenity concerns.	Rather than requiring an approval/authorisation, the **MPTG Act** now provides that the OTP scheme will be moving to registration scheme, under which a medical practitioner or nurse practitioner seeking to prescribe/supply/administer OTP treatment to a patient does not need an approval/authorisation, and only needs to register in relation to that patient. In addition, pharmacies must also register under the OTP scheme in order to be able to dispense under the program. Consistent with the existing practice that occurs via policy guidelines, this will allow a pharmacy to register as a dosing point and in turn allow medical practitioners and nurse practitioners to identify pharmacy dosing points that their patients can attend to receive their ODT dose. Registration by a doctor or nurse practitioner to supply/prescribe/administer ODT to a patient would not be required in certain situations, including: – where the administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds a registration, by:

Current situation (under PTGR)	Proposed change under the MPTG Regulation
The reason an authority is required is to ensure there is only one practitioner prescribing/supplying to a patient. Only a medical practitioner/nurse practitioner may prescribe/supply ODT because these are Schedule 8 medicines (and this is the recommended control for this category under the Poisons Standard).	– a practitioner on the same premises (including a correctional centre) as the practitioner holding the approval, or – by a practitioner nominated by the practitioner who is registered; or – where the administration/supply/or prescription is to initiate or continue treatment to an inpatient or emergency department presentee in a public hospital (other than a public OTP clinic) or a private health facility; or – where the administration/supply/or prescription is for the purpose of continuing treatment of an OTP patient in the 21 days after their release from a correctional centre. The draft **MPTG Regulation** would remove the 65-patient cap for retail pharmacies, and instead require pharmacies to comply with enforceable 'OTP standards'. The enforceable OTP standards, which are currently being developed, would be published on the NSW Health website and are anticipated to require pharmacies to develop and comply with an amenity plan if they seek to dose more than 80 OTP patients per day (excluding patients who are not daily-dosing with OTP treatment, e.g., depot buprenorphine). Separate published enforceable OTP standards would also apply to doctors and nurse practitioners administering/supplying/prescribing to OTP patients.

Source: ACIL Allen and NSW Ministry of Health.

The broad goal of opioid dependence treatment is to reduce harm due to non-medical use of opioids. To achieve this broad goal, the OTP takes a patient centred approach. This involves using treatment programs that incorporate ODT, such as methadone and buprenorphine treatment, which can lead to psychological stability, improved control over drug use, and eventual abstinence from opioid drugs.

The proposed registration scheme (which is a feature of the MPTG Act, not of the proposed MPTG Regulation) seeks to increase transparency of supply under the OTP scheme without creating barriers to access via an approval process. Regulatory control and patient safety would be maintained through the use of regulatory tools such as Real Time Prescription Monitoring (SafeScript NSW) and the Authority Management System (under development). The Authority Management System would be accessible to the practitioners seeking to register to prescribe, supply, or administer ODT for their patient. The regime would ensure only one medical practitioner or nurse practitioner is registered for an individual patient, and that the patient only receives one treatment dose, whether this is by oral administration per day, or by long-acting depot injection.

The cap of dosing 65 daily patients for pharmacies in the PTGR was legislated in the context of a model of care that required patients to attend daily for supervised doses of methadone. There were some public concerns about the impact of large numbers of patients congregating in the retail area of a pharmacy. The proposed removal of the dosing cap for pharmacies under the MPTG Regulation reflects the availability of new opioid agonist medications with improved safety profiles that are more suitable for unsupervised dosing. With fewer patients needing to attend pharmacies daily to receive treatment, concerns about congregation of large numbers of people may no longer be relevant.

While the OTP Standards are still being finalised, a draft version of these is provided in Box 5.1 (notably, these have not been finalised and hence are subject to change).

Box 5.1 Proposed OTP Standards under the MPTG Regulation

OTP standards — practitioner requirements

1. A medical practitioner or nurse practitioner cannot initiate a patient on methadone unless:
   - they are an 'accredited prescriber' or
   - they have the prior approval of the Health Secretary.

   To be an accredited prescriber, a practitioner must:
   - complete the Opioid Treatment Accreditation Course (OTAC), either through attendance at a workshop or through the web-based course and successfully pass end of course examination; and
   - complete a workplace assessment (a 2–3-hour clinical placement); and
   - be recommended for approval by the Secretary, i.e., recommended by the Opioid Pharmacotherapy Subcommittee (of the Clinical Advisory Committee).
2. An unaccredited medical practitioner or nurse practitioner can only register to prescribe/supply/administer:
   - methadone for ≤ 10 patients at any one time; and
   - to maximum of 100 patients at any one time for methadone (≤ 10 patients) and buprenorphine, unless they have the prior approval of the Health Secretary.
3. An accredited medical practitioner or nurse practitioner can only prescribe/supply/administer to a maximum of 200 patients at any one time, unless they have the prior approval of the Secretary.
4. An unaccredited medical practitioner or nurse practitioner cannot transfer a patient from methadone to buprenorphine, using the microdosing or bridging methods (as outlined in specific policies and protocols available to practitioners).
5. An unaccredited medical practitioner or nurse practitioner cannot transfer a patient from buprenorphine to methadone.
6. A medical practitioner or nurse practitioner in a correctional centre can only issue a written direction for 21 days treatment when discharging a patient from the correctional centre.

OTP standards — Requirements applying to registered pharmacies

1. A pharmacy supplying under supervised dosing arrangements to more than 80 patients per day must have an approved amenity plan in place.
2. A pharmacy must comply with a requisite approved amenity plan.
3. A pharmacy must have procedures and processes in place to ensure safe and quality use of medicine, including:
   a) ensuring processes are in place for accountability including record-keeping of Schedule 8 substances
   b) ensuring processes and equipment are in place to ensure security and quality assurance of Schedule 8 substances
   c) ensuring processes are in place for maintenance of dosing equipment as per the operational protocols of the equipment used and policies published on the NSW Health website'.

OTP standards — Requirements applying to OTP clinics

A clinic must have procedures and processes in place to ensure safe and quality use of medicine, including:

— ensuring processes are in place for accountability including record-keeping of Schedule 8 substances

— ensuring processes and equipment are in place to ensure security and quality assurance of Schedule 8 substances

— ensuring processes are in place for maintenance of dosing equipment as per the operational protocols of the equipment used and policies published on the NSW Health website.

Source: NSW Ministry of Health.

5.3.6 Approval to administer/prescribe/supply Schedule 8 substances

Table 5.5 provides a summary of the proposed changes to the circumstances where a practitioner would require an approval to administer/prescribe/supply a Schedule 8 substance under the MPTG Regulation, compared to the current PTGR.

Schedule 8 substances are drugs of addiction that should be available for therapeutic use but require restriction on manufacture, supply, distribution, possession and use with an aim to reduce abuse, misuse and physical or psychological dependence.

In 2022, the Ministry held workshops with a number of stakeholders to scope views on necessary controls in relation to the administration, prescription and supply of certain Schedule 8 substances in high-risk circumstances. The key controls proposed to be included in the MPTG Regulation reflect the results of this consultation process.

Additional details of the proposed controls and their rationale are included in Table 5.6.

Table 5.5 Proposed changes to the circumstances where a practitioner would require an approval to administer/prescribe/supply a Schedule 8 substance under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
The current regulatory framework creates sub-classes of Schedule 8 substances. The current controls for these sub-classes in the PTGA/PTGR framework are set out below. – *Type A Drugs of Addiction*— a medical practitioner or nurse practitioner requires authority to supply or prescribe a Type A drug of addiction. – *Type B Drugs of Addiction* — a medical practitioner or nurse practitioner requires authority to supply or prescribe if it would result in the patient having >2 months continuous supply/prescription of a Type B drug of addiction. – *Type C Drugs of Addiction* — a medical practitioner or nurse practitioner requires authority to supply or prescribe if it is to a patient who is drug dependant. – *Unregistered Type C Drugs of Addiction* — only a medical practitioner can issue a prescription for, or supply, for the purposes of a clinical trial, and must hold an authority to do so. The PTGA and PTGR create specific obligations in relation to prescription and supply of Schedule 8 substances for OTP. OTP applies to buprenorphine and methadone (which are both Type B Drugs of Addiction).	Sections 68 and 69 of the MPTG Act set out that a practitioner is required to hold an approval to administer/supply/prescribe Schedule 8 substances (and other prescribed substances) in the circumstances set out in the MPTG Regulation. The proposed controls under the MPTG are often similar to the controls under the PTGA and the PTGR, but there have been some adjustments, including new controls to better address risk. Additional details of the proposed controls and their rationale are included in Table 5.6

Source: ACIL Allen and NSW Ministry of Health.

Table 5.6 Proposed Schedule 8 controls

Category	Approval required to administer, prescribe or supply	Circumstance in which an approval is required	Exemption to the requirement to get an approval under draft MPTG Regulation	Rationale for proposed change in controls
A	Specified stimulant in Schedule 8 (dexamfetamine, lisdexamfetamine, methylphenidate)	**Current Regulation (PTGR)** Requires authority to prescribe or supply. **Draft MPTG Regulation** Requires a medical practitioner or nurse practitioner to obtain approval unless exempted (e.g., psychiatrist, paediatrician, neurologist, sleep physician within dosage limits specified by the Secretary and published on the NSW Health website would not require approval. A range of exemptions apply more broadly, including in relation to palliative care for a patient)	– The administration/supply/or prescription is for a palliative care patient.[48] – The administration/supply/or prescription is by AHPRA registered medical practitioners registered in the specialty of palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology. – The administration/supply/or prescription is by AHPRA registered medical practitioners registered in the specialty of psychiatry and paediatric and child health, and the specialty fields of neurology and respiratory and sleep medicine, within dose limits set by the Health Secretary and published on the NSW Health website. – The administration/supply/or prescription is to initiate or continue treatment for a patient (both an inpatient or emergency department presentee) in a public hospital or private health facility. – The administration/supply/or prescription is for an inmate in a correctional centre when the administration/supply/or prescription is for the purpose of continuing the treatment that the person was receiving immediately before the person became an inmate. – The administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds an approval who is temporarily on leave, by: – a practitioner on the same premises as the practitioner holding the approval, or – by a practitioner nominated by the practitioner holding the approval.	The current controls for Schedule 8 stimulants should be continued with exemptions in place. Exemptions applying to medical practitioners registered in the specialties of psychiatry and paediatric and child health, and the specialty fields of neurology and respiratory and sleep medicine, is to be limited to the prescribing, supply or administration of a Schedule 8 stimulant in a dose below thresholds set by the Health Secretary and published on the NSW Health website. This is the recommendation from consulted specialists advising Schedule 8 stimulants above certain doses should not be used, unless the circumstances are assessed and are extremely extraordinary.
B	Alprazolam, flunitrazepam, methadone (non-OTP), and any Schedule 8 in an injectable or intranasal preparation	**Current Regulation (PTGR)** Requires authority if it results in a patient's continuous use >2 months of this drug, or any other, Type B drug of addiction.	– The administration/supply/or prescription is for a palliative care patient. – The administration/supply/or prescription is by an AHPRA registered medical practitioners registered in the specialty of palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology. – The administration/supply/or prescription is to initiate or continue treatment for a patient (both an inpatient or emergency department presentee) in a public hospital or private health facility. – The administration/supply/or prescription is for an inmate in a correctional centre when the administration/supply/or prescription is for the purpose of continuing the	This control is to be applied to select Schedule 8 substances that are deemed to be high-risk when used for chronic treatment. This continues the current Schedule 8 control relating to Type B drugs of addiction where an authority is required if treatment continues beyond 2 months, however modified for a period beyond 3 months (clinical advice is that 3

[48] Palliative treatment, in relation to the supply, administration or issue of a prescription for a scheduled substance, means the palliative treatment of patient who has: (a) an incurable, progressive, far-advanced disease or medical condition, and (b) a prognosis of a limited life expectancy where death is expected within the next 24 months because of the disease or medical condition.

Category	Approval required to administer, prescribe or supply	Circumstance in which an approval is required	Exemption to the requirement to get an approval under draft MPTG Regulation	Rationale for proposed change in controls
		Draft MPTG Regulation Requires a medical practitioner or nurse practitioner to obtain approval where treatment > 3 months with this drug, or any other drug in this category, unless exempted.	treatment that the person was receiving immediately before the person became an inmate. – The administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds an approval who is temporarily on leave, by: – a practitioner on the same premises as the practitioner holding the approval, or – by a practitioner nominated by the practitioner holding the approval.	months is the line where treatment shifts from being acute treatment to chronic treatment). Methadone for the purposes of OTP is excluded as this is captured with OTP registration.
C	Fentanyl, hydromorphone, morphine, oxycodone	**Current Regulation (PTGR)** The only current control on fentanyl and oxycodone is that they cannot be supplied or prescribed to a drug dependant patient without authority. Hydromorphone requires authority if it results in a patient's continuous use >2 months of this drug, or any other, Type B drug of addiction. Hydromorphone is also subject to the control that it cannot be supplied or prescribed to a drug dependant patient without authority. **Draft MPTG Regulation** Requires a medical practitioner or nurse practitioner to obtain approval where the dose > 100mg Oral Morphine Equivalent Daily Dose (OMEDD), requires approval unless exempted	– The administration/supply/or prescription is for a palliative care patient. – The administration/supply/or prescription is by an AHPRA registered medical practitioners registered in the specialty of palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology. – The administration/supply/or prescription is to initiate or continue treatment for a patient (both an inpatient or emergency department presentee) in a public hospital or private health facility. – The administration/supply/or prescription is for an inmate in a correctional centre when the administration/supply/or prescription is for the purpose of continuing the treatment that the person was receiving immediately before the person became an inmate. – The administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds an approval who is temporarily on leave, by: – a practitioner on the same premises as the practitioner holding the approval, or – by a practitioner nominated by the practitioner holding the approval.	**This control is new** and is to address the concern that the high strength opioids in Schedule 8 are misused or trafficked (in particular fentanyl and oxycodone), and that the risk of significant patient harm is high at high doses of opioids. Notably, not all Schedule 8 opioids are captured in this control.

Category	Approval required to administer, prescribe or supply	Circumstance in which an approval is required	Exemption to the requirement to get an approval under draft MPTG Regulation	Rationale for proposed change in controls

D	Any Schedule 8 (other than a Schedule 8 used for the purposes of the OTP)	**Current Regulation (PTGR)**
		Authority is required to prescribe or supply any Schedule 8 substance to a drug dependant person[49].
		
		Draft MPTG Regulation
		Requires a medical practitioner or nurse practitioner to obtain approval to supply, prescribe, administer to a *substance dependent*[50] person, unless exempted
			– The administration/supply/or prescription is for a palliative care patient.
			– The administration/supply/or prescription is by an AHPRA registered specialist in in the specialty of palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology.
			– The administration/supply/or prescription is to initiate or continue treatment for a patient (both an inpatient or an emergency department presentee) in a public hospital or private health facility.
			– The administration/supply/or prescription is for an inmate in a correctional centre when the administration/supply/or prescription is for the purpose of continuing treatment (i.e., no exemption to initiate treatment) that the person was receiving immediately before the person became an inmate.
			– The administration/supply/or prescription is for no more than 3 days' treatment with a Schedule 8 substance for the urgent care of a patient that is for the purposes of pain relief.
			– The administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds an approval who is temporarily on leave, by:
			  – a practitioner on the same premises as the practitioner holding the approval, or
			  – by a practitioner nominated by the practitioner holding the approval.
				The current controls regarding the prescribing and supply of Schedule 8 substances to drug dependent persons should be continued. For the purpose of this control, drug dependent person is to be replaced with substance dependence, with the definition of substance dependence to be within the meaning of International Classification of Diseases 11th Edition (ICD-11). However, the substance must be a prohibited drug or a prohibited scheduled substance other than a Schedule 4 medicine that is specified in Appendix D (5) of the National Poisons Standard, so not to capture alcohol, caffeine, and nicotine (which are substances that are also listed in ICD-11) which is outside the remit of this control. Diagnosing a patient for substance dependence is within the scope of practice for a medical practitioner or nurse practitioner.

E	Compounded Schedule 8 substances	**Current Regulation (PTGR)** Authority is required to prescribe or supply. **Draft MPTG Regulation** Requires a medical practitioner, nurse practitioner,	– The administration/supply/or prescription is for a palliative care patient. – The administration/supply/or prescription is by an AHPRA registered specialists in palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology. – The administration/supply/or prescription is to initiate or continue treatment a patient (both an inpatient or emergency department presentee) in a public hospital or private health facility.	This existing control is to continue as unlike other medications which are listed on the ARTG, there is no Commonwealth assessment of quality, safety and efficacy under the *Commonwealth Therapeutic Goods Act 1989*. In addition, veterinary practitioners would need to seek an approval to

[49] *Drug dependent* person means a person who has acquired, as a result of repeated administration of: (a) a drug of addiction, or (b) a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985, an overpowering desire for the continued administration of such a drug.
[50] *Substance dependence* would be defined as someone displaying at least 2 of the 3 symptoms listed for substance dependence in the International Classification of Diseases, 11th Edition, but only when the substance of dependence is a *prohibited drug* or a *prohibited scheduled substance*.

