Consultation Draft:
Medicines, Poisons and Therapeutic Goods Bill 2022

Discussion Paper

Contents

1. Purpose

Medicines, poisons (chemicals), and therapeutic goods are an essential part of people's lives and our society. These substances are beneficial to health and are necessary in many industries. However, these substances can also pose a risk to the health and safety of individuals when used inappropriately. The current *Poisons and Therapeutic Goods Act 1966* (**PTGA**) and the *Poisons and Therapeutic Goods Regulation 2008* (**PTGR**) constitute the primary legislative framework governing the control of medicines, poisons, and therapeutic goods in NSW. The PTGA and PTGR restrict who can manufacture, supply by wholesale, supply, prescribe, use or administer these substances. However, the Act is over 50 years old, is difficult to understand, and has not kept pace with changes in practice and within the relevant industries. As such, the Ministry of Health (**the Ministry**) is reviewing the PTGA and PTGR to ensure that the framework regulating medicines, poisons, and therapeutic goods is contemporary, robust, safe, and efficient.

As part of the review, the Exposure Draft *Medicines, Poisons and Therapeutic Goods Bill 2022* (**Draft MPTG Bill**) has been prepared for public consultation. The Draft MPTG Bill will be supported by regulations, which will be the subject of a separate consultation process, at a later date. This paper seeks submissions on whether the Draft MPTG Bill provides for a framework that is fit for purpose in contemporary practice. The public consultation process will be supported by targeted engagement with key stakeholders to ensure the proposed reforms are appropriate.

The Ministry is seeking submissions on the issues raised in this paper and on any other issues in the Draft MPTG Bill. Individuals and organisations should be aware that generally submissions may be made publicly available under the *Government Information (Public Access) Act 2009* (NSW). The Ministry, in considering its response to the submissions, may also circulate information for further comment to other interested parties or publish parts of submissions. If you wish your submission (or any part of it) to remain confidential, subject to the *Government Information (Public Access) Act 2009* (NSW), this should be stated clearly and marked.

Submissions should be sent via email to MOH-MPTG-Submissions@health.nsw.gov.au or sent in hardcopy to:

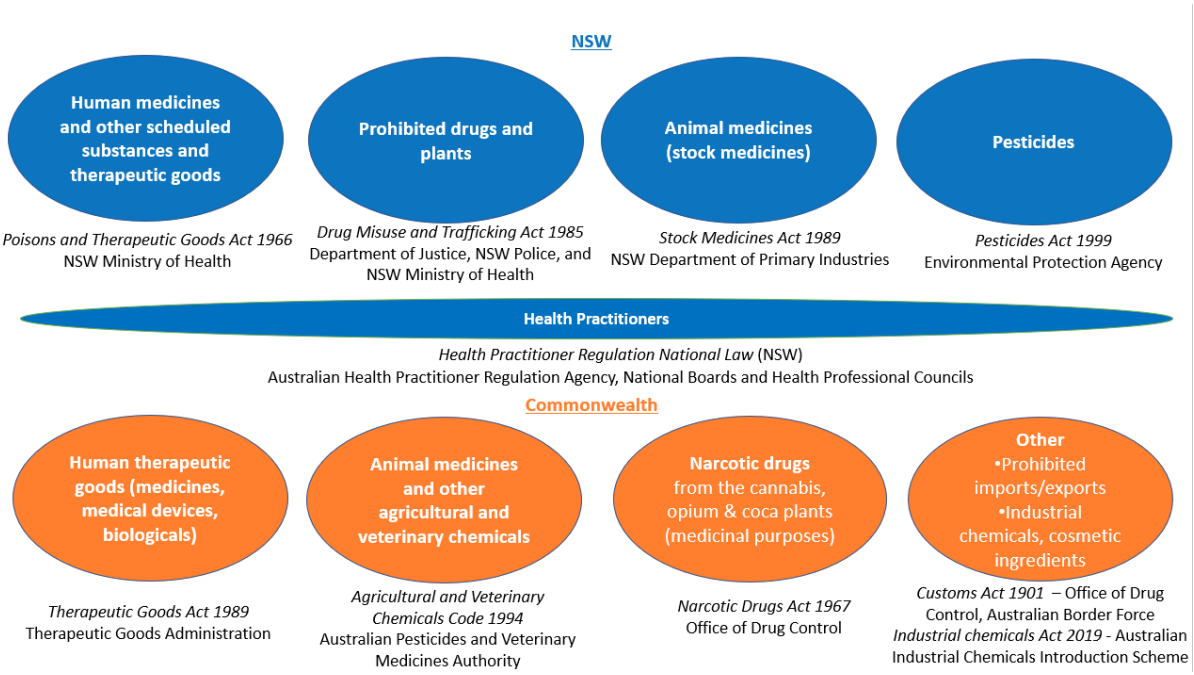
MPTGB Project Team
Legal and Regulatory Services Branch
NSW Ministry of Health
Locked Mail Bag 2030
St Leonards NSW 1590

Submissions should include the reference **DG22/2088** and must be received by **9 June 2022**.

2. Overview of the regulatory framework

The medicines, poisons, and therapeutic goods regulatory framework is expansive and relevant Commonwealth and State/Territory legislation often intersects and interacts. The control of these substances and goods is largely achieved through the various legislation depicted in **Figure 1**.

Figure 1: Key NSW and Commonwealth regulatory regimes for medicines, poisons and therapeutic goods



Broadly, the Commonwealth laws regulate how a medicine, poison (chemical), or therapeutic good legitimately comes to be in Australia. For example, the Commonwealth licences: the cultivation, production and manufacture of narcotic plants for medicinal purposes or for research, the manufacture of medicines and other therapeutic goods, and the importation of such goods. Additionally, the Commonwealth laws seek to ensure that medicines and other therapeutic goods are assessed for quality, safety or efficacy through registration, or otherwise through approval, authorisation or exemption from registration.

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). Each Schedule contains a list of substances that share similar risks, for which control measures are recommended to reduce the risks. 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 can be found in **Table 1** below**.**

In NSW, the PTGA and PTGR chiefly regulate the supply within, and from, NSW of medicines and poisons, or substances listed in the Schedules ('scheduled substances'). The PTGA and PTGR also regulate activities such as the issuing of prescriptions, storage, labelling, packaging, record keeping, disposal, administration, and use of scheduled substances. Additionally, the PTGA and PTGR aim to reduce opportunities for misuse of scheduled substances, including their diversion to the illicit supply chain, by restricting who has access to such substances.

Table 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.

3. Overview of the Draft Medicines, Poisons and Therapeutic Goods Bill 2022

The Draft MPTG Bill replaces the PTGA to provide for better regulation of scheduled substances and other therapeutic goods, in the interest of public health and safety. It updates and modernises language and accommodates modern business and clinical practices where safe and appropriate to do so, and provides for mechanisms to facilitate these practices.

The Draft MPTG Bill:

- includes an objects clause for the first time (section 3);
- automatically adopts the Schedules of the National Poisons Standard (with a power to vary the schedules by regulation) (section 6);
- consistent with the existing framework, makes it an offence to supply scheduled substances and prescribed therapeutic goods by wholesale unless authorised by the Draft MPTG Bill (section 15). In general, wholesalers will be required to be licensed, but the Draft MPTG Bill also allows certain wholesaling activities to now occur without a licence, including movement of stock between public health entities and certain wholesale supply between pharmacies that have a common financial interest;
- makes it an offence to supply (non-wholesale) scheduled substances and prescribed therapeutic goods unless authorised by the Draft MPTG Bill (section 30). Consistent with the PTGA, certain registered health practitioners will be able to supply medicines and issue prescriptions. The Draft MPTG Bill also allows for other health practitioners to be prescribed by the regulation to be able to supply medicines and issue prescriptions. However, in some cases, as with the existing PTGA, additional approvals will be required to supply or issue prescriptions for particular scheduled substances. The Draft MPTG Bill also moves to normalise the opioid treatment program by requiring medical practitioners and nurse practitioners to register as the prescriber for their patient, rather than seeking approval, before treating a patient with opioid agonist therapy (treatment with methadone or buprenorphine for people dependent on different types of opioids). Similarly, community pharmacies dispensing under the opioid treatment program will need to register as an available dosing point;
- creates a new offence of obtaining a wholesale supply unless authorised by the Draft MPTG Bill (section 23). In general, persons authorised to supply or prescribe will be able to obtain a wholesale supply. In addition, certain organisations, such as public health entities, private health facilities, and residential aged care facilities, will be able to obtain a wholesale supply of certain medicines for use by their authorised staff. The regulations will permit other organisations and persons to obtain wholesale supplies of scheduled substances, and it is expected that regulations will be made to ensure that anyone currently permitted to obtain a wholesale supply will continue to be able to do so;
- consistent with the current PTGA, creates a regulation making power to provide for offences where there is a failure to comply with prescribed requirements in relation to the possession, manufacture, supply, use, prescription, administration, storage, and disposal of scheduled substances and therapeutic goods used for cosmetic purposes (section 51);
- in order to protect patients and the public, allows the Health Secretary to issue a 'restriction order' that prevents a person from supplying, prescribing, administering, or obtaining a wholesale supply (section 50);
- consistent with the PTGA, applies the Commonwealth *Therapeutic Goods Act 1989* as a law of NSW (Chapter 4);
- modernises enforcement tools by updating penalties to reflect the seriousness of offences (section 116), updating powers of authorised officers (Chapter 5), allowing for the making of penalty notice offences (which will allow the issuing of on-the-spot fines) (section 120), allowing for the making of compliance notices (section 115), and continuing offences (section 118);

- provides the Health Secretary with the power to make orders to protect the public, which:
    - prohibit the supply of a substance pending an evaluation of its toxic or deleterious properties (section 141)
    - authorise a specified person, or class of persons, to possess, supply, wholesale supply, obtain wholesale supply, administer, dispense, use, prescribe, manufacture, store, or dispose of therapeutic goods or stock medicines. Such an order is called a 'public health risk authorisation order' and may be issued to deal with a situation that presents a health or safety risk (section 138);
- establishes the Medicines, Poisons and Therapeutic Goods Fund, which will be the recipient of the fines and fees collected under the Draft MPTG Bill (section 143). The moneys in the MPTG Fund may be used to meet costs incurred in providing training and education to stakeholders, which will help improve their understanding of the Draft MPTG Bill, and other costs associated with the administration of the Bill;
- updates the functions and membership of the Regulatory Advisory Committee (currently titled the Poisons Advisory Committee) and the Clinical Advisory Committee (currently titled the Medical Committee) to reflect a skills and expertise based constitution (sections 126 and 127 and Schedule 1);
- amends the *Drug Misuse and Trafficking Act 1985* (**DMTA**) and other legislation, including to:
    - move and expand offences which were originally in the PTGA across to the DMTA, which will now regulate the manufacture, production, supply, and possession of any Schedule 4D or Schedule 8 substance that is not a prohibited drug (Schedule 4)
    - the *Electronic Transactions Act 2000* to increase transparency by allowing certain activities to be supported by way of electronic transactions. This will allow the regulations to support electronic prescribing (Schedule 5) (rather than by allowing this through individual exemptions as is the case under the PTGR);
- allows regulations to be made in a range of areas, including: manufacturing, wholesale supply, supply, issuing prescriptions, labelling, reviews of decisions, and fees. As noted above, the regulations will be the subject of a later consultation process (section 148).