Category	Approval required to administer, prescribe or supply	Circumstance in which an approval is required	Exemption to the requirement to get an approval under draft MPTG Regulation	Rationale for proposed change in controls
		or veterinary practitioner to obtain approval, unless exempted.	– The administration/supply/or prescription is for an inmate in a correctional centre when the administration/supply/or prescription is for the purpose of continuing the treatment that the person was receiving immediately before the person became an inmate. – The administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds an approval who is temporarily on leave, by: – a practitioner on the same premises as the practitioner holding the approval, or – by a practitioner nominated by the practitioner holding the approval.	prescribe/supply/administer a compounded schedule 8 medication (this is a new control).
F	MDMA and psilocybine	**Current Regulation**: Requires authority to prescribe or supply **Draft MPTG Regulation**: Requires a medical practitioner or nurse practitioner to obtain approval unless exempted	– The administration/supply/or prescription is for a palliative care patient. – The administration/supply/or prescription is by AHPRA registered medical practitioners registered in the specialty of palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology. – The administration/supply/or prescription is to initiate or continue treatment for a patient (both an inpatient or emergency department presentee) in a public hospital or private health facility. – The administration/supply/or prescription is for an inmate in a correctional centre when the administration/supply/or prescription is for the purpose of continuing the treatment that the person was receiving immediately before the person became an inmate. – The administration/supply/or prescription is to continue treatment on behalf of a practitioner who holds an approval who is temporarily on leave, by: – a practitioner on the same premises as the practitioner holding the approval, or – by a practitioner nominated by the practitioner holding the approval.	The current controls for MDMA and psilocybine should be continued with exemptions in place. Notably, only psychiatrists meeting certain Commonwealth requirements are eligible to be issued an authority. The MPTG Regulation would mirror this restriction whereby only doctors who are psychiatrists are to be granted an approval to prescribe/supply/administer MDMA or psilocybine, consistent with the Commonwealth's recommended restrictions.

Source: NSW Ministry of Health.

5.3.7 New controls to administer/prescribe/supply and manufacture certain Schedule 4 substances

The MPTG Act provides the ability to create subcategories within Schedules by way of regulation to allow for more targeted regulation of groups of medicines. The MPTG Regulation would create the following subcategories of Schedule 4 substances:

- Schedule 4D — those medicines in Schedule 4 that are identified as liable to misuse and diversion, such that the storage, prescribing, and supply of these medicines should be more restricted than other Schedule 4 medicines. These are consistent with the current substances listed in Appendix D of the PTGR.
- Nominated Schedule 4 substances — those medicines in Schedule 4 that are identified as liable to misuse (but not diversion).
- Monitored Schedule 4 substances — medicines that are listed in Appendix E of the current PTGR.

In addition to these categorisation changes to Schedule 4, the MPTG Regulation would impose the following additional controls to these substances:

- The substances included in the list of Nominated Schedule 4 substances would be adjusted to more closely reflect the recommendations of the National Poisons Standard and the approach taken in other jurisdictions.
- Approval would be required by a medical practitioner, nurse practitioner, and veterinary practitioner to prescribe, supply or administer compounded Schedule 4D substances for non-topical use noting the increased risks posed by these substances.
- Authorisation would be required by a dentist, veterinary practitioner or medical practitioner who seek to manufacture (compound) a Schedule 4D substance for non-topical, use unless subject to an exemption.

Table 5.7 provides a summary of the proposed changes to the circumstances where a practitioner would require an approval to administer/prescribe/supply a Schedule 4 substance under the MPTG Regulation, compared to the current PTGR.

Table 5.7 Proposed changes to the controls to administer/prescribe/supply and manufacture a Schedule 4 substance under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
Currently: – Approval to prescribe, supply or administer Schedule 4 substances is only required for certain substances that the National Poisons Standard recommends should be restricted to particular specialties. – There are no controls under the NSW framework for dentists/veterinary practitioners/medical practitioners who compound Schedule 4 substances. Similarly, the Commonwealth framework creates carve-outs for these practitioners, in that they do not need to hold a Commonwealth manufacturer's licence to compound these substances.	The draft Regulation would require that an approval to administer/prescribe/supply a Schedule 4 substance is sought in the following circumstances: – A medical practitioner, nurse practitioner and veterinary practitioner require approval to supply/prescribe/administer any compounded substance listed in Schedule 4 Appendix D of the National Poisons Standard that is for non-topical use – Any health practitioner (i.e., excluding veterinary practitioner) supplying/prescribing/administering certain Schedule 4 (prescription only) medicines, such as acitretin, unless the prescriber is in a specific specialty (such as dermatology). These would be called 'Nominated Schedule 4 substances', and certain specialties would be exempt from the requirement to hold an approval (for example, a Dermatologist would not require an approval to prescribe, supply or administer acitretin). In addition: – An *authority* would be required for dentists/veterinary practitioners/medical practitioners who seek to manufacture (compound) Schedule 4 Appendix D that is for non-topical use, unless subject to an

Current situation (under PTGR)	Proposed change under the MPTG Regulation
	exemption. This authority would be *in addition to the approval* to administer/prescribe/supply these substances noted above. – The number of nominated Schedule 4 substances would increase (i.e., there would be more nominated Schedule 4 substances than are currently listed at Clause 37 of the PTGR).

Source: ACIL Allen and NSW Ministry of Health.

Table 5.8 provides additional details about how the treatment of Schedule 4 substances would change.

Table 5.8 Changes to Nominated Schedule 4 substances

Current regulation (PTGR)		Draft MPTG Regulation	
Schedule 4 substance	**Exemptions for approval (i.e., who does not require an approval to prescribe/supply/administer)**	**Schedule 4 substance (these substances will be called 'nominated Schedule 4 substances' under the new regulation) Veterinary practitioners are not required to obtain approval for these substances**	**Exemptions for approval (medical practitioner holding a specialty listed in this column would not require an approval to prescribe/supply/administer the substance and would only need to write 'Approval exempt' in the prescription) Veterinary practitioners are not required to obtain approval for these substances**
Acitretin	– Veterinary practitioner (through the Regulation) – Other practitioner class-exemptions authorised by way of a legislative instrument (i.e., not explicitly written into the regulation), e.g., currently dermatologists who are fellows of the relevant College	Acitretin	– Dermatology – Physician
Clomiphene	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: endocrinology, and obstetrics and gynaecology specialists who are fellows of the relevant College	Clomifene	– Endocrinology – Obstetrics and gynaecology
Cyclofenil	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: endocrinology, and obstetrics and gynaecology specialists who are fellows of the relevant College	Cyclofenil	– Endocrinology – Obstetrics and gynaecology
Dinoprost	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: obstetrics and gynaecology specialists who are fellows of the relevant College	Dinoprost	– Obstetrics and gynaecology
Dinoprostone	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: obstetrics and	Dinoprostone	– Obstetrics and gynaecology

Current regulation (PTGR)		Draft MPTG Regulation	
Schedule 4 substance	**Exemptions for approval (i.e., who does not require an approval to prescribe/supply/administer)**	**Schedule 4 substance (these substances will be called 'nominated Schedule 4 substances' under the new regulation) Veterinary practitioners are not required to obtain approval for these substances**	**Exemptions for approval (medical practitioner holding a specialty listed in this column would not require an approval to prescribe/supply/administer the substance and would only need to write 'Approval exempt' in the prescription) Veterinary practitioners are not required to obtain approval for these substances**
	gynaecology specialists who are fellows of the relevant College		
Etretinate	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: dermatologists who are fellows of the College	Etretinate	– Dermatology – Physician
Follitropin beta	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: endocrinology, and obstetrics and gynaecology specialists who are fellows of the relevant College	Folitropin beta	– Endocrinology – Obstetrics and gynaecology
Hydroxychloroquine	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: – Dermatology – Intensive care medicine – Paediatrics and Child health – Emergency medicine – Specialist physician – A general practitioner when prescribing to continue treatment initiated by a practitioner in the above specialties, or to treat patients of a public hospital – A dentist registered in the specialty of oral medicine when prescribing for the treatment of recalcitrant erosive and ulcerative oral lichen planus.	Hydroxychloroquine	– Dermatology – Emergency medicine – Intensive care medicine – Paediatrics and Child health – Physician
Isotretinoin for oral use	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: dermatology specialists who are fellows of the relevant College	Isotretinoin for oral use	– Dermatology – Physician
Luteinising hormone	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: endocrinology, and obstetrics and gynaecology specialists who are fellows of the relevant College	Luteinising hormone	– Endocrinology – Obstetrics and gynaecology

Current regulation (PTGR)		Draft MPTG Regulation	
Schedule 4 substance	**Exemptions for approval (i.e., who does not require an approval to prescribe/supply/administer)**	**Schedule 4 substance (these substances will be called 'nominated Schedule 4 substances' under the new regulation) Veterinary practitioners are not required to obtain approval for these substances**	**Exemptions for approval (medical practitioner holding a specialty listed in this column would not require an approval to prescribe/supply/administer the substance and would only need to write 'Approval exempt' in the prescription) Veterinary practitioners are not required to obtain approval for these substances**
Tretinoin for oral use	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: dermatology and haematology specialists who are fellows of the relevant College	Tretinoin for oral use	– Dermatology – Haematology
Urofollitrophin (human follicle stimulating hormone)	– Veterinary practitioner (through the Regulation) – Exemptions authorised by way of a legislative instrument: endocrinology, and obstetrics and gynaecology specialists who are fellows of the relevant College	Urofollitropin (human follicle stimulating hormone)	– Endocrinology – Obstetrics and gynaecology
		Alefacept	– Dermatology
		Bexarotene	– Dermatology – Haematology – Medical Oncology – Physician
		Corifollitropin alfa	– Obstetrics and gynaecology
		Folitropin delta	– Obstetrics and gynaecology
		Macitentan	– Physician
		Riociguat	– Physician
		Teriparatide	– Haematology – Medical oncology
		Thalidomide	– Dermatology – Haematology – Medical oncology – Physician

Source: ACIL Allen and NSW Ministry of Health.

5.3.8 Prescription approval number requirements for Schedule 4 and 8 substances

This change would require that a prescription includes an approval reference number if the substance is:

1. a compounded Schedule 8 substance
2. a specified stimulant (methylphenidate, lisdexamfetamine or dexamfetamine)
3. N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and psilocybine

4. a nominated Schedule 4 substance
5. a compounded Schedule 4D for non-topical use.

The intent is that a prescriber would need to include the approval number on a prescription when they prescribe the above substances (or write 'Approval exempt' if a relevant exemption from the requirement to get approval applies); and given a pharmacist can only dispense a prescription if it is in the correct form, the pharmacist would need to confirm that the prescription includes the above approval number (pharmacists would be subject to a penalty for dispensing prescriptions for the above substances on which the doctor has not included the approval number). Notably, prescribers and pharmacists already have obligations around *some* of these substances (see Table 5.9).

The proposed changes aim adopt controls recommended by the Commonwealth, and to reduce abuse, misuse and physical or psychological dependence of these substances by ensuring integrity of the supply chain and ensuring that prescriptions for certain high-risk substances are only dispensed when the prescriber has been approved to prescribe that substance.

Table 5.9 Requirements for prescribers and pharmacists under the current regulation (PTGR)

Substance	Prescriber requirements	Pharmacist requirements
Compounded Schedule 8 substance	Prescribers are already under an obligation to include an authority number in relation to these substances under Clause 80(1)(i) of the PTGR. Given this, this change does not impose additional obligations on prescribers.	Pharmacists are already under an obligation to ensure that prescriptions for these substances include the authority number under Clause 80(1)(i) and Clause 85(1) of the PTGR. Given this, this change does not impose additional obligations on pharmacists.
Specified stimulant (methylphenidate, lisdexamfetamine or dexamfetamine)	Prescribers are already under an obligation to include an authority number in relation to these substances under Clause 80(1)(i) of the PTGR. Given this, this change does not impose additional obligations on prescribers.	Pharmacists are already under an obligation to ensure that prescriptions for these substances include the authority number under Clause 80(1)(i) and Clause 85(1) of the PTGR. Given this, this change does not impose additional obligations on pharmacists.
N,α-dimethyl-3,4-(methylenedioxy) phenylethylamine (MDMA) and psilocybine	Prescribers are already under an obligation to include an authority number in relation to these substances under Clause 80(1)(i) of the PTGR. Given this, this change does not impose additional obligations on prescribers.	Pharmacists are already under an obligation to ensure that prescriptions for these substances include the authority number under Clause 80(1)(i) and Clause 85(1) of the PTGR. Given this, this change does not impose additional obligations on pharmacists.
Nominated Schedule 4 substance	Prescribers are already under an obligation to include an authority number in relation to these substances under Clause 37 of the PTGR. However, as mentioned in Section 5.3.7, the number of nominated Schedule 4 substances is increasing (i.e. there would be more nominated Schedule 4 substances than are currently listed at Clause 37 PTGR – see Table 5.8). The increase in the number of substances listed in Schedule 4 would impose additional obligations on prescribers for certain Schedule 4 substances.	Pharmacists are already under an obligation to ensure that prescriptions for these substances include the authority number under Clause 39 and Clause 52(3)(c)(i) of the PTGR. However, the number of nominated Schedule 4 substances is increasing. The increase in the number of substances listed in Schedule 4 would impose additional obligations on pharmacists for certain Schedule 4 substances.
Compounded Schedule 4D for non-topical use	There is currently no requirement to include an authority number on a prescription for these substances, so. this change would impose additional obligations on prescribers.	There is currently no requirement to check that prescriptions include the authority number, so this change would impose additional obligations on pharmacists.

Source: ACIL Allen and NSW Ministry of Health.

5.3.9 Compounding controls

Compounding is 'the preparation and supply of a single 'unit of issue' of a therapeutic product intended for supply for a specific patient in response to an identified need'[51]. Compounding may involve modification of a manufactured product or the preparation of a compound from raw ingredients.

Table 5.10 outlines the proposed changes to compounded substances under the MPTG Regulation, compared to the current PTGR.

Table 5.10 Proposed changes to compounded substances under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
The manufacture of therapeutic goods in Australia generally requires a TGA manufacturing licence, however, a manufacturing licence from the TGA is not required if 'medicines are compounded only on a prescription or order for, or on request by a particular person, for therapeutic application to that person, or on a request from an authorised prescriber for use in their surgical/clinic/treatment room for an individual named patient'[52]. A manufacturing licence from the TGA is required if a pharmacist intends to compound biologicals, or compound medicines in a pharmacy and supply these by wholesale, for example to other pharmacies. In this case, if the compounded medicine is not for supply to an individual named patient (e.g., by way of a prescription or order), it would also need to be included in the ARTG.[53] Due to the non-wholesale supply licence and ARTG exemption, compounded medicines are not subject to evaluation by the TGA. Furthermore, while licensable manufacturers of compounded medicines have to meet the TGA's *Compounded medicines and good manufacturing practice (GMP), Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products*[54] (referred to as the 'TGA GMP Guide'), this guide is not required to be adopted by pharmacists performing compounding for individual patients.	The MPTG Regulation would require: – Compliance with the TGA GMP Guide when compounding sterile compounded preparations. A sterile compounded preparation is defined in the MPTG Act as: *a compound of substances, whether or not containing scheduled substances, that is required to be kept sterile, and includes a preparation in —* *(a) parenteral dosage form, other than an intradermal or subcutaneous injection of an allergen extract, and* *(b) ophthalmic dosage form.* – That a dentist, veterinary practitioner or medical practitioner who seek to manufacture (compound) a Schedule 8 or Schedule 4D substance for non-topical use obtains authorisation from the Secretary to do so, or be subject to an exemption.

Source: ACIL Allen and NSW Ministry of Health.

5.3.10 Emergency use provisions

The Pharmaceutical Benefits Scheme (PBS) allows certain pharmaceutical benefits to be provided to medical practitioners and nurse practitioners without charge, who in turn can supply or administer them free to patients for emergency use (this is colloquially referred to as 'doctor's bag supplies').

[51] Pharmaceutical Society of Australia 2017, *Professional Practice Standards*, Version 5, https://my.psa.org.au/servlet/fileField?entityId=ka10o0000001DYHAA2&field=PDF_File_Member_Content__Body__s, Accessed 20 June 2023.

[52] Pharmacy Board of Australia 2020, *Frequently asked questions for pharmacists on the compounding of medicines,* June, https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD15%2F16634&dbid=AP&chksum=gMF1UYEc8RzLm0y41TbNqw%3D%3D, Accessed 20 June 2023.