4. Key provisions of the Draft Medicines, Poisons and Therapeutic Goods Bill 2022

4.1. Objects and Guiding Principle (section 3)

The PTGA is one of the primary pieces of health legislation in NSW that regulates the supply of scheduled substances and other therapeutic goods in order to protect public health and safety. However, it lacks an objects clause clearly setting out these objectives.

As such, the Draft MPTG Bill includes a clear objects and guiding principles section. Section 3 provides that the objects of the Bill are:

(a) to regulate activities involving scheduled substances and other prescribed therapeutic goods to protect the health and safety of the public;
(b) to use the Commonwealth Poisons Standard as the basis for classifying and regulating certain substances;
(c) to complement the Commonwealth therapeutic goods laws, including by providing for the laws to apply as a law of New South Wales in relation to the activities of persons who are not corporations;
(d) to provide for authorisations to do regulated activities involving scheduled substances and prescribed therapeutic goods, including when the activities prohibited by or under another law;
(e) to provide for effective administration and enforcement mechanisms concerning scheduled substances and prescribed therapeutic goods;
(f) to confer additional powers to deal with scheduled substances and other therapeutic goods posing serious risks to health or safety.

Importantly, the Draft MPTG Bill also provides that in the exercise of functions under the Bill, the protection of the health and safety of the public must be the paramount consideration (section 3(2)). Having an objects clause and a guiding principle will assist in the interpretation of the provisions of the Draft MPTG Bill. However, the Ministry is seeking submissions on whether the objects section requires any amendment.

Question 1
Should any changes be made to the objects and the guiding principle in the Draft MPTG Bill?

4.2. Adoption of the National Poisons Standard (section 6)

The Draft MPTG Bill moves to automatically adopt the Schedules in the National Poisons Standard (section 6). The National Poisons Standard defines poisons, or scheduled substances, to include medicines for human therapeutic use, veterinary medicines, agricultural, and domestic and industrial chemicals where there is a potential risk to public health and safety. Substances are scheduled according to the risk of harm and the level of access and control required to protect consumers. State and Territory governments are responsible for imposing legislative controls on the supply of poisons. Generally, these controls flow from the Schedule in which the substance has been included. Provisions for the scheduling of substances such as medicines and chemicals are set out in the Commonwealth *Therapeutic Goods Act 1989* and associated Regulations. They have been developed to ensure operational effectiveness while supporting the existing high level of scheduling uniformity across States and Territories.

Currently, the PTGA requires a proclamation to be made to form the NSW Poisons List. However, the PTGA only allows nine Schedules to be included in the NSW Poisons List, which reflects the nine Schedules of the National Poisons Standard as it was prior to the addition of Schedule 10 in 2016. There is no current ability to include Schedule 10 of the National Poisons Standard in the NSW Poisons List as the PTGA has not been updated to reflect Schedule 10. However, the PTGR prohibits the supply, manufacture and use of a Schedule 10 substance unless the person is authorised.

Other States and Territories have applied the National Poisons Standard in various ways, including by way of regulation, disallowable instrument, or in the case of Queensland, by automatically adopting the Schedules of the National Poisons Standard.

The Draft MPTG Bill follows the Queensland approach. Section 6 of the Draft MPTG Bill proposes to automatically adopt all the Schedules of the National Poisons Standard by reference, to form the NSW Poisons Schedules. The Draft MPTG Bill provides for a regulation-making power to allow changes to be made to the NSW Poisons Schedules, should there be a need to address a specific concern in NSW. Further, the Draft MPTG Bill provides for the ability to create subcategories within Schedules by way of regulation, to allow for more targeted regulation of such groups of medicines. For example, Schedule 4D is a subcategory of Schedule 4 that will be proposed to be created by way of regulation.[1] Schedule 4D medicines are 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.

Automatic adoption of the Schedules of the National Poisons Standard into the NSW Poisons Schedule helps promote national consistency in relation to the regulation of scheduled substances and ensures consistent terminology in relation to substances.

Question 2
Do you have concerns about NSW automatically adopting the Schedules of the National Poisons Standard?

[1] This is expected to be consistent with the current substances listed in Appendix D of the PTGR.

5. Regulation of supply, prescribing and other activities (Chapter 2)

5.1. Wholesale supply (Part 2.2 and 3.2)

Consistent with the current PTGA, section 15 of the Draft MPTG Bill makes it an offence to engage in wholesale supply of medicines and certain poisons unless authorised by the Bill. Supply by wholesale means supply for the purposes of resupply. For example, a licensed medicine wholesaler when supplying medicines to a pharmacy is supplying by wholesale, or supplying for the purpose of resupply, as the pharmacy will then resupply the medicine to a patient on prescription. In general, only licensed wholesalers can supply by wholesale and wholesalers can only supply to a person who is able to obtain the substances under the Draft MPTG Bill.

However, the Draft MPTG Bill expressly recognises that some activities are not supply by wholesale, including the supply of medicines by employers to their healthcare staff who will then supply or administer the medicines to patients, and the supply between registered health practitioners who work in the same practice.

In addition, in recognition of modern, appropriate and safe practices, the Draft MPTG Bill expressly allows certain wholesaling to take place without a licence. For example, the Draft MPTG Bill permits supply by wholesale between NSW Health entities (section 18) in recognition that medicines may need to be shared across the entire public health system. This would allow the transfer from one hospital to another of life-saving anti-venoms that are only available in limited amounts or the supply of vaccines from the State Vaccine Centre to a Local Health District. The supply of certain scheduled substances between community pharmacies where there is an owner in common is also allowed, to facilitate business practices and to regulate such practices to ensure safety.

The Draft MPTG Bill also makes clear that Schedule 2, 3, and 4 substances may be transferred between pharmacies that have a common owner and from one pharmacy owner to another in the event of a business sale. In order to minimise the risk of diversion, Schedule 4D and Schedule 8 substances will only be permitted to be transferred between pharmacies in the event of a business sale (section 19).

The Draft MPTG Bill also proposes processes to allow for the wholesale supply by an external administrator if a pharmacy goes out of business. In such a case, if there is an approval of the Health Secretary, the administrator will be able to sell the stock by wholesale to another pharmacy.

5.1.1. Wholesale supply of Schedule 7 substances

The PTGA prohibits the supply by wholesale of a Schedule 7 substance. 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. The PTGR prohibits the supply of a Schedule 7 substance without authorisation, but not if the supply is by wholesale. Schedule 7 substances are not used therapeutically, which means the supply by wholesale of Schedule 7 substances can occur without a licence in NSW. There is scope to strengthen the current regulation of Schedule 7 substances. The NSW Coroner has previously highlighted concerns about the current controls in relation to Schedule 7 substances such as cyanide, arsenic and strychnine.[2]

In order to better protect the public, the Draft MPTG Bill will:

[2] Inquest into the death of SS.

- prohibit the wholesale supply of Schedule 7 substances for domestic use (section 17); and

- require a wholesale licence to supply Schedule 7 substances prescribed by the regulations (section 17). It is intended that the regulations will list the more dangerous Schedule 7 substances, being those listed in Appendix J of Schedule 7, such as cyanide, arsenic and strychnine. However, a licence will not be required where the wholesale supply is otherwise authorised under the *Pesticides Act 1999* or the *Stock Medicines Act 1989*.

Question 3
(a) Are the controls in relation to wholesale supply appropriate? (b) Should external administrators of a pharmacy business be able to wholesale supply in limited cases? (c) Are the provisions relating to Schedule 7 substances and wholesaling appropriate?

5.2. Obtaining a wholesale supply of medicines (Parts 2.3 and 3.2)

The Draft MPTG Bill introduces the new regulated activity of obtaining wholesale supplies. The Draft MPTG Bill makes it an offence to obtain supplies by wholesale of scheduled substances and other prescribed therapeutic goods, unless authorised by the Bill (section 23). A person or entity authorised to obtain wholesale supplies may be supplied scheduled substances by a wholesaler. The purpose of the new provision is to be more transparent in relation to the supply chain and to ensure that where appropriate and safe, certain organisations can obtain a wholesale stock of medicines to be used by their staff.

In general, the PTGA and PTGR currently provide that only individuals who are authorised to supply scheduled substances can receive a wholesale stock of medicine. The PTGA does not generally allow organisations to obtain a wholesale stock of medicine to be used by appropriate staff. Rather, under the PTGA and PTGR, organisations have obtained wholesale stock of medicines either by one registered health practitioner obtaining a stock that is then used by the whole organisation or the organisation obtaining a wholesale licence.

The available mechanisms under the PTGA can be inadequate, and in some respects inappropriate, particularly for contemporary healthcare settings. Large healthcare organisations, such as hospitals, require medicines for any of their authorised staff to access and supply or use on patients. Where the organisation is highly regulated, it may be more appropriate for the organisation to obtain the stock rather than one individual practitioner obtaining the stock. In relation to wholesale licences, the conditions that would normally be expected to apply to a wholesaler are not appropriate for organisations obtaining stocks for their staff. For example, a wholesale licence condition would normally require compliance with the Code of Good Wholesaling Practice. This code has standards for the warehousing of medicines, including in relation to the building and grounds, storage facilities, security of stocks, personnel handling, stock handling, transport, and other processes. These standards are appropriate for companies in the business of wholesaling medicines not organisations running healthcare services.

Under the Draft MPTG Bill, specified individuals who can supply (non-wholesale) scheduled substances will be able to obtain a stock of such substances, this includes medical practitioners, pharmacists, certain other registered health practitioners and veterinary practitioners (section 24). In addition, the Draft MPTG Bill recognises certain entities as being able to obtain a wholesale stock of scheduled substances for use by their staff (sections 24, 25, and 26). The entities recognised under the Draft

MPTG Bill as those that may obtain wholesale supplies of medicines are highly regulated under other frameworks, such as public health entities, private health facilities, residential care facilities, managed correctional centres, detention centres, and immigration detention centres. The regulation may prescribe other persons and entities to be able to obtain wholesale supplies of scheduled substances. There are many organisations and industries that need access to a limited a stock of certain scheduled substances. Consistent with the current PTGR, where this can occur safely without the need for specific assessment, the regulations will set out which persons and organisations can obtain such a stock.

However, there will be cases where an individual assessment is required before a person or organisation would be allowed to obtain a stock of scheduled substances. Such an assessment would generally be required where obtaining a wholesale supply of the substances may pose a significant risk to members of the organisation or to the public at large. As such, the Draft MPTG Bill provides for a new licensing scheme to allow the obtaining of certain scheduled substances (section 54). The case-by-case assessment will allow consideration of a range of issues, including probity checks to be conducted and assurances of safe medicine handling policies, prior to a licence being granted.