[53] Ibid.

[54] The purpose of the TGA GMP Guide is to clarify the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products PE-009 requirements for the manufacture of extemporaneously compounded medicines.

Clause 46 and Clause 97 of the PTGR provide the legislative mechanism facilitating a emergency use order, and more broadly, an order by an authorised practitioner (including a veterinary practitioner), being supplied by a pharmacist in NSW for emergency use.

Table 5.11 outlines the proposed changes to emergency use provisions under the MPTG Regulation, compared to the current PTGR.

Table 5.11 Proposed changes to emergency use provisions under the MPTG Regulation

Current situation (under PTGR)	Proposed change under the MPTG Regulation
Clause 46 and Clause 97 of the PTGR enable a pharmacist to provide an authorised practitioner with Schedule 4 and Schedule 8 substances (excluding unregistered Schedule 8s) for emergency use, on a written order signed and dated by the authorised practitioner. An authorised practitioner for these provisions means: – in relation to Schedule 8 substances, a medical practitioner, nurse/midwife practitioner, endorsed nurse/midwife, dentist or vet – in relation to Schedule 4 substances, a medical practitioner, nurse/midwife practitioner, vet, dentist, or an endorsed nurse/midwife/podiatrist/optometrist.	Under the MPTG Regulation: – A health practitioner would only be able to obtain a substance for emergency use that is listed on the ARTG (i.e., compounded medication and non-registered medication would be excluded) – A veterinary practitioner would only be able to obtain a substance for emergency use that is listed on the ARTG or the APVMA.

Source: ACIL Allen and NSW Ministry of Health.

The aims of the changes outlined in Table 5.11 are:

— To reduce risks to patient safety by recognising that unregistered medicines have not been assessed for quality, safety and efficacy unlike registered medicines. Registered medicines are thoroughly evaluated and are subject to ongoing monitoring, including via Commonwealth adverse event reporting.

— To address the risks related to compounded veterinary medicines (veterinary chemical products). The current regulatory framework enables pharmacists to prepare large batches of compounded medicines for animal use with minimal Commonwealth or state oversight.

  Medicines for animals that are compounded by a pharmacist on the instruction of a veterinary surgeon are exempt from registration by the APVMA and are therefore not subject to the same restrictions and safety testing as other animal medicines. Unlike the equivalent framework regulating human medicines (i.e. under the TGA) under which a pharmacist is restricted to only supplying a compounded medicine for a single individual human patient per prescription (which somewhat limits the risks related in case of a bad batch, as the medicine only impacts on the person), under the APVMA framework, veterinary chemical products that are compounded by a pharmacist on the instruction of a veterinary surgeon do not need to be for an individual animal/flock on prescription, but rather, only need to be prepared by a pharmacist 'in accordance with the instructions of a veterinary surgeon' or be a veterinary surgeon. This means that the risk if it is a bad batch of medicine can be more far reaching.

5.3.11 New and increased licence fees

Table 5.12 outlines the proposed changes under the MPTG Regulation, compared to the current PTGR. This proposed change entails:

- increasing existing fees collected under the PTGR for retail and wholesale supply licence applications and renewals for Schedule 2, 3, 4 and 8 substances
- creating new fees for:
  - wholesale licences for Schedule 9 and 7J substances
  - retail licences for Schedule 7J substances
  - amendments to licences
  - obtaining a licence.[55]

Table 5.12 Proposed changes to licence fees under the MPTG Regulation

Licence type	Current license fees (last changed 2013)	Proposed license fees for application and annual renewal (MTPGA 2022 and MPTGR 2023)
Wholesale licences		
Application fee for wholesaler licence involving Schedule 7Js	NA (no current fee for a wholesaler licence or authority)	$770 Amendment fee = 385
Annual renewal fee for wholesaler licence involving Schedule 7s		$330 Amendment fee = $165
Application fee for obtain licence involving Schedule 7s	NA (no current fee for obtain licence)	$330 Amendment fee = $165
Annual renewal fee for obtain licence involving Schedule 7s		$330 Amendment fee = $165
Application fee for wholesaler licence or obtain licence involving Schedule 8s and Schedule 9s	– S8 wholesaler licence - $356 – S8 obtain licence - No current fee for S8 obtain licence, however many of the entities which previously sought a wholesaler licence, would now seek an obtain licence – S9 wholesaler licence - NA (no current fee for a wholesaler or obtain licence or an authority) – No current amendment fee for any licence	$2,930 Amendment fee = $1,465
Annual renewal fee for wholesaler licence or obtain licence involving Schedule 8s and Schedule 9s	– S8 wholesaler licence - $356 – S8 obtain licence - No current fee for S8 obtain licence, however many of the entities which previously sought a wholesaler licence, would now seek an obtain licence	$2,520 Amendment fee = $1,260

[55] The concept of 'obtaining a licence' is new and was introduced with the MPTG Act. It allows an entity to apply for a licence to receive/obtain a wholesale supply of stocks of medicines. Previously, under the PTGR framework, entities such as paramedic companies applied for a wholesaler licence and then wholesale supplied those medicines to their employee paramedics. The MPTG Act recognises that providing stock to employees is not really wholesale supply. In the paramedic company example, the company only needs to obtain the wholesale supply of stock, which is then administered/supplied by employees in the course of the practice of their profession. Under the new framework, entities such as paramedic companies would be applying for an obtain licence, rather than a wholesaler's licence.

Licence type	Current license fees (last changed 2013)	Proposed license fees for application and annual renewal (MTPGA 2022 and MPTGR 2023)
	– S9 wholesaler licence - NA (no current fee for a wholesaler or obtain licence or an authority) – No current amendment fee	
Application fee for wholesale or obtain licence involving Schedule 2s, Schedule 3s, and Schedule 4s	– $533 – No current amendment fee	$1,650 Amendment fee = $825
Annual renewal fee for wholesale or obtain licence involving Schedule 2s, Schedule 3s, and Schedule 4s	– $533 – No current amendment fee	$1,250 Amendment fee = $625
Retail licences		
Application fee for Schedule 2 retail licence and Schedule 7J retail licence	– S2 — $90 – S7J - NA (no current fee for a retail licence for an S7J) – No current amendment fee	$330 Amendment fee = $165
Annual renewal fee for Schedule 2 retail licence and Schedule 7J retail licence	– S2 — $90 – S7J - NA (no current fee for a retail licence for an S7J) – No current amendment fee	$330 Amendment fee = $165

Notes: All fees can be waived by the Secretary/delegate. The following persons can seek an obtain licence:
- private OTP clinics
- corporation that provides paramedical services
- a person providing ambulance transport with the consent of the Health Secretary under the Health Services Act 1997, section 67E
- a person engaged in the administration of a vaccination program for humans
- a person on behalf of a university
- a person on behalf of a prescribed research institution, other than a university
- a person on behalf of an analytical or research and development laboratory.

Source: NSW Ministry of Health.

The rationale for the proposed changes to licence fees is as follows.

— The current licence fees are out of step with other states/territories (despite the majority of medicines wholesalers being in NSW, refer to the jurisdictional comparison of fees across states/territories in Table 5.13).

— The Ministry notes that the fees collected under the current framework are not commensurate with the time involved for authorised officers to undertake the significant work involved in assessment of applications and renewals of licences. The proposed fees are a result of cost-recovery work undertaken by relevant areas of the Ministry to quantify the costs associated with administration of the scheme.

Table 5.13 Jurisdictional comparison of supply licences' fees

Licence type	NSW (current)	QLD	WA	NT	VIC	TAS	ACT
Application to supply S2 by retail	$90	$215.76[a]		$134	$1329.20		$155
Application to supply S7J by retail	NA	$215.76		$201	$1,329.20		
Application for wholesaler licence (S8)	$356	$618.59 [a]	$307	$201	$1502.60	$195	$457
Application for wholesaler licence (S2, S3, S4)	$533	$618.59 [a]	$307	$201	$1,329.20	$195	$457
Amendment fee	NA	$618.59 or $215.76					
Application for wholesaler licence (S7J)	NA	For low risk fluoroacetic acid baits $173.23; otherwise, $618.59 [a]		$201	$1.329.20		$457
Applications from public institutions	$80	NA		NA	NA		$44
Applications from charitable institutions	$18	NA		NA	NA		
Application for obtain licence: – a provider under the Opioid Treatment Program, – a corporation that provides paramedical services, – a person providing ambulance transport with the consent of the Health Secretary under the Health Services Act 1997, section 67E, – a person engaged in the administration of a vaccination program for humans, – a person on behalf of a university, – a person on behalf of a prescribed research institution, other than a university, – a person on behalf of an analytical or research and development laboratory							
Application for obtaining a Schedule 7J substance							
Application for obtaining a prescribed Schedule 10 substance that is not a prohibited drug							
Renewal for S2 retail licence	$90	$215.76		$67	$292.60	$195	
Renewal for S7J retail licence	NA	$210.50		$134	$292.60		
Renewal for wholesaler licence (S8)	$356	$618.59	$255	$134	$322.80	$195	$457

Licence type	NSW (current)	QLD	WA	NT	VIC	TAS	ACT
Renewal for wholesaler licence (S2, S3, S4)	$533	$618.59	$255	$134	$292.60	$195	$457
Renewal for wholesaler licence S7J		$618.59		$134	$292.60		
Renewal for public institutions	$80	$618.59		NA	NA		
Renewal for charitable organisations	$18	$618.59		NA	NA		
Research institution (e.g., possess S9)							$44
Renewal of obtain licence: – a provider under the Opioid Treatment Program, – a corporation that provides paramedical services, – a person providing ambulance transport with the consent of the Health Secretary under the Health Services Act 1997, section 67E, – a person engaged in the administration of a vaccination program for humans, – a person on behalf of a university, – a person on behalf of a prescribed research institution, other than a university, – a person on behalf of an analytical or research and development laboratory							
Renewal of obtain licence for a Schedule 7J substance							

[a] In Queensland, the processing fee for an initial application for a licence for dealing with a medicine which is added to an initial application is $144.01. Processing fee for an initial application for a licence for dealing with a hazardous pois which is added to an initial application is $144.01.

Source: NSW Ministry of Health

6 Impact analysis

This chapter assesses the impacts of the options outlined in Chapter 5. It first assesses the expected impacts of the Base Case (i.e., of letting the PTGR sunset and not replacing it with a new Regulation) and then assesses the impacts of the proposed Draft MPTG Regulation (Option 2) against the status quo (Option 1, remaking the PTGR).

Notably, the costs and benefits associated with the alternative options have been analysed in this RIS mostly qualitatively. This is because the benefits and costs associated with the alternative options are not amenable to easy quantification due to:

— limited data available to comprehensively demonstrate the effectiveness of the MPTG Regulation

— the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the MPTG Regulation in a robust way.

Further, in preparing this RIS, selected stakeholder consultations were conducted with several organisations.[56] Where relevant, comments by stakeholders have been included in the discussion. These views need to be further tested during the public consultation period before finalising the Regulation. Comments received from stakeholders about areas of the Regulation for which changes are not being proposed are presented for future consideration by the Ministry in Appendix B.

6.1 Impacts of no Regulation (the Base Case)

As noted in Section 5.1, the likely general implications of letting the PTGR sunset when the MPTG Act commences and not replacing it with a new Regulation are that:

— the Act would be unable to fully operate in the absence of legislative detail

— there would be no mechanism for a number of stakeholders to be able to wholesale supply, obtain wholesale supply or non-wholesale supply of medicines, resulting in a break in the supply chain of medicines across NSW, and an interruption to patient care

— there would not be restrictions/controls on the administration of medication (unlike the existing framework, the MPTG Act provides that supply does not include administration and generally does not regulate the administration of medication but focuses instead on controlling wholesale supply or supply)

— the health practitioners allowed to (non-wholesale) supply or prescribe medicines would be limited to those specifically authorised under the Act. Practitioners not specifically authorised under the Act (but authorised under the proposed Regulation) would not be able to supply, prescribe or administer medicines (e.g., pharmacists would not be able to administer

[56] Further information about the stakeholder consulted can be found in Appendix **Error! Reference source not found.**.

vaccines, and nurses supplying medicines to patients under the direction of a doctor would not be carved-out from the supply offence provisions)

- medication prescription criteria would be absent
- patient medication labelling obligations would not exist
- there would be no obligations regarding cleanliness and handling of substances
- healthcare and clinical tools, such as SafeScript NSW, which supports practitioners who prescribe and supply high risk medicines to patients, would no longer have a lawful basis
- there would be no controls regarding storage, disposal and destruction of high risk scheduled medicines
- mechanisms to authorise persons to undertake research with high-risk substances would be more limited
- penalty infringement notices (on-the-spot fines) would not be able to be issued, as the offences for which these are prescribed are set in the MPTG Regulation.

Benefits

Broadly, the benefits of letting the PTGR sunset and not replacing it with a new Regulation would include:

- elimination/reduction of compliance and administrative costs for certain stakeholders/sectors.
- reduced regulatory costs for the NSW Government in administering the regulatory regime, including administrative, monitoring and enforcement costs.

Costs

The costs associated with eliminating the Regulation include:

- increased risk to the health and safety of the public and a potential increase in illness and disease rates and associated costs to the community due to a dysfunctional supply chain of medicines across NSW
- unnecessary restrictions on the prescribing, and supply of certain medicines in certain circumstances by certain practitioners which are not explicitly included in the Act, which could result on:
  - a potential decrease in the quality of services to patients
  - inconsistent patient care for NSW patients as distinct from patients in other jurisdictions where a broader scope of health practitioners can obtain, supply, prescribe, and administer medications.
  - inefficiencies in patient care. Not having the MPTG Regulation would result in more restrictions and red tape in the administration, prescribing, and supply of certain medicines in certain (safe) circumstances.
- increased risks of:
  - inappropriate and / or dangerous use of medication
  - medication dispensing and administration errors due to the absence of administration and supply controls, prescription criteria and medication labelling obligations
  - diversion of drugs for personal use or trafficking purposes due to the lack of controls regarding storage, disposal and destruction of high risk scheduled medicines
  - patient safety due to no standards regarding cleanliness and handling of substances and the absence of healthcare and clinical tools that support practitioners to manage patient risks
- reduced efficacy of the MPTG Act in protecting the health and safety of NSW residents, as the Act relies on the existence of the MPTG Regulation to fully operate

— having an enforcement and compliance regime that is unable to operate properly.

Conclusion

Overall, letting the PTGR sunset and not replacing it with a new Regulation is not considered appropriate as the risks and costs associated with eliminating legislative detail in relation to permitted wholesale supply, obtaining wholesale supply, and the administration, prescribing, supply, handling, storage, labelling, disposal and destruction of certain medicines are considered to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

It is noted that all stakeholders consulted for the RIS agreed that letting the Regulation sunset is not an appropriate option as the Regulation is central to the operation of the Act and maintaining adequate standards for patient and public safety.

6.2 Impacts of the proposed Regulation (Option 2)

This section assesses the impacts of the Draft MPTG Regulation (Option 2) against Option 1 (remaking the PTGR). This analysis has been structured around the impacts of each of the substantive changes proposed for the Regulation, namely changes that relate to:

— more regular periodical inventory of stock of drugs of addiction
— wholesale supply of medicines and poisons in the absence of a wholesaler licence in a wider range of circumstances
— licensing of retail supply and wholesale supply of certain Schedule 7 substances
— restrictions on administration of Schedule 2, 3, 4 and 8 substances
— compliance standards for the Opioid Treatment Program
— approval to administer/prescribe/supply Schedule 8 substances (as distinct from the current authority requirements), with approval requirements more targeted to risk
— approval to administer/prescribe/supply certain Schedule 4 substances (as distinct from the current authority requirements) with approval requirements aligning more closely with Commonwealth recommendations, and compounding authority required under certain circumstances
— specific approval number requirements for Schedule 4 and 8 substances
— new compounding controls on products required to be sterile and authority requirements for a dentist, veterinary practitioner or medical practitioner who seek to compound a Schedule 8 or Schedule 4D substance for non-topical use
— new restrictions to emergency use provisions
— clarifying the powers developed in the MPTG Act, including to specify which offences would be subject to on-the-spot fines / penalty infringement notices
— increased retail and wholesale supply licence fees, fees applying to an obtain licence, new fees applying to retail supply and wholesale supply of certain Schedule 7 substances, and fees applying to amend an existing licence.

6.2.1 Periodical inventory of stock of drugs of addiction

The proposed MPTG Regulation would increase the number of times that people authorised to be in possession of a drug of addiction (Schedule 8 substances) must do an inventory of the stock of these drugs, from twice per year to every month. The purpose of this change is to reduce the risk of diversion of these substances, as there are many instances in which these substances are lost, stolen, and diverted for personal use or trafficking purposes.