The Draft MPTG Bill allows a person to apply to the Health Secretary for an 'obtain licence', which would authorise them to obtain a wholesale supply of specified scheduled substances, or other prescribed therapeutic goods, for use by 1 or more of the following entities:

- private Opioid Treatment Program clinics
- paramedic service companies
- patient transport services
- vaccination providers
- rural and remote medical clinics
- private health facilities in relation to Schedule 8 medicines
- universities, research institutions and laboratories requiring certain scheduled substances for research and analysis
- other entities to be prescribed by the regulations.

Each application for a licence would be assessed on a case-by-case basis.

Question 4
(a) Are the provisions in relation to obtaining a wholesale supply of scheduled substances appropriate? (b) Is the list of organisations that would require a licence before being able to obtain a wholesale stock scheduled substances appropriate? (c) Are there other entities that should be eligible to apply for an 'obtain licence'? (d) Are there other means by which entities should be able to receive medicines?

5.3. Prescribing and supply (Parts 2.4, 2.5, 3.3, and 3.4)

5.3.1. Health practitioner prescribing and supply

Consistent with the current PTGA and PTGR, the Draft MPTG Bill makes it an offence to supply (non-wholesale) or prescribe scheduled substances unless authorised under the Bill (Sections 30 and 37).

Certain practitioners are able to supply or prescribe in the course of their profession, including:

- medical practitioners, dentists, nurse practitioners, and veterinary practitioners;

- nurses and midwives, podiatrists and optometrists whose registration has an endorsement under the *Health Practitioner Regulation National Law* (NSW) or who are otherwise qualified;
- pharmacists, who may supply certain scheduled substances in certain settings, and dispense on prescription.[3]

The Draft MPTG Bill includes a regulation making power to allow other health practitioners to prescribe or supply. This recognises that there may be a future need for other health practitioners to supply or prescribe.

While certain health practitioners can generally supply or prescribe medicines in the course of their profession, consistent with the current PTGA and PTGR, the Draft MPTG Bill provides that certain administration, prescribing, or supply can only occur subject to additional approvals or requirements. The Draft MPTG Bill allows for regulations to be made to restrict the administration, prescribing, and supply of certain medicines in certain circumstances (section 13). Under section 67 of the Draft MPTG Bill, a health practitioner must not administer, supply, or prescribe a Schedule 8 or other prescribed substance in the circumstances set out in the regulations. Consistent with the current PTGA and PTGR, it is expected that these restrictions will apply to a limited number of scheduled substances in circumstances where the supply of such a substance may result in harm to the patient or where there is a high risk that the supply of the substance may be diverted into the criminal supply chain. For example, consistent with the current PTGA and PTGR, it would be expected that prescribing a Schedule 8 opioid medicine to a patient with substance dependence will require an approval.

Under Part 3.3 of the Draft MPTG Bill, before such medicines are administered, supplied or prescribed, a practitioner will need to seek approval from the Health Secretary who will then assess the application to determine if it is appropriate (section 67).

An approval to administer, prescribe or supply in otherwise restricted circumstances may be granted by the Health Secretary on application. The Ministry is developing a new Authority Management System that will allow a practitioner to make an electronic application for such an approval, and to receive the approval, if granted, through the same system.

5.3.2. Restriction orders (Part 2.8)

Consistent with the PTGA and PTGR, under the Draft MPTG Bill, a person's ability to possess, supply, wholesale supply, obtain, administer, dispense, use, prescribe, manufacture, store, or dispose of scheduled substances may be restricted by the Health Secretary by issuing a restriction order (section 50). This is a power used to help protect the public or following a request from a practitioner. It may be used, for example, if a registered health practitioner has conditions placed on their registration that prohibits the supplying of or prescribing or medicines, or the Ministry of Health has conducted an investigation and considers that a practitioner is misusing or misappropriating Schedule 8 substances (i.e. drugs of addiction).

Under Part 2.8 of the Draft MPTG Bill, a restriction order may be made on the following grounds:

a. the person has made a written request, or given written agreement, for the order;
b. the person is charged or convicted [or an order is made under section 10(1) of the *Crimes (Sentencing Procedure) Act* 1999] in relation to an offence, or alleged offence, against the Draft MPTG Bill or a "relevant law";

[3] In addition, it is expected that regulations under the Draft MPTG Bill will also provide for the continuation of existing supply and administration by pharmacists of specific vaccines, in a continuation of the existing authorisation provided for at clause 48A PTGR.

c. the Health Secretary considers the person has previously contravened a restriction order;
d. the Health Secretary considers the person is someone who should be restricted or prohibited from doing a regulated activity for the purpose of protecting the health or safety of the person or another person, whether or not the other person is identifiable;
e. the practitioner has a condition or other restriction imposed on the practitioner's right to practice by, or under, the Health Practitioner Regulation National Law or the *Veterinary Practice Act 2003*;
f. other grounds prescribed by the regulations.