Since the original requirements for 6 monthly checks in the PTGR (which go back over 40 years), there have been major significant increases in the prescribing and dispensing of Schedule 8 substances. A community pharmacy may manage thousands of Schedule 8 in a six-month period (for instance, a pharmacy dosing 40 OTP patients 5 times per week alone could easily have 5,200 stock movements over 6 months). This means that being able to ascertain missing drugs in the register over a six-month period becomes problematic.

As an indication of the frequency of these events, Table 6.1 outlines the number of notifications for lost/stolen Schedule 8 substances that have been received by the Ministry in 2023.[57] As shown in this table, over the five months to May 2023, the Ministry received over 700 notifications of lost/stolen Schedule 8 substances (an average of 140 notifications per month). Indeed, according to the Ministry, there are now over 2,000 lost/stolen drug reports received by the Ministry each year. In addition, OTP audits demonstrate many unaccountable losses of methadone, including many examples of large volumes not accounted for.

Table 6.1 Notifications for lost/stolen Schedule 8 substances in 2023

Month	Notifications for lost/stolen Schedule 8 substances
January	134
February	155
March	182
April	103
May	127

Source: NSW Ministry of Health.

Benefits

To the extent that increased supervision of stocks of Schedule 8 substances reduces the amount of these substances diverted for trafficking purposes and for inappropriate and dangerous use, this change would result in reduced drug misuse, drug abuse and poisoning and by doing so, prevent illness and death.

Costs

The main cost associated with this change is the additional time that would need to be spent doing inventory to comply with the MPTG Regulation. While it is hard to accurately estimate the additional time and cost associated with more frequent inventories, we have developed an indicative estimate of these costs based on existing data on the number of persons who hold Schedule 8 substances in NSW and a number of assumptions (see Table 6.2).

The increased frequency of inventories may result in better managing and investigating of the number of existing unexplained losses of high-risk medication, and an increase in the number of notifications of loss/stolen substances (and earlier detection of diversion), which may increase the cost of administering the regulation as the Ministry would have to log and review an increased number of notifications, and some of these may require further investigation.

[57] The PTGR requires people authorised to be in possession of a drug of addiction (Schedule 8 substance) or a prescribed restricted substance (Schedule 4 Appendix D substance) to immediately notify the Secretary of Health of any loss or theft of these drugs.

Table 6.2 Indicative cost of undertaking additional inventories of Schedule 8 substances under the MPTG Regulation (compared to the status quo)

People who can hold S8 substances across NSW	Estimated people who hold S8 substances	Time taken per inventory (mins)	Time spent under PTGR (2 inventories/yr)	Time spent under MPTG (12 inventories/yr)	Cost of additional time $/yr [i]
Researchers [a]	282	5	940	5,640	$16,100
Licensed wholesalers [b]	119	180	42,840	257,040	$244,584
Pharmacies [c]	2,000	60	240000	1,440,000	$1,370,216
Manufacturers [d]	18	180	6,480	38,880	$36,996
Private health facilities [e]	220	90	39,600	237,600	$226,086
Private OTP clinics [f]	11	60	1,320	7,920	$7,536
Public hospitals/health services [g]	293	120	70,400	422,400	$401,930
Medical practitioners [h]	16,971	5	169705	1,018,230	$968,886
Total	**19,914**	**700**	**573,165**	**3,438,990**	**$3,272,333**

Note: S8 stands for Schedule 8.

[a] Data from the Ministry indicates that 282 authorities were issued from 1 February 2022 to 31 January 2023 to possess and/ or supply Schedule 8, 9 and 1 substances for the purpose of research, instruction and analysis. It has been assumed that, given the small amount of stock researchers are likely to hold of Schedule 8 substances, it would only take them 5 minutes to undertake an inventory.

[b] Data from the Ministry indicates that 119 licences were issued for wholesalers from 1 February 2022 to 31 January 2023 in relation to Schedule 8 substances. It has been assumed that, given the relatively large amounts of stocks that wholesalers are likely to hold of Schedule 8 substances, it would take them 3 hours to undertake an inventory.

[c] Data from the Ministry indicates that there are approximately 2,000 pharmacies across NSW. It is unknown how many of these pharmacies hold Schedule 8 substances and the amount of stock held by those who hold them. For this indicative estimate, it has been assumed that all the pharmacies in NSW hold these substances and that it takes them, on average, 1 hour to undertake an inventory.

[d] Data from the Ministry indicates that 18 authorities were issued to manufacturers from 1 February 2022 to 31 January 2023 in relation to Schedule 8 substances. It has been assumed that, given the relatively large amounts of stocks that manufacturers are likely to hold of Schedule 8 substances, it would take them 3 hours to undertake an inventory.

[e] Data from the Ministry indicates that 220 licences were issued to private health facilities from 1 February 2022 to 31 January 2023 in relation to Schedule 8 substances. The time spent undertaking inventory depends on the amount of stock of these substances held. As this data is not available it has been assumed that it takes private health facilities, on average, 1.5 hours to undertake an inventory.

[f] Data from the Ministry indicates that 11 licences were issued to OTP clinics from 1 February 2022 to 31 January 2023 in relation to Schedule 8 substances. The time spent undertaking inventory depends on the amount of stock of these substances held. As this data is not available it has been assumed that it takes OTP clinics, on average, 1 hour to undertake an inventory.

[g] Data from the Ministry indicates there are more than 220 public hospitals and health service facilities across NSW. However, no data is available about the number of these entities which would require Schedule 8 substances. For this indicative estimate, it has been assumed that a third of these entities hold Schedule 8 substances and that it takes them, on average, 2 hours to undertake an inventory.

[h] There are a range of health practitioners who are able to prescribe/supply/administer Schedule 8 substances (e.g., doctors, nurse practitioners, podiatric surgeons etc). This indicative estimate only accounts for medical practitioners. Data from the Australian Institute of Health and Welfare (AIHW) indicates that, in 2020 there were 33,941 medical practitioners in NSW. For this indicative estimate, it has been assumed that 50% of these practitioners hold Schedule 8 substances and that it takes them, on average, 5 minutes to undertake an inventory as practitioners generally hold small quantities for urgent or immediate use.

[i] The time for undertaking inventory has been valued using data on average weekly earnings in NSW from the Australian Bureau of Statistics (ABS), excluding tax (an average tax rate of 20% was assumed) and including an on-cost multiplier of 1.75 to account for non-wage labour on-costs.[58]

Source: ACIL Allen and NSW Ministry of Health.

Conclusion

The more frequent inventory requirements proposed under the MPTG Regulation would result in additional administrative/compliance costs for parties holding stocks of Schedule 8 substances (which could be in the order of $3.3 million per year). There is limited evidence to measure the impact that increased supervision of stocks of drugs of addiction would have on diversion, however the Ministry reports many instances of stock lost or not accounted for. Indeed, there are now over 2,000 lost/stolen drug reports received by the Ministry each year and OTP audits indicate that pharmacies participating in the OTP scheme across the state also have had circumstances of

[58] The Commonwealth Regulatory Burden Measurement Framework Guidance Note (p.11) states that average weekly earnings need to be 'scaled up using a multiplier of 1.75 (or 75% as it is input into the Regulatory Burden Measure) to account for the non-wage labour on-costs (for example, payroll tax and superannuation) and overhead costs (for example, rent, telephone, electricity and information technology equipment expenses).'

missing drugs (over 100 audits have been undertaken by NSW Health inspectors during 2023, with almost all pharmacies showing missing stock). By being able to more clearly ascertain when the stocks of these substances go missing, the proposed control would assist in investigating and regulating diversion of these high-risk substances. Further, the risks posed by misuse and abuse of drugs of addiction have been well documented. On this basis, and noting that the aim of the Regulation (and the Act) is to protect the health and safety of NSW residents (including by monitoring and controlling scheduled substances to mitigate the risk of diversion), a precautionary approach to regulating stocks of drugs of addiction is considered appropriate.

6.2.2 Wholesale supply of medicines and poisons

The proposed changes to the circumstances in which a person/entity can wholesale supply medicines and certain poisons.

In principle, the MPTG Act generally requires those engaged in wholesale supply of medicines and certain poisons to be licensed. However, in recognition of modern, appropriate and safe practices, the MPTG Act expressly allows certain wholesaling to take place without a licence (subject to appropriate safeguards). The additional circumstances in which this can occur are outlined in the MPTG Regulation. As outlined in Table 5.1, the additional circumstances in which wholesale supply of medicines/poisons is allowed under the proposed MPTG Regulation are summarised below.

- Substances may be transferred between pharmacies:
  - where there is a change in ownership or the pharmacy is subject to liquidation, bankruptcy or external administration (S2, S3, S4, S8 substances)
  - where the substance is within 6 months of expiry and not reasonably likely to be used by the pharmacy (S2, S3, S4 substances but not S4D or S8 substances)
  - where the pharmacy has the exact ownership structure as the other pharmacy (S2, S3, S4 substances but not S4D or S8 substances).
- Pharmacies can wholesale supply:
  - where it is to a pharmacy, private health facility or public health entity for a specific patient who needs it (or return of such stock to the original supply). Note: private health facilities and public health entities can also wholesale supply with pharmacies and other private health facilities and public health entities in these circumstances.
  - to first aiders (specified first aid medication)
  - to masters of vessels or racing yachts subject to certain threshold criteria
  - to residential care facilities for urgent care of residents
  - to authorised practitioners for the purposes of a 'doctor's bag emergency supply'.

In addition, the MPTG Regulation would impose additional restrictions on the provision of clinical samples by manufacturers and wholesalers (samples of Schedule 8 and Schedule 4D substances would not be authorised and health practitioners and veterinarians would be required to fill out a written order in an approved form to receive samples of Schedule 2, 3, or 4 substances).

Benefits

The main benefit of this change would be:

- reduction of compliance and administrative costs for pharmacies as the change would facilitate business practices
- reduction on the risk of diversion of samples of Schedule 2, 3, 4 8 and 4D substances
- reduced regulatory costs for the NSW Government, as there would be a reduction in the number of times that the Ministry would need to grant a licence / issue an authority to enable supply to occur.

Costs

This change recognises that subject to risk mitigation measures (such as record keeping obligations) certain wholesaling can safely occur without a licence, so it is not expected that it would result in any increase in the risk of diversion or misuse of scheduled substances. Indeed, to minimise the risk of diversion, Schedule 4D and Schedule 8 substances would only be permitted to be transferred between pharmacies in the event of a change in ownership, liquidation, bankruptcy, or external administration.

Conclusion

To the extent that the proposed changes to the circumstances when wholesale supply can occur without a licence facilitates business practices and reduce compliance costs for pharmacies without increasing risks of diversion, the change is expected to be overall beneficial.

Notably, this change was broadly supported by all stakeholders consulted for the RIS and no concerns were raised about unintended consequences.

6.2.3 Retail supply and wholesale supply of Schedule 7 substances (dangerous poisons)

A Schedule 7 substance is a substance not used therapeutically which has a high potential for causing harm at low exposure and therefore, its availability, possession, storage, and use needs to be proportionately regulated.

The proposed MPTG Regulation strengthens the regulation of Schedule 7J substances (Schedule 7 substances specified in Appendix J of the Commonwealth Poisons Standard). Currently, under the PTGR, supply by wholesale of Schedule 7 substances can occur without a licence (noting that, as with the current framework, no licence is required in circumstances where the end-user is authorised to possess/use the substance under the *Pesticides Act 1999*, **and an authority instrument only applies to certain highly dangerous Schedule 7 substances**). The MPTG would:

— prohibit the wholesale supply of Schedule 7J substances for domestic use

— require a wholesale licence to supply Schedule 7J substances and an obtain licence to obtain wholesale supplies of Schedule 7J substances.

Benefits

By strengthening the regulatory framework for Schedule 7J substances, the MPTG Regulation would reduce the risk of misuse of these substances. Indeed, the NSW Coroner has previously highlighted concerns[59] about the current controls in relation to Schedule 7 substances such as cyanide, arsenic and strychnine which have been used in self-inflicted deaths.

By lowering the risk of misuse of Schedule 7J substances, the proposed change to the Regulation has the potential to prevent illness and death (and the economic and social costs related to these) associated with poisoning by these substances.

Costs

The new licencing requirements for Schedule 7J substances may result in:

— additional administrative/compliance costs for wholesalers who, under the current regulatory framework, were able to wholesale supply without a licence. The Ministry noted that there are

[59] See for instance: State Coroner's Court of New South Wales 2014, *Inquest into the death of SS*, File number 2012/00354086.

only a few wholesalers involved in Schedule 7J substances, so this change is unlikely to affect many in the industry

— an increase in the costs of administering and enforcing the Regulation of these substances by the Ministry.

Conclusion

Overall, it is considered that the benefits from reduced risks of substance misuse stemming from the increased requirements for wholesale supply of Schedule 7J substances are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.

Notably, all stakeholders consulted for the RIS supported this proposed change.

6.2.4 Restrictions on administration of schedule 2, 3, 4 and 8 substances

The MPTG Act provides that supply does not include administration and does not specifically regulate the administration of medication. However, the Act allows the regulations to restrict administration in specific circumstances.

As discussed in Section 5.3.4, there is a variety of people who need to be able to administer medicines (including medical practitioners, nurses, paramedics, dentists, veterinary practitioners, first aid officers and carers) under different circumstances (e.g., at hospitals, workplaces and homes). Given this, the draft MPTG Regulation creates consistent parameters around lawful administration of scheduled substances, with additional record keeping requirements applying in certain settings (see additional detail in Table 5.3). The proposed restriction on the scheduled substances reflects the recommendations of the National Poisons Standard.

Notably, the risks associated with administration of medicines are further controlled through:

— restrictions in the MPTG Act and the Regulation on who can get access to scheduled substances

— professional standards to which registered health practitioners are subject to (which help ensure that practitioners only administer medicines when it is within their scope of practice and that they only allow appropriately qualified persons to administer under their direction and supervision)

— the MPTG Act explicit regulation of administration in high-risk settings (this is discussed in more detail in the following sections).

Benefits

Broadly, the benefits associated with the administration requirements proposed in the MPTG Regulation are:

— increased clarity around the definition of administration and the requirements for lawful administration of scheduled substances

— increased accountability for administration of medicines in certain settings (such as a hospital, private health facility, managed correctional centre, residential care facility and opioid treatment clinics)

— a potential reduction of risks of inappropriate administration of certain medicines by certain people

— consistency in the approach to regulate administration of scheduled substances.

Costs

While the proposed changes to record keeping obligations in relation to administration that occurs in public health entities, private health facilities, residential care facilities, managed correctional centres or OTP clinics align with the existing record keeping obligations set out in Clause 58/120 of the PTGR (and hence would not impose additional obligations from what is currently required), the changes may result in additional administrative/compliance costs for facilities due to potential revisions to their policies/guidelines.

In addition, this proposed change may result in increased costs of administering and monitoring the Regulation for the Ministry, as clear separation of administration from supply means the Ministry may be able to respond to circumstances of inappropriate administration where the current framework is unclear.

Conclusion

To the extent that the proposed changes to the administration and record keeping requirements increase clarity and consistency about the lawful administration of scheduled substances, and potentially reduce the risk of inappropriate or unsafe practices when treating patients, the change is expected to be overall beneficial.

While all the stakeholders consulted for the RIS broadly agreed with the proposed restrictions on administration of scheduled substances, one stakeholder raised concerns about the impracticability of overseen compliance for Schedule 2 medicines which are broadly available.

6.2.5 Compliance standards for Opioid Treatment Program

As discussed in Section 5.3.5, the MPTG Regulation:

- outlines the circumstances in which OTP registration is not required
- sets out certain standards (OTP Standards) that:
  - practitioners would have to comply with when prescribing, supplying or administering opioids under the OTP scheme
  - pharmacists who dispense under the OTP scheme would have to comply with
  - OTP clinics must have in place to ensure safe and quality use of medicine.

To assess the likely impact of the proposed OTP Standards, Table 6.3 provides additional information about how these compare with existing practice that occurs via OTP policy guidelines.

Table 6.3 How proposed OTP Standards compare to current OTP Guidelines

	Is this currently in the OTP Guidelines?	If not, how are they different to current arrangements?
Proposed OTP standard for practitioners		
A medical practitioner or nurse practitioner cannot initiate a patient on methadone unless: a) they are an 'accredited prescriber'[60] or	Yes	No change

[60] To be an accredited prescriber, a practitioner must:

- complete the Opioid Treatment Accreditation Course (OTAC), either through attendance at a workshop or through the web-based course and successfully pass end of course examination; and
- complete a workplace assessment (a 2–3-hour clinical placement) and
- recommended for approval by the Secretary, i.e., recommended by the Opioid Pharmacotherapy Subcommittee (of the Clinical Advisory Committee).

	Is this currently in the OTP Guidelines?	If not, how are they different to current arrangements?
b) they have the prior approval of the Health Secretary.		
An unaccredited medical practitioner or nurse practitioner can only register to prescribe/supply/administer: – methadone for ≤ 10 patients at any one time; and – to maximum of 100 patients at any one time for methadone (≤ 10 patients) and buprenorphine, unless they have the prior approval of the Secretary.	Yes, in modified form (text highlighted in blue indicates new requirements)	The only change is in relation to buprenorphine. The maximum number of patients that can currently be dosed on buprenorphine by an unaccredited practitioner is 20 patients. The change to 100 patients total has been made to ease regulation in relation to maximum patients.
An accredited medical practitioner or nurse practitioner can only prescribe/supply/administer to a maximum of 200 patients at any one time, unless they have the prior approval of the Secretary.	Yes The OTP Guidelines currently refer to the 200-person limit. Also, it allows for up to 300 persons in public OTP clinics. The 200/300-person cap is also a specific condition of a practitioner's approval under the PTGA.	No change
An unaccredited medical practitioner or nurse practitioner cannot transfer a patient from methadone to buprenorphine, using the microdosing or bridging methods (as outlined in forthcoming policy).	No	This is a new method/protocol available to practitioners, but there is nothing currently obliging compliance with it.
An unaccredited medical practitioner or nurse practitioner cannot transfer a patient from buprenorphine to methadone.	Yes	No change.
A medical practitioner or nurse practitioner in a correctional centre can only issue a written direction for 21 days treatment when discharging a patient from the correctional centre.	Referred to in Guidelines, but not as an obligation.	21 days is not specified in OTP Guidelines, however, Clause 83 of the PTGR creates an ability for an accredited prescriber to prescribe to a released OTP inmate in the 21 days post release from a correctional centre, provided the inmate was subject to an authority before they were incarcerated.
Proposed OTP standards for pharmacies		
A pharmacy supplying under supervised dosing arrangements to more than 80 patients per day must have an approved amenity plan in place.	No The PTGR currently limits retail pharmacies to dosing 65 patients per day to address perceived amenity concerns. Pharmacies seeking to dose more than 65 patients per day need to seek an exemption from the Ministry.	The draft MPTG Regulation would remove the 65-patient cap for retail pharmacies, and instead would require pharmacies to develop and comply with an amenity plan if they seek to dose more than 80 OTP patients per day (excluding patients who are not daily-dosing with OTP treatment, e.g., depot buprenorphine). The amenity plan is likely to require: – adequate storage arrangements (but likely to be no more onerous that current PTGR and new MPTGR) – separate entry to pharmacy (and/or purpose-built consult/dosing room) – security of the site/area itself
A pharmacy must comply with a requisite approved amenity plan.		

	Is this currently in the OTP Guidelines?	If not, how are they different to current arrangements?
		– setting out a plan as to how to manage the numbers of OTP patients, including removing opportunities for congregation by OTP patients. – consultation by pharmacies on proposed plans with council. – upper limit on pharmacy dosing. – adequate staffing arrangements commensurate to the number of OTP patients.
A pharmacy must have procedures and processes in place to ensure safe and quality use of medicine, including: a) ensuring processes are in place for accountability including record-keeping of Schedule 8s b) ensuring processes and equipment are in place to ensure security and quality assurance of Schedule 8s c) ensuring processes are in place for maintenance of dosing equipment as per the operational protocols of the equipment used and policies published on the NSW Health website'.	NA	NA
Proposed OTP standards for clinics		
A clinic must have procedures and processes in place to ensure safe and quality use of medicine, including: a) ensuring processes are in place for accountability including record-keeping of Schedule 8 substances b) ensuring processes and equipment are in place to ensure security and quality assurance of Schedule substances c) ensuring processes are in place for maintenance of dosing equipment as per the operational protocols of the equipment used and policies published on the NSW Health website'.	This is currently no existing explicit condition on OTP licence holders to develop these procedures and processes. However, it is expected/implied that compliance with the PTGR occurs, and this is assessed when the licence is applied for.	No change

Source: NSW Ministry of Health.

Importantly, recent reforms to opioid dependence treatment (ODT) access by the Commonwealth Government will also have an impact on pharmacies supplying OTP patients in NSW. In March 2023, the Pharmaceutical Benefits Advisory Committee (PBAC) considered the Interim Report for the Post-market Review of ODT medicines[61] and made a recommendation for ODT

[61] This report was prepared by the Australian Government Department of Health and Aged Care for a post-market review of the medicines available under the PBS Opiate Dependence Treatment Program. The post-market review was approved by the former Minister for Health and Aged Care, the Hon Greg Hunt, and announced on 24 March 2021 to consider stakeholder concerns about access and affordability of medicines for opioid dependence access and affordability of medicines for opioid dependence.

medicines to be listed on the PBS Section 100 Highly Specialised Drugs (HSD) Program (Community Access).

These changes mean that, from 1 July 2023, ODT medicines will be dispensed in the same way as other community access Section 100 HSD Program medicines from section 90 approved community pharmacies, section 92 approved medical practitioners, and section 94 approved hospital authorities (public and private).[62]

Under the Section 100 HSD Program, PBS-eligible patients will pay the PBS co-payment to access their treatment (for up to 28 days' supply per pharmaceutical benefit prescribed) and the amount paid will contribute towards their PBS Safety Net threshold. Additional private dispensing or dosing fees cannot be charged by section 90 community or section 94 hospital pharmacies to patients for access to ODT medicines under the PBS.

The changes will also result in consistency of access across all of Australia – everyone accessing opioid dependence treatment from pharmacies will pay the same, regardless of where they are in Australia, and they enable important supply to people in correctional facilities and to GP clinics.

Supplying patients with methadone liquid, buprenorphine sublingual tablets and buprenorphine + naloxone sublingual films often requires more frequent activities relating to in-pharmacy and take-away dosing. Therefore, from 1 July 2023, a community pharmacy program for ODT medicines was established, including on-site pharmacist administration of injectable buprenorphine, that introduces nationally consistent payment arrangements for ODT services provided by community pharmacists.[63]

Under the status quo (the PTGR), the Commonwealth's changes to OTP medication on the PBS are likely to result in more pharmacies dosing a higher number of patients per day[64], and hence, more pharmacies seeking an exemption from the Ministry to dose a higher patient limit[65] (more than 65 patients).

While the impacts of the PBS changes on pharmacies are acknowledged, it is important to note that these impacts are *independent* of any impact from the proposed MPTG Regulation (i.e., a higher number of pharmacies would seek to dose a higher patient limit *regardless* of whether the PTGR or the MPTG Regulation are in place).

In practical terms, the effect of the proposed MPTG Regulation would be to:

— reduce the compliance and administrative costs for pharmacies dosing between 65 and 80 patients per day, which before needed to seek an exemption for dosing a higher number of patients per day and under the MPTG Regulation would not need to do so

— increase compliance and administrative costs for pharmacies dosing more than 80 patients per day, which under the MPTG Regulation, instead of simply seeking an exemption to dose more patients, they would need an amenity plan.

As noted above, the changes to the PBS are likely to result in an increase in the number of pharmacies dosing between 65 and 80 patients per day and the number of pharmacies dosing

[62] Department of Health and Age Care 2023, *Opioid Dependence Treatment Program*, The Pharmaceutical Benefits Scheme, https://www.pbs.gov.au/info/browse/section100-md, accessed 27 July 2023.

[63] Ibid.

[64] The Ministry noted that the change to the PBS potentially means that it is less commercially viable to run private OTP clinics, and hence dosing arrangements in future potentially will rely more heavily on pharmacies.

[65] Notably, currently there are only two pharmacies that have approval to dose over 65 patients per day in NSW.

more than 80 patients per day. However, this is not an impact that can be attributed to the proposed MPTG Regulation.

While it is difficult to estimate the number of pharmacies that would seek to dose over 80 patients per day, the Ministry anticipates the number to be fairly low.

Benefits

Broadly, the benefits of the proposed changes to OTP are the following.

The removal of the requirements for practitioners to obtain authorisation from the Health Secretary prior to administering, prescribing, or supplying any Schedule 8 medicine to a drug dependent person under the OTP would result in:

  - lower costs of administering the Regulation for the Ministry, as the prescribing or supply of ODT to any drug dependent person under the OTP would no longer need to be assessed by the Health Secretary for appropriateness
  - reductions in compliance costs for practitioners – the use of the AMS system to manage registration would mean that practitioners do not need to email/fax/post application forms, thereby reducing their administrative burden
  - increased efficiency of care– the exemptions mean practitioners no longer need not await the issuance of an authority prior to prescribing/supplying under the OTP, thereby saving time and may result in better patient outcomes.
  - reduction of barriers to access to ODT for opioid dependence treatment
  - increased transparency of supply under the OTP scheme.
- The proposed OTP Standards are likely to result in:
  - reductions of compliance and administrative costs for retail pharmacies dosing between 65 and 80 patients per day (which before needed to seek an exemption for dosing a higher number of patients per day and under the MPTG Regulation would not need to do so)
  - the normalisation of ODT as an established treatment for persons with substance dependence
  - lower risks to patient safety by restricting transfers of patients from methadone to buprenorphine and vice versa by unaccredited medical practitioners or nurse practitioners.

Costs

The exemptions to the registration scheme to prescribe or supply for the OTP are unlikely to result in additional costs/negative consequences, as regulatory oversight and patient safety would be maintained (in part) through the use of SafeScript NSW.

As noted above, the proposed OTP Standards are likely to increase compliance and administrative costs for pharmacies dosing more than 80 patients per day, which would need to develop an amenity plan (instead of simply seeking an exemption for dosing a higher number of patients per day). However, the Ministry anticipates that the number of pharmacies that would seek to dose over 80 patients per day would be fairly low.

Conclusion

The proposed change is expected to be overall beneficial given that:

- the proposed exemptions to registration would result in cost/time efficiencies for practitioners and the Ministry, increased efficiency of care and reductions of barriers to access to ODT for opioid dependence treatment
- the OTP standards

- would maintain patient safety by mitigating risks in treatment
- are expected to impose additional compliance costs only to a fairly low number of pharmacies dosing over 80 patients which would require an approved amenity plan in place (and pharmacies dosing between 65 and 80 patients per day would experience reductions in compliance and administrative costs due to the removal of the requirement to seek an exemption to dose more than 65 patients per day).

The views expressed by stakeholders consulted with respect to the OTP standards are as follows (noting that a copy of the proposed standards in Box 5.1 was not provided to stakeholders during consultations for this RIS as these were being developed by the Ministry).

- Stakeholders consulted indicated that the exemptions to OTP registration proposed in the Regulation appeared appropriate. A stakeholder suggested that there needs to be consideration about whether the regulation should also exempt medical/nurse practitioners prescribing/supplying/administering to patients in police watchhouses. However, in this respect it is noted that, given police custody arrangements come within the legislative definition of 'correctional centre', these facilities would already be covered by the same exemption applying to correctional centres.[66]
- A representative of the Royal Australian College of General Practitioners (RACGP) noted that:
  - Requiring doctors to comply with OTP standards would only work if the standards are limited to tangible regulatory / non-clinical issues. It was argued that clinical treatment of a patient requires delicate balancing and hence clinical decision-making is not appropriate for enforceable OTP standards.
  - The risk profile of methadone is different to buprenorphine (it carries more risks), and prescribers may be reticent to prescribe on the OTP scheme at all, given the methadone concerns.

6.2.6 Approval to administer/prescribe/supply Schedule 8 substances

As discussed in Section 5.3.6, the proposed MPTG Regulation sets out the circumstances in which a practitioner is required to hold an approval to administer/supply/prescribe Schedule 8 substances. While the proposed controls are similar to the controls under the PTGA and the PTGR, there have been some adjustments, including:

- new controls to better address risk
- some exemptions to the approval requirements (certain specialist medical practitioners would have class-approval to prescribe/supply/administer certain substances and the administration/supply/prescription of some Schedule 8 substances would be exempted for certain patients and/or under certain circumstances – e.g., a palliative care patient). Additional details about these exemptions are included in Table 5.6.

In general, the draft MPTG Regulation would require that an approval is sought in the following circumstances.

- Supplying/prescribing/administering any Schedule 8 substance (i.e., a drug of addiction) to a patient who has substance dependence.
- Supplying/prescribing/administering specified stimulant Schedule 8 substances (dexamfetamine, lisdexamfetamine, methylphenidate) unless an exemption applies (for example, certain specialties of medical practitioner would not need to have an approval).
- Supplying/prescribing/administering, N,*α*-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and psilocybine unless an exemption applies.

[66] See s.3 *Crimes (Administration of Sentences) Act 1999*.

— Supplying/prescribing/administering any Schedule 8 in an injectable or intranasal preparation, alprazolam, flunitrazepam, methadone for more than 3 months unless exempted.
— Supplying/prescribing/administering fentanyl, hydromorphone, morphine, or oxycodone in a dose > 100mg OMEDD unless exempted.

As discussed in Section 6.2.5, OTP methadone and buprenorphine will move from authority to registration. The prescribing, supply and administration of methadone or buprenorphine for the purposes of the OTP is recognised as appropriate medical treatment, therefore seeking approval is not required. However, controls should be in place to ensure the patient only receives one dose per day (i.e., avoid double dosing, thereby minimising diversion and optimising treatment). The registration scheme seeks to ensure this by minimising risk and increasing the transparency of prescribing and, significantly, supply and administration under the OTP scheme, without creating barriers to access via an approval process.

Benefits

New and tightened controls of Schedule 8 substances in the proposed MPTG Regulation are likely to reduce the risks of misuse or abuse of these substances and increase patient safety.

In terms of the proposed exemptions, these are likely to:

— reduce compliance and administrative costs for practitioners that were required to seek approval under the PTGR and would now be exempt of the approval requirements under the proposed MPTG Regulation
— reduced regulatory costs for the Ministry in administering and enforcing approvals for some of these substances.

The change from OTP methadone and buprenorphine from authorisation to registration is not expected to result in significant time savings for practitioners, as the Ministry expects the registration process would roughly take the same time as the current approval/authorisation requirements.

Costs

New and tightened controls of Schedule 8 substances may result in:

— additional administrative/compliance costs for practitioners who, under the current regulatory framework, were able to administer/supply/prescribe fentanyl, hydromorphone, morphine, and oxycodone without approval in some circumstances
— an increase in the costs of administering and enforcing the Regulation of these substances by the Ministry (including by increasing the size of the Medical Committee that reviews authorities from three doctors to six).

To understand whether the increase in compliance costs due to the new proposed controls would be higher/lower than the decreases in compliance costs associated with the proposed exemptions, we have developed indicative estimates of these costs based on existing data provided by the Ministry and a number of assumptions.

Under proposed technology improvements being introduced with the AMS (which will commence prior to, and regardless of, the MPTG Regulation) there will be streamlined efficiencies. Each authority to prescribe or supply Schedule 8 substances will require a digital form to be filled out by a doctor or nurse practitioner (an authority application). Of these applications, approximately 20% will be approved automatically[67], while the remainder will be reviewed manually. Around 1% of

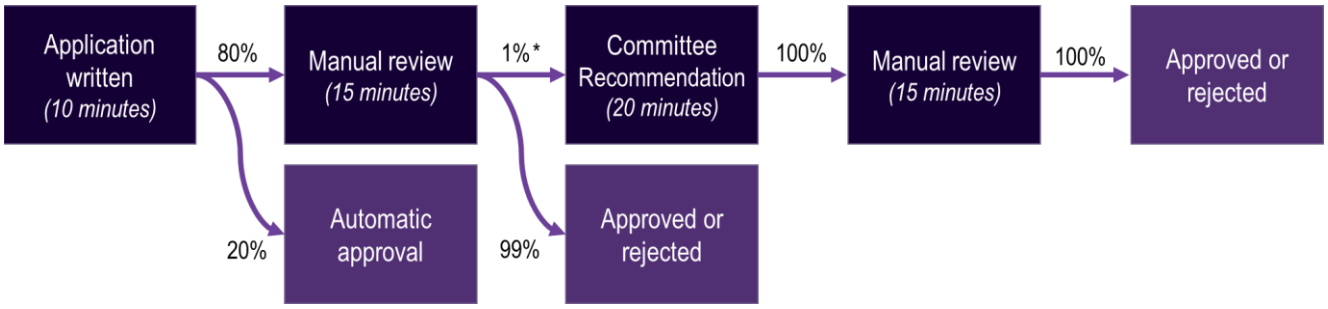
[67] The automatic approval process is currently being implemented by NSW Health. As this change is happening alongside the change to regulations, rather than as a result of it, it is assumed that this change

those reviewed manually will then be reviewed by a committee of three doctors (note, this will be increased to 6 doctors under the new MPTG Regulation). It is assumed that it takes a doctor 15 minutes to fill out a form, 15 minutes for Ministry staff to review that form manually and 20 minutes of committee time to come to a decision on each authority that comes before them. The overall process for approving an authority to administer, prescribe or supply Schedule 8 substances is summarised in Figure 6.1. The process itself for approving an authority would not change as a result of the proposed MPTG Regulation, what would change under the MPTGR is the following:

— the total number of authorities that doctors and nurse practitioners would seek (see Table 6.5)

— the cost of each authority reviewed by the committee, as the committee size would increase from 3 to 6 doctors (see Table 6.6). [68]

Figure 6.1 Process for approving an authority to administer, prescribe or supply Schedule 8 substances



NOTE: This process is modelled to represent the process after the technology improvements being introduced with the AMS to automatically approve authorities will roll out.