These grounds are similar to those prescribed under the current PTGR, with the exception of the grounds being extended to where a practitioner has a condition on their registration or a conviction for an offence against a relevant law, being:

- the Agricultural and Veterinary Chemicals (Agvet) Codes within the meaning of the *Agricultural and Veterinary Chemicals Act 1994* (Cth);
- the Commonwealth therapeutic goods laws [the *Therapeutic Goods Act 1989* (Cth) and all regulations, orders, and manufacturing principles in force under that Act];
- the *Narcotic Drugs Act 1967* (Cth);
- the *Drug Misuse and Trafficking Act 1985* (NSW);
- the *Hemp Industry Act 2008* (NSW);
- the *Pesticides Act 1999* (NSW);
- the *Poppy Industry Act 2016* (NSW);
- the *Stock Medicines Act 1989* (NSW);
- a regulation made under a law specified above;
- another law, whether of New South Wales or another Australian jurisdiction, prescribed by the regulations.

Question 5
Do you have any comment on the prescribing and supply provisions under the Draft MPTG Bill?

5.4. Administration

The current 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 in certain settings, such as hospitals.

The administration of medicines can be performed by a variety of people, including medical practitioners, nurses, to paramedics, dentists, veterinary practitioners, first aid officers and carers. Administration 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 will need to be able to administer medicines, and the different circumstances in which administration may occur, the Draft MPTG Bill will not, in most cases, specifically regulate who can administer medicines and, in that regard, the Bill expressly excludes administration from the definition of supply.

There are, of course, risks associated with administration and these are dealt with in a variety of ways:

- the Draft MPTG Bill limits who can get access to medicines;

- registered health practitioners are subject to professional standards that help ensure that the practitioner only administers 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 Draft MPTG Bill expressly regulates administration in high-risk settings. For example, administration of specific Schedule 8 substances to a patient with substance dependence will require approval from the Health Secretary (section 67), and administration by a medical practitioner or nurse practitioner, or a person requiring acting under the practitioner's direction and supervision, to a patient on Opioid Agonist Treatment will require registration (section 74);
- the Draft MPTG Bill will allow for regulations to be made in relation to administration. This means that if there are high risk settings where additional controls relating to administration are required, then regulations can be made to mitigate the risks.

Question 7

(a) Are there any issues relating to the controls on administration under the Draft MPTG Bill?
(b) Do you support the Draft MPTG Bill explicitly excluding administration from the definition of supply?

5.5. Registration scheme to prescribe or supply for Opioid Treatment Program (Part 3.4)

The broad goal of opioid dependence treatment is to reduce harm due to non-medical use of opioids. The term harm encompasses negative health, social, and economic effects on both individuals and the community. To achieve this broad goal, the NSW Opioid Treatment Program (**OTP**) takes a patient centred approach. This involves using treatment programs that incorporate patient preferences, needs, and realistic individual goals. Opioid Agonist Treatment (**OAT**), such as methadone and buprenorphine treatment, can lead to psychological stability, improved control over drug use, and eventual abstinence from opioid drugs.

One of the current controls under the PTGA is to require 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 OAT to any drug dependent person under the OTP must be assessed by the Health Secretary for appropriateness. The Draft MPTG Bill changes this approach, so as to not require specific approval for supplying of prescribing under the OTP scheme. This change aims to normalise such treatment.

However, Schedule 8 medicines are drugs of addiction and more liable to be diverted into the criminal supply chain. As such, there needs to be appropriate processes in place to ensure that patients are not provided with such medicines more than is actually clinically required. Accordingly, the Draft MPTG Bill introduces a registration scheme which seeks to increase transparency of supply under the OTP scheme without creating barriers to access via an approval process. Regulatory control and patient safety is maintained through the use of new regulatory tools such as Real Time Prescription Monitoring and the Authority Management System under development.

Under Part 3.4 of the Draft MPTG Bill, a medical practitioner or nurse practitioner must not administer, prescribe or supply a Schedule 8 substance listed in the regulation unless they have registered under the OTP scheme (section 74). In addition, pharmacies must also register under the OTP scheme in order to be able to dispense under the OTP. 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 OAT dose.

The Authority Management System will be accessible to the practitioners seeking to register to prescribe or supply for their patient. The regime will 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 administration per day, or by long-acting depot injection.

Question 6
Is registration scheme sufficient control in the administration, prescribing and supply of methadone or buprenorphine under the OTP?

6. Dealing with public health risks and responding to serious safety risks

6.1. Responding to public health risks (Part 7.4)

The Draft MPTG Bill, consistent with the PTGA, has strict controls in place in relation to the supply of scheduled substances. However, recent emergencies, such as the COVID-19 pandemic, the 2019/20 bushfires, and the recent floods, have highlighted the need to ensure there is a mechanism to respond to different needs in emergencies. For example, pharmacists are generally only able to supply Schedule 4 substances on prescription (subject to certain exceptions, such as for continued dispensing in certain circumstances). However, during natural disasters, patients may be forced from their homes and not have access to their medicines, their prescription nor be able to obtain a new prescription in the timeframes available. Or while generally stocks of medicines should only be available from licensed wholesalers, there may be a need for NSW Health to distribute medicines to residential aged care facilities or general practice clinics, as occurred during the pandemic.

The current PTGA has mechanisms to allow the Health Secretary to authorise such activity but they are inefficient and lack transparency. In order to ensure that there is a transparent and flexible approach, the Draft MPTG Bill includes a clear mechanism, which allows the Health Secretary to deal with risks associated with the spread of an infectious condition or another risk to public health or safety. Part 7.4 in the Draft MPTG Bill allows the Health Secretary to make a 'public health risk authorisation order'. Such an order may authorise persons to do something that would otherwise breach the legislation (for example, the person may be authorised to possess, supply, administer, dispense, use, or prescribe scheduled substances). A public health risk authorisation order may be made if the Health Secretary considers on reasonable grounds that a situation presents, or is likely to present, a risk to the health or safety of humans or animals and the order is necessary or convenient to deal with the risk and its possible consequences. Such orders last 90 days and must be published in the NSW Gazette (though a failure to publish the order in the Gazette does not invalidate the order).