* Only the changes to the three month rule and the >100mg OMEDD rule will result in changes to the number that go to committee.

Source: ACIL Allen and NSW Ministry of Health.

Table 6.4 identifies the responsible party at each stage, the cost of each party's time (including overheads), and the time taken to process an authority at each stage. This is combined to give a cost for an authority at each stage. The cost per authority at each stage can be considered the administrative cost burden of an authority addressed by each person.

The figures Table 6.4 provide an understanding of the marginal cost of additional authorities. To get an understanding of the likely aggregate impact of the reforms, the figures above must be combined with the total change in the number of authorities. Estimates of the total change in authorities were provided by the Ministry, based on the new rules and SafeScript data. By regulatory change, these would be:

— drug of addiction to substance dependent patient: -6,160[69]

— changes to requirements prescription of specified stimulants[70]: -9,844[71]

would happen anyway. Therefore, for the purpose of this modelling exercise, the impact of this change is not costed.

[68] On the advice of NSW Health, it is assumed that that only the 3-month rule on supply of Type B drugs of addiction and >100mg OMEDD approval requirement changes will flow through to savings or costs to the committee process. This is due to the types of authorities the committee reviews.

[69] Assumption based on current authorities.

[70] Dexamfetamine, lisdexamfetamine, methylphenidate.

[71] Based on SafeScript data. There were 158,341 patients dispersed stimulants on SafeScript, 109,175 prescribed by a specialist on the PBS who would be exempt in the new framework. Therefore 49,166 patients were not prescribed on the PBS. We have assumed all PBS specialist prescribers have CNS/s28c authority. The new MPTG framework exempts certain specialists from the requirement to obtain an authority. We have chosen a conservative assumption that 20% of these would be exempted from an authority, which means a reduction of 9,844 authorities.

— 3-month rule on supply of Type B drugs of addiction: -2, 764[72]

— >100mg OMEDD approval requirement: + 5, 512[73]

— changes to authorities for compounded S8: 0.[74]

— supplying/prescribing/administering MDMA and psilocybine: 0[75]

These would represent additional costs and savings through the process as shown in Figure 6.1. Based on these estimates, it is estimated that most of the proposed changes under the MPTG Regulation would decrease the number of authorities that doctors and nurse practitioners would seek. Combining these figures with the costs calculated in the table above, the indicative net cost of changes can be calculated. In total, it is estimated that the proposed changes would *reduce* the level of administrative burden across NSW by a total of approximately $803,000 dollars per year. This is a sum of the changes captured in Table 6.5 and Table 6.6.

The change in cost from committee administration of authorities includes both the change in cost due to the expansion of the committee and the change in volume of authorities that go to it. This is summarised in Table 6.6.

Table 6.4 Cost per authority to administer, prescribe or supply Schedule 8 substances

	Fill out form	Manual review*	Committee review (pre-MPTG reg)	Committee review (post-MPTG reg)
Responsible party	Doctors (95%) Nurses (5%)	Ministry staff	Three doctors Ministry staff	Six doctors Ministry staff
Cost of responsible parties' time (per hour)	Doctor: $152.00 [a] Nurse practitioner: $65.75 [b] Average cost: $147.69[c]	Ministry staff: $55.70[d]	Committee of six doctors: $456 [e] Ministry Staff: $55.70 [g]	Committee of six doctors: $912 [e] Ministry Staff: $55.70 [g]
Cost of parties' time (per hour) including overheads (75%)	$258.45	$103.20	$1,596.00	$1,596.00
Time taken	10 minutes	15 minutes	20 minutes	20 minutes
Cost per authority by activity	**$43.08**	**$25.80**	**$306.34**	**$572.34**

* Manual review includes manual review after committee recommendation

[a] Indeed.com "General practitioner salary in New South Wales", accessed 15 May 2023. https://au.indeed.com/career/general-practitioner/salaries/New-South-Wales

[b] iworkfor.nsw.gov.au Palliative care nurse practitioner listing, accessed 15 May 2023 https://iworkfor.nsw.gov.au/job/nurse-practitioner-palliative-care-400174

[c] Assumes 95% of authorities are requested by doctors, and 5% by nurse practitioners

[d] Grade 9 NSW Health clerk salary, assuming 1,976 working hours per year. https://www.health.nsw.gov.au/careers/ministry/Pages/current-rates-of-pay.aspx

[e] Assumes each doctor's rate is equivalent to a general practitioner's cost of time

[f] The Commonwealth Regulatory Burden Measurement Framework Guidance Note (p.11) states that average weekly earnings need to be 'scaled up using a multiplier of 1.75 (or 75% as it is input into the Regulatory Burden Measure) to account for the non-wage labour on-costs (for example, payroll tax and superannuation) and overhead costs (for example, rent, telephone, electricity and information technology equipment expenses)'.

[g] Grade 11 NSW Health clerk salary, assuming 1,976 working hours per year. https://www.health.nsw.gov.au/careers/ministry/Pages/current-rates-of-pay.aspx

[72] Based on analysis by the Ministry of available SafeScript data. On the existing Type B rule, there were 10,982 patients requiring an authority. With the extended period to 3 months and removal of hydromorphone (non-injections) and buprenorphine (temgesic sublingual) this came to 8,218. The difference is therefore -2,764.

[73] Based on analysis by the Ministry of available SafeScript data.

[74] This figure is based on regulatory impact of change on medical practitioners and nurse practitioners but excludes regulatory impact on veterinary practitioners, who will now require an approval to prescribe, supply or administer compounded Schedule 8 substances. The Ministry do not currently collect data to quantify this change for veterinary practitioners.

[75] The requirements for an authority for MDMA and psilocybine is a new Schedule 8 control in the current framework in response to the changes in their scheduling by the Commonwealth Government. This rule will continue in the regulation and so the Ministry expects no change in the number of applications received.

Table 6.5 Change in administrative costs due to changes in the number of authorities required, per year

Change	Number of forms filled out	Number reviewed manually*	Total
Drug of addiction to substance dependent patient	-$265,345	-$127,146	-$392,491
Specified stimulants	-$424,035	-$203,186	-$627,222
3-month rule	-$119,061	-$57,051	-$176,111
>100mg OMEDD	$237,432	$113,771	$351,203
Compounded S8	$0	$0	$0
MDMA and psilocybine	$0	$0	$0
TOTAL	**-$571,009**	**-$273,612**	**-$844,621**

NOTE: changes due to the committee process are handled separately below

** Manual review includes manual review after committee recommendation*

Source: ACIL Allen analysis of NSW Ministry of Health data

Table 6.6 Change in committee costs, per year

	Committee – pre-MPTG reg	Committee – post MPTG reg
Applications*	110	132
Committee size	3	6
Committee cost per application	$306	$572
Total committee cost	$33,698	$75,540
Committee cost change		**$41,842**

* The application count is based on the number of applications considered in 2021 and 2022. The change pre- and post-MPTG regulation are a result of the 3-month rule on supply of Type B drugs of addiction and >100mg OMEDD approval requirement changes.

Source: ACIL Allen analysis of NSW Ministry of Health data

In terms of the impact of the proposed exemptions on risks, it is considered unlikely that the exemptions to the approval requirements for Scheduled 8 substances proposed in the MPTG Regulation would increase risks to patient safety due to the following.

- The proposed exemptions relate to two areas:
  - The status of the patient – the MPTG Regulation proposes exemptions for the administration/supply/prescription of some Schedule 8 substances for palliative care patients. The rationale for this exemption is that palliative/end of life care should not be impeded by regulatory controls.
  - The doctor prescribing the substance – the MPTG Regulation proposes exemptions to the approval requirements for Schedule 8 substances for certain specialists that are considered sufficiently qualified to assess the risks associated with these substances. Notwithstanding these exemptions, the proposed regulation does not relieve these specialists from their professional obligations (hence, while they do not need an approval for these substances, they may not prescribe a substance if it its outside their area of expertise).
- The proposed MPTG Regulation also includes provisions relating to quantity and purpose of these substances that would act as a safety net:
  - doctors cannot prescribe in a quantity or for a purpose that is outside the therapeutic standard (offences that would apply)

  - pharmacists cannot dispense in a quantity or for a purpose that is outside the therapeutic standard (offences that would apply).
- The Ministry would have visibility of when these substances are prescribed and supplied so that unusual prescription or supply can be flagged.
- The palliative care definition for the purposes of the exemption is limited to 2 years (palliative treatment, in relation to the supply, administration or issue of a prescription for a scheduled substance, means the palliative treatment of patient who has: (a) an incurable, progressive, far-advanced disease or medical condition, and (b) a prognosis of a limited life expectancy where death is expected within the next 24 months because of the disease or medical condition).

Conclusion

To the extent that the proposed changes to the circumstances in which a practitioner is required to hold an approval to administer/supply/prescribe Schedule 8 substances decrease risks of misuse and abuse of these substances and reduce overall compliance costs for practitioners, the change is expected to be overall beneficial.

Notably, most of the stakeholders consulted for the RIS supported this change. The Australian Medical Association noted their support for systematising prescribing, increasing oversight of dangerous substances and creating better guardrails for those practitioners who are unaware of patients' habits, however they raised concerns regarding some of the proposed exemptions.

- Some exemptions are considered inappropriate, these include exemptions for Category A (dexamfetamine, lisdexamfetamine, methylphenidate) and Category B (alprazolam, flunitrazepam, non-OTP methadone and any Schedule 8 in an injectable or intranasal preparation) substances for:
  - palliative care patients
  - AHPRA registered medical practitioners registered in the specialty of palliative medicine, and the specialty fields of paediatric palliative medicine, medical oncology, and paediatric medical oncology.
- The list of exemptions for opioids is considered insufficient (e.g., pain physicians who deal with patients with chronic, severe, disabling pain and are long-term opioids users are not included in the exemptions).

6.2.7 New controls to administer/prescribe/supply and manufacture certain Schedule 4 substances

As discussed in Section 5.3.7, the proposed changes to the treatment of Schedule 4 substances are that the draft MPTG Regulation:

- contains more nominated Schedule 4 substances than are currently listed at Clause 37 of the PTGR
- requires approval to prescribe, supply or administer compounded Schedule 4D substances for non-topical use
- requires a dentist, veterinary practitioner or medical practitioner who seek to manufacture (compound) a Schedule 4D substance for non-topical use to obtain authorisation, unless subject to an exemption.

Benefits

Broadly, the benefits associated with the proposed changes to the treatment of Schedule 4 substances in the MPTG Regulation are:

- consistency with the National Poisons Standard in the approach to regulate prescription, supply and administration of nominated Scheduled 4 substances
- alignment with the controls of compounded Scheduled 8 substances which are in the current PTGR
- increased control and oversight of the supply of manufactured Schedule 4D substances, which are not captured by regulatory oversight by the TGA[76]
- reductions in the risks of:
  - misuse and diversion of compounded Schedule 4D substances for non-topical use
  - inappropriate prescription/supply/administration of certain (nominated Schedule 4) medicines by certain people.

Costs

New and tightened controls of Schedule 4 substances would result in:

- Additional administrative/compliance costs for practitioners who, under the current regulatory framework, were able to administer/supply/prescribe certain nominated Schedule 4 substances without approval. The Ministry noted that this change is unlikely to result in a large increase in applications for approvals, as the Regulation recognises the specialities that generally prescribe these substances who are exempted from seeking an approval.
- Additional administrative/compliance costs for dentists, veterinary practitioners and medical practitioners who, under the current regulatory framework, were able to compound Schedule 4D substances for non-topical use without the need to seek an authority. The Ministry do not currently collect figures about the number of dentists/veterinary practitioners/medical practitioners who compound Schedule 4D substances for non-topical use, and so it is not possible to ascertain the likely magnitude of these costs.
- An increase in the costs of administering and enforcing the Regulation of these substances by the Ministry.

Notably, with regards to compounded Schedule 4D substances for non-topical use, the Ministry noted that there are only limited circumstances in which there would be a need to compound the substances, as there are already a number of legitimate/approved equivalents on the Australian Register of Therapeutic Goods (ARTG) or registered with the APVMA which the TGA and APVMA have already tested for quality, safety and efficiency or which have undergone quality assurance assessments (compounded substances are not assessed by the TGA for quality, safety and efficiency nor undergone APVMA quality assurance assessments).

Conclusion

Overall, it is considered that the benefits from reduced risks of substance misuse stemming from the new and tightened controls of Schedule 4 substances are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.

Stakeholders were consulted about the proposed changes to the list of nominated Schedule 4 substances and the new approval requirements to prescribe, supply or administer compounded Schedule 4D substances for non-topical use. In principle, all stakeholders consulted for the RIS

[76] The manufacture of therapeutic goods generally requires a TGA manufacturing licence, but compounded substances by pharmacists are subject to an exemption to the TGA's manufacture licence.

supported these proposed changes, but some noted the difficulty to monitor/enforce the administration of these substances.

Notably, stakeholders interviewed for the RIS were not specifically consulted on the proposed changes to the authority requirements for dentists, veterinary practitioners and medical practitioners who seek to compound Schedule 4D substances for non-topical use, as these changes were drafted in the Regulation after the conclusion of the consultations.

6.2.8 Prescription approval number requirements for Schedule 4 and 8 substances

As discussed in 5.3.8, the MPTG Regulation seeks to further control Schedule 4 and 8 substances by requiring that a prescription includes an approval number if the substance is a compounded Schedule 8 substance, MDMA or psilocybine, a specified stimulant (methylphenidate, lisdexamfetamine or dexamfetamine), a nominated Schedule 4 substance or a compounded Schedule 4D for non-topical use.

Benefits

Broadly, the benefits associated with the approval number requirements for Schedule 4 and 8 substances in the MPTG Regulation are:

— increased control and oversight of the supply of compounded Schedule 8 and 4D non-topical substances, nominated Schedule 4 substances, specified stimulants, MDMA and psilocybine
— reductions in the risks of abuse, misuse and physical or psychological dependence of these substances
— increased accountability for the prescription and supply of these substances.

Costs

As noted in Table 5.9, the proposed approval number requirements for:

— compounded Schedule 8 substances, MDMA and psilocybine, and specified stimulants would not impose additional obligations/compliance costs on prescribers or pharmacists
— the increased number of substances listed as nominated Schedule 4 substances would impose additional obligations/compliance costs on prescribers for certain Schedule 4 substances
— compounded Schedule 4D substances for non-topical use would impose additional obligations/compliance costs on prescribers and pharmacists as there is currently no requirement to include an authority number on a prescription for these substances

In addition, there would be an increase in the costs of administering and enforcing the Regulation of these substances by the Ministry.

Conclusion

If the proposed approval number requirements achieve the right balance of increasing patient safety without substantial increases in compliance costs for prescribers and pharmacists, then the change would be overall beneficial.

While, in principle, all the stakeholders consulted for the RIS supported this change, the following concerns were raised about the new requirement:

— Concerns were raised about how prescribers would respond to the requirement (i.e., about whether prescriptions would be written correctly). It was argued that pharmacies already receive a significant number of prescriptions that are not in the appropriate form, and they frequently have to ring doctors to get an approval number, which significantly increases their administrative/compliance time and costs.

— Pharmacies' representatives were concerned that pharmacies would have to check that when 'approval exempt' is written in a prescription, the prescriber has a lawful exemption (the Ministry confirmed that this would not be the case). In this respect, the Ministry has confirmed that it does not expect that pharmacists need to 'look behind' a prescription that has the words 'approval exempt'.

6.2.9 Compounding controls

Compounded medicines play an important role in meeting the healthcare needs of the NSW community when commercial preparations are unavailable or individualised dosing is required (for instance, compounding is often needed for paediatric patients). However, compounded products can pose serious health and safety risks, in particular those medicines required to be sterile, such as injectables and eyedrops.