6.2. Responding to serious safety risks (Part 7.4)

The Draft MPTG Bill also retains the existing powers under the PTGA, which enable the Health Secretary to issue an order prohibiting the supply of a substance that the Secretary considers should not be supplied pending the evaluation of its toxic or deleterious properties.

It is not the normal function of the Health Secretary under the PTGA or the Draft MPTG Bill to evaluate substances or ban harmful substances. Rather, there are other powers in the regulatory framework to deal with substances posing risks, including evaluation. This includes the recall powers of the Secretary of the Australian Department of Health (or their delegate) under the *Therapeutic Goods Act 1989* (Cth), which can be utilised to protect public health; the evaluation of medicines by the Therapeutic Goods Administration; the power of authorised officers under the *Food Act 2003* (NSW) to seize food which may contain scheduled substances; and the regulatory remit of NSW Fair Trading regarding unsafe and defective products.

However, in rare cases it may be necessary for the NSW Health Secretary to take action to protect the public. For example, if there are significant harms associated with a product that appears to be incorrectly labelled, such as a product being sold in a retail setting for domestic use that may contain an undisclosed scheduled substance such as lead. In these circumstances, it is advantageous for the Health Secretary to have a power to make an order prohibiting the sale of the relevant product until an evaluation of the properties of the substance can occur, which will also allow time to consider if any other regulatory action is required. The power to make an order of this nature, called a 'supply prohibition order', is provided for in section 141 of the Draft MPTG Bill. The review presents an opportunity to consider whether the power remains relevant and appropriate.

Question 8

(a) Are the new powers relating to public health risk authorisation orders appropriate?
(b) Are supply prohibition orders, which enable the Secretary to restrict supply of substances pending evaluation of their risk, appropriate?

7. Investigation, penalties, enforcement, and compliance (Chapters 5 and 6)

The Draft MPTG Bill updates and modernises provisions in the Bill relating to penalties, enforcement, and compliance. Prosecution for an offence is generally the only available enforcement tool under the PTGA. Prosecution is costly and not always appropriate for minor offences such as not making an entry in a drug register. Further, the existing maximum financial penalties and/or imprisonment terms do not reflect the seriousness of many of the more serious offences in the PTGA. For example, the current financial penalty for unauthorised supply by wholesale is 20 penalty units, which is $2,200.[4] In addition, there are no differential penalties for corporations.

Therefore, the Draft MPTG Bill modernises and updates the penalties for offences (section 116) by:

- increasing penalties for more serious offences and having increased penalties for corporations;
- aligning the penalty to the seriousness of the offence so that the penalty is commensurate to the risk and harm posed by contravention of the offence provision;
- allowing for the issuing of penalty infringement notices (on-the-spot fines) for offences prescribed in the regulations (section 120);
- allowing for the issuing of compliance notices. A compliance notice requires a person to remedy a particular contravention of the Act or Regulation in a specified timeframe. Non-compliance will be an offence (section 115).

Penalty infringement notices (PINs) and compliance notices will allow for a more flexible, responsive, and proportionate response to breaches of the Draft MPTG Bill. Compliance notices will allow for a more appropriate option in certain circumstances, especially where non-compliance with the Draft MPTG Bill is not intentional. A compliance notice will provide a mechanism to help ensure that persons comply with the legislation without having to resort to a prosecution.

Question 9
Do you support the introduction of PIN offences and Compliance Notices as additional enforcement tools?

7.1 Authorised officer powers

The powers of authorised officers have been modernised under the Draft MPTG Bill.

Under the PTGA, an inspector can enter premises without a warrant and exercise a range of powers on those premises, provided they have a reasonable belief the premises is being used for the supply of substances/goods and that entering the premises is for the purpose of ascertaining compliance with the PTGA, PTGR, or an approval, authority or licence. An inspector can only enter premises or parts of premises used for residential purposes with the consent of the occupier or in accordance with a search warrant. There is no ability for an inspector to require a person to produce documents or answer questions unless the officer is on the premises. This limitation can impede investigations.

[4] Note that the maximum penalty for the offence of supply by wholesale is 20 penalty units ($2,200) or imprisonment for 2 years, or both, if the offence involves a restricted substance of a kind prescribed by the regulations for the purposes of section 9 of the *Poisons and Therapeutic Goods Act 1966* (NSW). Also see clause 61(2) of the *Poisons and Therapeutic Goods Regulation 2008* (NSW).

Under the Draft MPTG Bill, inspectors will be known as authorised officers. As is currently the case under the PTGA, authorised officers will be appointed staff of NSW Health and police officers. They will retain the power to enter premises.

In addition, new investigatory powers are included in the Draft MPTG Bill to allow authorised officers who are not police officers, to require the production of documents, or require a person to answer questions, regardless of whether or not the inspector is on the premises. Currently, an authorised officer can only require a person to produce documents or answer questions when they are on premises being inspected. However, there may be occasions when an authorised officer may require further information to assist with an investigation following an inspection. The MPTG Bill provides protections from self-incrimination in relation to the new powers.

Question 10
Are the proposed powers of authorised officers appropriate?