As noted by Feldschuh in the Australian Prescriber, while 'there have been few confirmed incidents of harm from compounded products in Australia, the potential is great in the absence of enforceable quality control measures'[77]. While there have been few reported incidents of harm from compounded products in Australia, the potential is great in the absence of enforceable quality control measures. Indeed, the Ministry has become aware of incidents both in Australia and overseas where complications have arisen from the use of compounded of medicines. These include (but are not limited to):

— In Australia:
  — seven cases of probable endotoxin poisoning that were linked to contaminated glutathione infusion compounded by a pharmacist
  — five patients went blind following administration of eyedrops compounded by a pharmacist who was found to have used the wrong ingredient in a batch of eyedrops
  — a case where a woman ended up in in an Intensive Care Unit (ICU) after being administered a compounded injectable at an infusion clinic in NSW
  — a case where potassium iodide was compounded for a patient for oral administration at 10 times the recommended dose (the patient had to be admitted to hospital).
— Various reports of serious events in the USA, including:[78]
  — meningitis outbreaks traced to purportedly 'sterile' steroid injections contaminated with fungus or bacteria, which were made by compounding pharmacies and contaminated 700 patients across 20 states, causing 64 deaths
  — adulteration (dilution) of oncology medications to increase profits
  — an outbreak of *Serratia marcescens* bacteremia, which infected 19 patients at six hospitals, 9 of whom died, was caused by contaminated total parenteral nutrition bags from a compounding pharmacy.

Compounded medicines pose additional risks to patients because:

— pharmacy compounding has significantly less rigorous regulatory oversight than that required for TGA and APVMA registered drugs
— pharmacy-compounded products:
  — are not clinically evaluated for safety, quality or efficacy
  — do not have standard product labelling or prescribing information with instructions for safe use
  — are not tested to assess consistent product quality or stability (setting of expiry dates)

[77] Feldschuh, M. 2008, *Compounding in community pharmacy*, Australian Prescriber, Aust Prescr 2008;31:115-8. https://doi.org/10.18773/austprescr.2008.016, Accessed 20 June 2023.

[78] Gudeman, Jennifer & Jozwiakowski, Michael & Chollet, John & Randell, Michael 2013, *Potential Risks of Pharmacy Compounding. Drugs in R&D*, 13. 10.1007/s40268-013-0005-9.

- compounding drugs in the absence of good manufacturing practice regulations increases the potential for preparation errors
- compounded products may provide an access route for medicines where use is currently experimental and more clinical trial evidence is needed to support use.

Given these risks, it is important to ensure that poor practices are appropriately regulated.

The new control for sterile compounded substances proposed in the MPTG Regulation aims to reduce the risks for patients and improve patient outcomes and safety by requiring that substances compounded without a TGA licence comply with the TGA GMP Guide, which describes a set of principles and procedures that, when followed, help ensure that therapeutic goods are of high quality.

The new authorisation requirements for dentists, veterinary practitioners and medical practitioners who seek to compound a Schedule 8 or Schedule 4D substance for non-topical use aim to reduce the risks posed by these substances (including of diversion for personal use or trafficking purposes) by ensuring appropriate oversight of high risk compounding activities.

Benefits

By strengthening the regulation of compounded substances, the proposed changes to the MPTG would:

- create consistent compounding practices by pharmacies (including to improve the compounding practices of certain pharmacies)
- increase medication safety
- improve consistency in medicines prepared
- reduced patient risks (and the economic and social costs related to these).

Costs

Requiring compounding pharmacies without a TGA licence to comply with the TGA GMP Guide would result in:

- Increased compliance costs for compounding pharmacies (the Ministry expect these additional compliance costs to be minor/moderate). While some large and/or specialised compounding pharmacies may already have in place best practice compounding procedures similar to those in the TGA GMP Guide (and hence may not incur in significant additional compliances costs), the impact would be different for smaller compounding pharmacy businesses where there may be a greater variation in compounding practices.
- Potential increases in the cost of medicines for patients if compounding pharmacies pass on some of the additional compliance costs to consumers.
- A potential decrease in the accessibility to medicines by some patients (e.g., rural patients) if compounded medicines become commercially not viable for some pharmacy businesses as a result of increased compliance and administrative costs.
- Increased costs to the Ministry to monitor compounding pharmacies.

The new authorisation requirements for dentists, veterinary practitioners and medical practitioners who seek to compound a Schedule 8 or Schedule 4D substance for non-topical use would result in:

- increased compliance costs for these practitioners
- potential increases in the cost of medicines for patients if practitioners pass on some of the additional compliance costs to consumers
- increased costs to the Ministry to monitor these practitioners.

Conclusion

The proposed changes to the controls of sterile compounded substances which pharmacies are currently able to manufacture without a TGA licence are likely to increase the costs of regulatory compliance for pharmacies and the NSW Government. In addition, the new authority requirements for dentists/veterinary practitioners/medical practitioners who seek to compound a Schedule 8 or a Schedule 4D substance for non-topical use are likely to increase the costs of regulatory compliance for these practitioners and the NSW Government. However, given the potentially catastrophic consequences of worst-case safety/quality incidents related to compounded substances (which include illness, disability and death) and the lack of rigorous oversight of this sector, the proposed change is expected to be overall beneficial.

Notably, stakeholders interviewed for the RIS were not specifically consulted on the proposed changes to compounding, as these changes were drafted in the Regulation after the conclusion of the consultations. However, the Ministry undertook subsequent consultation with both the Pharmacy Guild and the Pharmaceutical Society of Australia (PSA) in relation to the proposed amendments to compounding of sterile substances. During these consultations, the PSA noted that, while it supports appropriate mechanisms to regulate compounding, these should align with the Pharmacy Board's guidelines. The Ministry notes that requiring compliance with the TGA GMP would create consistency of controls with Commonwealth licensed manufacturers.

No consultation was undertaken regarding the proposed changes to the authority requirements for dentists, veterinary practitioners and medical practitioners who seek to compound a Schedule 8 or a Schedule 4D substance for non-topical use.

6.2.10 Emergency use provisions

As discussed in Section 5.3.10, the MPTG Regulation would introduce new restrictions about what can be accessed under the emergency use provisions, in particular:

- In relation of Schedule 4 substances – Clause 46 of the PTGR currently allows order for emergency use in respect of any Schedule 4 substances. However, the MPTG Regulation includes a new exclusion in relation to unregistered Schedule 4 substances (i.e., substances not registered on the ARTG or, for veterinary practitioner emergency supply, substances not registered on the ARTG/APVMA) for both health practitioners and veterinary practitioners.
- In relation of Schedule 8 substances – Clause 97 of the PTGR currently allows for orders for emergency use:
  - for health practitioners for Schedule 8 substances (excluding unregistered Schedule 8). This provision would remain unchanged under the MPTG Regulation
  - for veterinary practitioners for **any** Schedule 8 substances. The MPTG Regulation includes a new exclusion in relation to Schedule 8 substances not registered with the APVMA.

This proposed change would mean that a health practitioner/veterinary would not be able to rely on the emergency use provision to obtain Schedule 4 or Schedule 8 substances that are unregistered with the ARTG or APVMA. A health practitioner or veterinary practitioner seeking to obtain these supplies from a pharmacist for a patient would need to issue a prescription, and the pharmacist could then compound or dispense the unregistered Schedule 4/8 substance to or for the patient or animal. For Schedule 4 and Schedule 8 substances that are registered with the ARTG/APVMA there would be no change to current practice. The main change under this amendment is that a practitioner cannot order compounded/unregistered stocks for future emergency use compounded/unregistered stock are not subject to PBS subsidies under PBS doctor's bag funding arrangements).

Benefits

Broadly, the benefits of the new restrictions proposed in the MPTG Regulation about what Schedule 4 and Schedule 8 substances can be accessed under the emergency use provisions would be:

- increased clarity regarding orders for emergency use
- limiting access to compounded and unregistered Schedule 4 substances to more closely align with the Commonwealth regulatory exemption (i.e., where it is for an individual specific patient treatment), which would result in increased patient safety
- reduced risks related to Schedule 8 substances that are used in animal treatment and are not registered with the APVMA
- reduced risks related to bulk batch compounded preparations for animal use. While compounded medicines for animals play an important role in meeting patient need when commercial preparations are unavailable or individualised dosing is required, allowing for bulk batch preparations for animal medicines with no Commonwealth/state oversight to ensure quality and safety of those medicine creates risk
- greater alignment across the Commonwealth regulatory framework and reduced risk of undermining the quality use of medicines.

Costs

The PBS provides select doctor's bag substances for human patients at no cost, so generally practitioners who obtain emergency supplies under the PBS's doctor's bag provisions would only obtain substances covered at no cost. The emergency supply substances which are subject to PBS subsidies are all ARTG products (that is, unregistered/compounded substances are not subject to PBS subsidies under the PBS doctor's bag list). Therefore, the effect of the restriction proposed under the MPTG Regulation is not anticipated to have financial impacts on current practice of medical practitioners.

Veterinary practitioners do not have access to free PBS substances on a doctor's bag order like the medical practitioners do. As such, pharmacies would not typically keep in stock non-ARTG/non-AVPMA substances to anticipate emergency supply to vets. Typically, the supply of non-ARTG/non-AVMPA substances is based on specific patient (animal/flock) need, (i.e., upon prescription). Therefore, the effect of the restriction proposed APVMA restriction under the MPTG Regulation is not anticipated to have financial impacts on veterinary practitioners.

However, there may be an increase in the costs of administering and enforcing these new restrictions by the Ministry.

Conclusion

The proposed exclusions from emergency use provisions of Schedule 4 substances not registered on the ARTG or, for veterinary practitioner emergency supply, substances not registered on the ARTG/APVMA and Schedule 8 substances that are unregistered with the APVMA for veterinarians are not anticipated to increase the costs of regulatory compliance for doctors/veterinary practitioners as unregistered/compounded products are not subject to PBS subsidies. However, the changes may result in an increase in the costs of administering and enforcing the regulation for the NSW Government.

As highlighted by the discussion on compounded substances in Section 6.2.9, the risks related to compounded/unregistered substances are high and the consequences of safety/quality incidents related to these substances potentially catastrophic. To the extent that reductions in the risks to patient safety from the proposed new restrictions more than offset the additional costs to the NSW Government, the proposed change is expected to be overall beneficial.

Notably, while stakeholders interviewed for the RIS were not consulted on the proposed changes to emergency use provisions (these changes were drafted in the Regulation after the conclusion of the consultations), the Ministry received correspondence from the Veterinary Practitioners Board of NSW noting that they do not support supply by wholesale to veterinarians of compounded medicine for emergency use. The Board noted that batch preparations of compounded products are not subject to the rigorous testing for quality, safety, stability and efficacy that applies to registered products and therefore pose a greater risk to animal health and welfare if made available to multiple animals by wholesale.

6.2.11 New and increased fees

As discussed in Section 5.3.11, the MPTG Regulation proposes to increase the fees collected under the PTGR for retail and wholesale supply licence applications and renewals for Schedule 2, 3, 4 and 8 substances and creating new fees for wholesale licences for Schedule 9 and 7J substances, retail licences for Schedule 7J substances, amendments to licences and obtaining a licence.

Benefits

The proposed amendments to fees in the MPTG Regulation would increase the level of cost recovery associated with the administration of the licencing scheme, hence increasing allocative efficiency.[79]

Costs

The proposed increases in fees are not considered a cost of Option 2 because of the following reasons.

— Best practice regulatory impact analysis suggests that administrative costs incurred by regulated entities to demonstrate compliance with the regulation should be included as a cost of a regulatory proposal, including the costs incurred in complying with government taxes, fees, charges and levies (for example, the time taken to pay a licence fee is a compliance cost), *but excluding the actual amount paid*[80]. This is because fees charged by the Ministry are a transfer of funds between the consumers of regulated goods and services and the provider of goods and services (government).

— The Commonwealth Government's agreed Regulatory Burden Measurement (RBM) framework used to quantify the regulatory impact of regulatory proposals on businesses, individuals and community organisations explicitly notes that charges attached to a regulation that are payable to government are not required to be considered in the costs of a regulatory proposal.[81]

However, to illustrate the impact that the proposed changes to licence fees would have on industry, we have developed an indicative estimate of the change in licence costs based on existing data on the number of current licences in NSW (see Table 6.7).

[79] Allocative efficiency is achieved when the value consumers place on a good or service equals the cost of resources used up in production of that good or service. By requiring payment for goods/services provided by government, cost recovery charges can give important signals to users about the costs of the resources involved in their provision (Victorian Department of Treasury and Finance 2013, *Cost Recovery Guidelines*, January).

[80] Department of the Prime Minister and Cabinet Office of Impact Analysis 2022, *Regulatory Burden Measurement Framework*, May, p. 2, https://oia.pmc.gov.au/sites/default/files/2023-05/regulatory-burden-measurement-framework.pdf, accessed 20 June 2023.

[81] Ibid, p. 3.

Conclusion

The proposed amendments to licence fees would represent a significant increase in the regulatory charges for suppliers, but would better reflect the costs of the regulatory activities by the Ministry, increase the level of cost recover and increase allocative efficiency.

Table 6.7 Illustrative impact of the proposed changes to licence fees for industry

Licence type	Number of current licences	Current fees	Current cost of licences for industry	Proposed fees	New cost of licence for industry	Additional cost of licence for industry
Wholesaler licences for Schedule S7J substance						
Application fee for wholesaler licence	13 [a]	$0	$0	$770	$10,010	$10,010
Annual renewal fee for wholesaler licence	13 [a]	$0	$0	$330	$4,290	$4,290
Application fee for wholesaler licence or obtain licence involving Schedule 8s and Schedule 9s						
S8	217	$356	$77,252	$2,930	$635,810	$558,558
S9	94 [b]	$0	$0	$2,930	$275,420	$275,420
Annual renewal fee for wholesaler licence or obtain licence involving Schedule 7Js, Schedule 8s and Schedule 9s						
S7Js	13 [a]	$0	$0	$2,520	$32,760	$32,760
S8	217	$356	$77,252	$2,520	$546,840	$469,588
S9	94 [b]	$0	$0	$2,520	$236,880	$236,880
Application fee for wholesale or obtain licence involving Schedule 2s, Schedule 3s, and Schedule 4s	501	$533	$267,033	$1,650	$826,650	$559,617
Annual renewal fee for wholesale or obtain licence involving Schedule 2s, Schedule 3s, and Schedule 4s	501	$533	$267,033	$1,250	$626,250	$359,217
Application fee for Schedule 2 retail licence and Schedule 7J retail licence						
S2	40	$90	$3,600	$330	$13,200	$9,600
S7Js	13 [c]	$0	$0	$330	$4,290	$4,290
Annual renewal fee for Schedule 2 retail licence and Schedule 7J retail licence						
S2	40	$90	$3,600	$330	$13,200	$9,600
S7Js	13 [c]	$0	$0	$330	$4,290	$4,290

[a] There are currently no wholesale licences for S7J substances, however, 13 authorities were issued between 1 February 2022 to 31 January 2023 to obtain and use highly dangerous substances (which include S7J substances). It is anticipated that the number of S7J wholesale licences would be similarly low, particularly given that any wholesale supply of a S7J for the purposes of a person who is already authorised under the Pesticides Act to possess and use that substance would not require a S7J wholesale licence. Some of the current authorities may change to obtain licence, however, as it is not know how many of these would, the estimates presented in these tables assume that all the current authorities change to wholesale licences.

[b] There are currently no licences for S9 substances as there is no current concept of an obtain licence, however, from 1 February 2022 to 31 January 2023, the NSW Health's Pharmaceutical Regulatory Unit issued 282 authorities to possess and/ or supply S8, S9 substances, and prohibited drugs listed in Schedule 1 of the *Drug Misuse and Trafficking Act 1985* (DMTA) for the purpose of research, instruction and analysis. For the purposes of this illustrative analysis, it has been assumed that a third of these authorities would represent the licences that would be sought for S9 substances under the new regulation.

[c] There are currently no retail licences for S7J substances, however, 13 authorities were issued between 1 February 2022 to 31 January 2023 to obtain and use highly dangerous substances (which include S7J substances). It is anticipated that the number of S7J retail licences would be similarly low, particularly given any supply of a S7J to a person who is already authorised under the Pesticides Act to possess and use that substance would not require a S7J retail licence.

Note: There is a cost for an initial licence (an application cost), and then each year after there is only a renewal cost.

Source: ACIL Allen and NSW Ministry of Health.

7 Conclusion

The following options have been considered in this RIS to achieve the objectives of government action outlined in Chapter 4.

— ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the PTGR sunset and not replace it with a new Regulation.

— ***Option 1*** — this option entails remaking the PTGR without any changes to align with the new MPTG Act (the *status quo* option).

— ***Option 2*** — this option entails making the proposed MPTG Regulation.

The Base Case option (letting the PTGR sunset when the new MPTG Act commences and not replacing it with a new Regulation) is not considered appropriate because of the following reasons:

— it would mean that the Act would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the Act operates

— it would result in a break in the supply chain of medicines across NSW, and an interruption to patient care

— it would increase the risks to patient safety (due to substance misuse or abuse) and the risks to the health and safety of the public due to increased risks of diversion of dangerous substances. The costs associated with these increased risks are likely to significantly outweigh any potential benefits to the NSW Government and industry related to reduced compliance and administrative costs.

The analysis of the impacts of the proposed MPTG Regulation has been undertaken by comparing the Draft MPTG Regulation (Option 2) against Option 1 (remaking the PTGR). This analysis has been structured around the impacts of each of the substantive changes proposed for the Regulation, namely changes that relate to:

— more regular periodical inventory of stock of drugs of addiction

— wholesale supply of medicines and poisons in the absence of a wholesaler licence in a wider range of circumstances

— licensing of retail supply and wholesale supply of certain Schedule 7 substances

— restrictions on administration of Schedule 2, 3, 4 and 8 substances

— compliance standards for the Opioid Treatment Program

— approval to administer/prescribe/supply Schedule 8 substances (as distinct from the current authority requirements), with approval requirements more targeted to risk

— approval to administer/prescribe/supply certain Schedule 4 substances (as distinct from the current authority requirements) with approval requirements aligning more closely with Commonwealth recommendations, and compounding authority required under certain circumstances

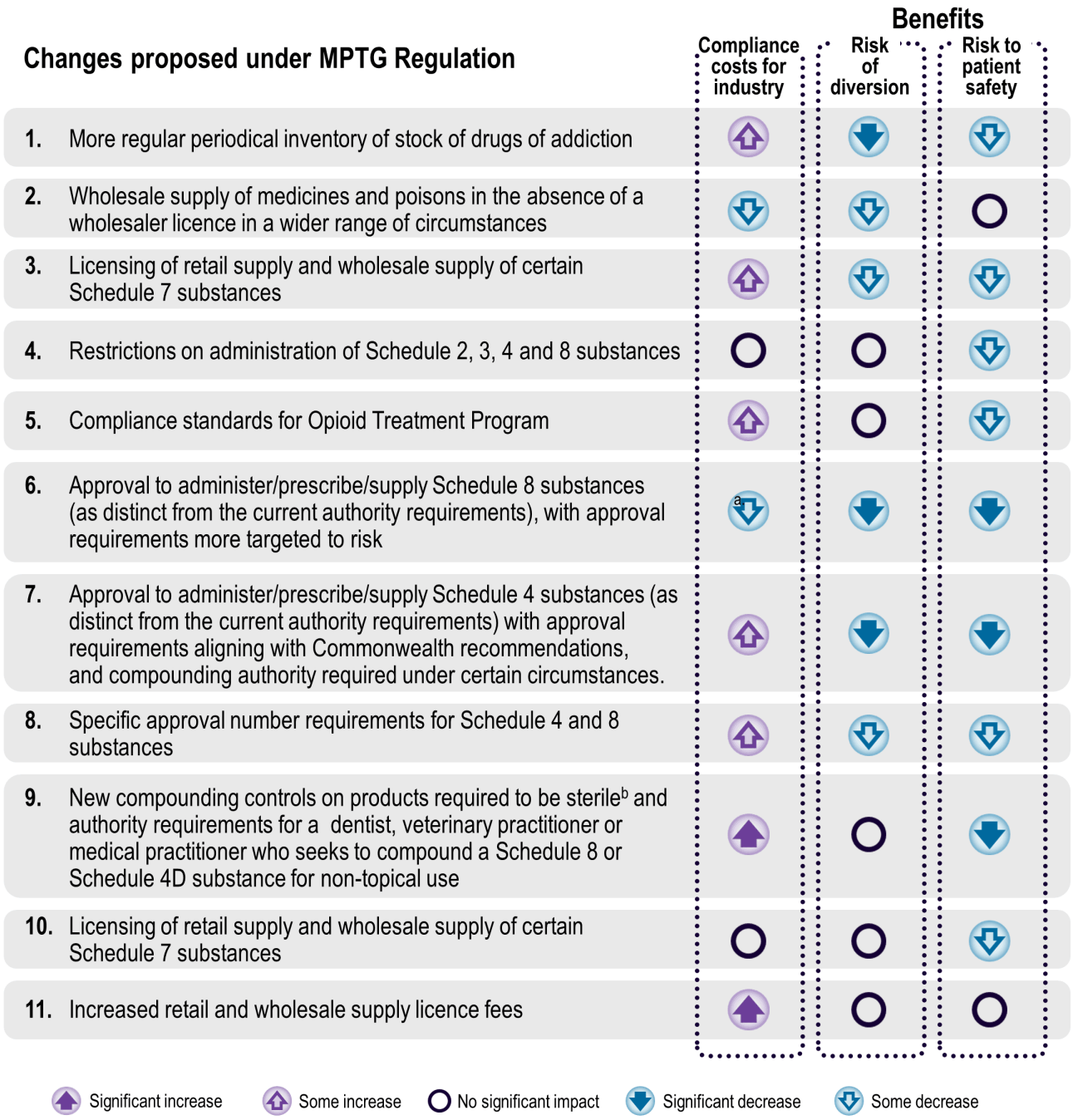
- specific approval number requirements for prescriptions for certain Schedule 4 and 8 substances
- new compounding controls on products required to be sterile and authority requirements for a dentist, veterinary practitioner or medical practitioner who seek to compound a Schedule 8 or Schedule 4D substance for non-topical use
- new restrictions to emergency use provisions
- clarifying the powers developed in the MPTG Act, including to specify which offences would be subject to on-the-spot fines / penalty infringement notices
- increased retail and wholesale supply licence fees, fees applying to an obtain licence, new fees applying to retail supply and wholesale supply of certain Schedule 7 substances, and fees applying to amend an existing licence.

As discussed before, the costs and benefits associated with the alternative options have been analysed in this RIS mostly qualitatively. This is because the benefits and costs associated with the alternative options are not amenable to easy quantification due to:

- limited data available to comprehensively demonstrate the effectiveness of the MPTG Regulation
- the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the MPTG Regulation in a robust way.

However, Figure 7.1 provides a summary of the relative nature of the benefits and costs of the changes proposed under Option 2 across the eleven areas outlined above, with respect to Option 1 (i.e., the *status quo*).

Figure 7.1 Summary of potential relative impacts of the proposed Draft Regulation across key areas of change (relative to the status quo)



[a] Based on regulatory impact of change on medical practitioners and nurse practitioners but excludes regulatory impact on veterinary practitioners, who will now require an approval to prescribe, supply or administer compounded Schedule 8 substances. The Ministry do not currently collect data to quantify this change for veterinary practitioners.

[b] Not including approval requirements for compounded Schedule 4D and Schedule 8 substances.

Source: ACIL Allen.

In summary, in relation to the proposed MPTG Regulation across its main areas of change (with respect to the PTGR):

1. There is limited evidence to measure the impact that increased supervision of stocks of drugs of addiction would have on diversion, however the Ministry reports many instances of stock lost or not accounted for. By being able to more clearly ascertain when the stocks of these substances go missing, the proposed change would assist in investigating and regulating

diversion of these high-risk substances and by doing so, reduce risks to patient safety. Given the well-known risks posed by misuse and abuse of these substances and the likely modest additional costs of compliance imposed by these changes, it is considered that the proposed **more frequent inventory requirements** are appropriate based on the precautionary principle.

2. To the extent that the proposed changes to the **circumstances when wholesale supply can occur without a licence** facilitates business practices and reduce compliance costs for pharmacies without increasing risks of diversion, the change is expected to be overall beneficial.
3. Overall, it is considered that the benefits from reduced risks of substance misuse stemming from the **increased requirements for wholesale supply of Schedule 7J substances** are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.
4. The proposed **changes to the administration** would increase clarity and consistency about the lawful administration of scheduled substances, and potentially reduce the risk of inappropriate or unsafe practices when treating patients. Accordingly, these changes are expected to be beneficial.
5. Given that the proposed **exemptions to the registration to prescribe/ supply for the OTP** would result in cost/time efficiencies for practitioners and the Ministry, increased efficiency of care and reductions of barriers to access to ODT; and the proposed **OTP standards** would maintain patient safety by mitigating risks in treatment, while imposing additional compliance costs to only a fairly low number of pharmacies dosing over 80 patients (which would require an approved amenity plan in place), the proposed change is expected to be overall beneficial.
6. The proposed changes to the circumstances in which a practitioner is required to hold an **approval to administer/supply/prescribe Schedule 8 substances** would decrease risks of misuse and abuse of these substances and reduce overall compliance costs for practitioners. Given this, the changes are expected to be beneficial.
7. Overall, it is considered that the benefits from reduced risks of substance misuse stemming from the **new and tightened controls of certain Schedule 4 substances** are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.
8. To the extent that the proposed **approval number requirements** increase patient safety without substantial increases in compliance costs for prescribers and pharmacists, then the proposed change would be overall beneficial.
9. The proposed changes to the **controls of sterile compounded substances** which pharmacies are currently able to manufacture without a TGA licence are likely to increase the costs of regulatory compliance for pharmacies and the NSW Government. In addition, the **new authority requirements for dentists/veterinary practitioners/medical practitioners who seek to compound a Schedule 8 or a Schedule 4D substance for non-topical use** are likely to increase the costs of regulatory compliance for these practitioners and the NSW Government. However, given the potentially catastrophic consequences of worst-case safety/quality incidents related to compounded substances (which include illness, disability and death) and the lack of rigorous oversight of this sector, the proposed change is expected to be overall beneficial.
10. The proposed **exclusions from emergency use provisions** of Schedule 4 substances not registered on the ARTG or, for veterinary practitioner emergency supply, substances not registered on the ARTG/APVMA and Schedule 8 substances that are unregistered with the APVMA for veterinarians are not anticipated to increase the cost of regulatory compliance for doctors/veterinary practitioners as unregistered/compounded products are not subject to PBS subsidies. However, the changes may result in an increase in the costs of administering and

enforcing the regulation for the NSW Government. To the extent that reductions in the risks to patient safety from the proposed new restrictions more than offset the additional costs to the NSW Government, the proposed change is expected to be overall beneficial.

11. The proposed amendments to **licence fees** would represent a significant increase in the regulatory charges for suppliers, but would better reflect the costs of the regulatory activities by the Ministry, increase the level of cost recovery and increase allocative efficiency.

Overall, it is considered that the key eleven changes proposed for the Draft MPTG Regulation achieve the right balance between reducing the risks to patient safety (due to substance misuse or abuse) and the risk of diversion of dangerous substances, with the additional red tape/compliance costs associated with the Regulation.

Notably, a key 'unintended' benefit from the proposed update of the Regulation (and the Act) highlighted by most stakeholders consulted for this RIS is the additional/better compliance with already existing requirements and obligations related to scheduled substances that would be achieved as a 'byproduct' of the process of educating people about the new requirements. Indeed, it was noted by several stakeholders that the practitioners' and pharmacists' knowledge of some of the current requirements is quite limited.

8 Consultation

The *Subordinate Legalisation Act 1989* requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation before a principal statutory rule is made.

Consistent with the *Subordinate Legislation Act 1998*, the Draft MPTG Regulation and this RIS will be open for public consultation for a period of at least 21 days, until 22 December 2023

Submissions about the Draft MPTG Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 2030
ST LEONARDS NSW 1590

Submissions may also be made via email to MOH-MPTG-Submissions@health.nsw.gov.au.

Submissions must be received by 22 December 2023.

Individuals and organisations should be aware that generally any submissions received will be publicly available under the *Government Information (Public Access) Act 2009* and may be published. The Ministry, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

Interested stakeholders are encouraged to consider aspects of the assessment contained within this RIS and the Draft MPTG Regulation. Key issues on which stakeholder views are sought include the following:

- Are there any costs and benefits of the Draft MPTG Regulation that have not yet been considered, and how material are these impacts?
- Are there any risks or unintended consequences of the Draft MPTG Regulation that have not yet been considered?
- Are there any additional amendments which could have a net positive impact on the proposed MPTG Regulation?
- Could the results of the proposed MPTG Regulation be achieved through any alternative options?
- Are there any clauses in the MPTG Regulation which require clarification?

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Appendices

Schedules of the National Poisons Standard

A

Table A.1 Schedules of the National Poisons Standard

Schedule 1	This Schedule is intentionally blank.
Schedule 2	Pharmacy Medicine – Substances, the safe use of which may require advice from a pharmacist, which should be available from a pharmacy, or where a pharmacy service is not available, from a licensed person.
Schedule 3	Pharmacist Only Medicine – Substances, the safe use of which requires professional advice, but which should be available to the public from a pharmacist without a prescription.
Schedule 4	Prescription Only Medicine, or Prescription Animal Remedy – Substances, the use or supply of which should be by, or on the order of, persons permitted by State or Territory legislation to prescribe, and should be available from a pharmacist on prescription.
Schedule 5	Caution – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
Schedule 6	Poison – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
Schedule 7	Dangerous Poison – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling, or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage, or use may apply.
Schedule 8	Controlled Drug – Substances, which should be available for use, but require restrictions regarding their manufacture, supply, distribution, possession, and use in order to reduce abuse, misuse, and physical or psychological dependence.
Schedule 9	Prohibited Substance – Substances which may be abused or misused, the manufacture, possession, sale, or use of which should be prohibited by law, except when required for medical or scientific research, or for analytical, teaching or training purposes with the approval of Commonwealth and/or State or Territory Health Authorities.
Schedule 10	Substances of such danger to health as to warrant prohibition of sale, supply, and use – Substances which are prohibited for the purpose, or purposes, listed for each poison.

Source: Commonwealth of Australia, Therapeutic Goods (Poisons Standard—February 2023) Instrument 2023.

Stakeholder consultations B

B.1 Consultations undertaken as a part of this RIS

As part of the development of this RIS, ACIL Allen undertook informal consultations during March-April 2023 with a limited number of stakeholders to gather stakeholder views about the impacts of potential amendments to the Regulation.

In addition to their views about potential amendments to the Regulation, through these consultations, stakeholders shared their views about a number of other issues related to the Regulation. These issues are outlined for future consideration in the following section.

The stakeholders consulted through these workshops are outlined in the table below.

Table B.1 Stakeholders consulted during preparation of this RIS

Organisation	Date
Nurses and Midwives Association	28 March 2023
Pharmaceutical Society of Australia	30 March 2023, follow up 30 March 2023
Professor John Saunders	31 March 2023, follow up 24 April 2023
Royal Australian College of General Practitioners	5 April 2023
Lyppard	14 April 2023 (group workshop)
Sigma Healthcare	
CH2	
Symbion	
Australian Medical Association	12 April 2023
Pharmacy Guild of Australia	21 April 2023

Source: ACIL Allen

B.2 Issues raised by stakeholders for future consideration

Peak bodies representing pharmacies consulted for this RIS suggested a number of other refinements to the overall regulatory framework around the areas dealt with by the Regulation. These are presented below for future consideration by the Ministry where feasible.

— To make permanent the special temporary authority to supply 1 month worth of medicine during an emergency situation that was in place during the COVID-19 pandemic.

— Tightening requirements for practitioners regarding when they can fax/email scripts (to only allow it in urgent/emergency situations).

- Nationally consistent regulations regarding Schedule 8 substances, particularly to allow patients to take with them their repeat scripts and to allow pharmacies to supply repeat scripts even if the original script was filled by another pharmacy (in NSW, repeats for S8 prescriptions are to be retained at the original dispensing pharmacy for paper-based prescriptions).
- Remove the requirement to 'personally hand' Schedule 3 medicines to patients (to allow these medicines to be posted).
- To ensure that any changes being made to the legislation of compounding aligns with the Pharmacy Board guidelines and professional practice guidelines such as the Australian Pharmaceutical Formulary compounding chapter to reduce confusion.
- That the list/names of registered pharmacies that provide OTP is not publicly available (just available to prescribers of OTP-related substances).
- For pharmacists to be allowed to annotate prescriptions as per Services Australia's guidance for pharmacists about clarifying prescriptions[82], which allows them to annotate a prescription to clarify a prescriber's intention.

[82] Services Australia 2023, *Clarifying a prescriber's intention*, https://www.servicesaustralia.gov.au/pharmacists-clarifying-prescribers-intention?context=22861, accessed 16 June 2023.

Melbourne
Suite 4, Level 19; North Tower
80 Collins Street
Melbourne VIC 3000 Australia
+61 3 8650 6000

Sydney
Suite 603, Level 6
309 Kent Street
Sydney NSW 2000 Australia
+61 2 8272 5100

Brisbane
Level 15, 127 Creek Street
Brisbane QLD 4000 Australia
+61 7 3009 8700

Canberra
Level 6, 54 Marcus Clarke Street
Canberra ACT 2601 Australia
+61 2 6103 8200

Perth
Level 12, 28 The Esplanade
Perth WA 6000 Australia
+61 8 9449 9600

Adelaide
167 Flinders Street
Adelaide SA 5000 Australia
+61 8 8122 4965

ACIL Allen Pty Ltd
ABN 68 102 652 148

acilallen.com.au