8. Drug Misuse and Trafficking Act 1985 interaction (Schedule 4 of Draft MPTG Bill)

8.1. Moving offences to the Drugs Misuse and Trafficking Act 1985 and new offences relating to "prohibited scheduled substances"

The Commonwealth's Scheduling Policy Framework indicates that substances included in Schedule 9, Schedule 8, and specified in Appendix 4D of the PTGR are liable to abuse, misuse, and trafficking and therefore, offences should apply to their unauthorised possession, supply, manufacture, and production. However, this is not currently reflected in the combined regulatory framework of the PTGA and the DMTA.

The DMTA prohibits the possession, supply, manufacture, and production of substances listed in Schedule 1 of the DMTA (prohibited drugs). Most prohibited drugs are also medicines regulated under the Draft MPTG Bill, namely Schedule 9, Schedule 8, and Schedule 4D substances. However, not all Schedule 9, Schedule 8, and Schedule 4D substances are prohibited drugs under the DMTA.

The DMTA also provides for summary offences applying to the possession, supply, manufacture and production of Schedule 9 substances that are not prohibited drugs. However, if a Schedule 8 and Schedule 4D substance is not listed as a prohibited drug, there are no DMTA offences that apply.

However, the PTGA does provide for an offence to possess Schedule 4D substances, and also includes deemed supply provisions. A deemed supply provision means that a person in possession of a certain quantity of a relevant substance is taken to have possession with the intention of supplying that substance to someone else, rather than it being for personal use. These have generally been enforced by NSW police officers. There is no stand-alone possession or deemed supply offence relating to Schedule 8 substances that are not prohibited drugs.

To better implement the recommendations of the Commonwealth's Scheduling Policy Framework, the draft MPTG Bill makes amendments to the DMTA such that the DMTA will not only prohibit regulated activities involving prohibited drugs, it will also automatically prohibit regulated activities involving all substances in Schedule 9, Schedule 8, and Schedule 4D that are not prohibited drugs. These substances will collectively be termed "prohibited scheduled substances". This means, it will be an offence under the DMTA to possess, supply, manufacture, or produce not only prohibited drugs and Schedule 9 substances, but Schedule 8 and Schedule 4D substances as well.

Substances newly added to Schedule 9 or Schedule 8 of the NSW Poisons Schedules, or categorised as a Schedule 4D under the regulations made under the Draft MPTG Bill, will automatically fall under the offence in the DMTA without having to be added to the list of prohibited drugs in Schedule 1 of the DMTA.

Significantly, a person manufacturing a prohibited drug or prohibited scheduled substance under a Commonwealth manufacturing licence or authorisation, under the *Therapeutic Goods Act 1989* and Agvet Code, would not fall within the scope of DMTA offences. Medical practitioners, dentists, pharmacists, and veterinary practitioners manufacturing (compounding) under a Commonwealth exemption will be recognised in the consequential amendments in the MPTG Bill, such that this manufacturing would not fall within the scope of DMTA offences.

Question 11
Are there concerns about including offence in the DMTA in relation to prohibited scheduled substances?

8.2. Drug Misuse and Trafficking Authorities (Part 3.5)

The DMTA sets out a range of offences relating to prohibited drugs and other substances. Most prohibited drugs are also medicines regulated under the Draft MPTG Bill, namely Schedule 8, Schedule 9, and Schedule 4D substances. If an activity is authorised under the PTGA, or the Draft MPTG Bill (such as the supply of a Schedule 8 medicine by a medical practitioner) this would not constitute an offence under the DMTA.

In addition, the DMTA also recognises that certain uses of prohibited drugs and other substances, such as research or study, may be appropriate. As such, the DMTA allows the Health Secretary to issue authorities for the use of drugs in some circumstances.

The Draft MPTG Bill moves the provisions relating to the Health Secretary's power to grant authorities to possess, supply, administer, manufacture, or produce a prohibited drug or prohibited scheduled substance from the DMTA to the Draft MPTG Bill. This will ensure the Health Secretary's powers to grant authorities are contained in one place.

In addition, the purposes for which these Drug Misuse and Trafficking (**DMT**) authorities may be granted will change from 'scientific research, instruction, analysis or study' (as currently expressed under the DMTA) and 'medical or scientific research, analytical, teaching or training purposes or for industrial or commercial purposes' (as currently expressed under the PTGA), to 'for medical or scientific research purposes, or for analytical, teaching or training purposes'. This amendment is consistent with the recommendations of the National Poisons Standard.

Question 12
Are there any circumstances when a DMT authority is required for a purpose other than medical or scientific research, or for analytical, teaching or training purpose?

9. Regulatory Advisory Committee and Clinical Advisory Committee (Part 7.1)

9.1. Regulatory Advisory Committee

The Draft MPTG Bill renames the Poisons Advisory Committee to the Regulatory Advisory Committee, and updates its functions and membership.

Under the PTGA, the Poisons Advisory Committee is established to advise the Minister for Health on recommendations relating to amendments to the PTGA or PTGR and any recommendations relating to amendments to the NSW Poisons List. Under the PTGA, the membership of the Poisons Advisory Committee is very fixed and inflexible, with members either:

- being the nominee of a person occupying a specified position such as the Head of the Department of Pharmacy at the University of Sydney or the Commissioner of Police; or
- being appointed by the Governor following their nomination by a specified organisation such as the Pharmacy Guild of Australia (NSW), the Australian Medical Association (NSW) Limited, or Avcare Limited.

This means that the membership of the current Poisons Advisory Committee is based around organisations rather than skills and expertise. That is not to say that an individual could not be both a member of a particular organisation and also have the necessary skills and expertise.

Under the Draft MPTG Bill, the functions of the Regulatory Advisory Committee are to advise the Health Secretary to inform policy, on matters referred by the Health Secretary relating to:

(a) the operation, administration or amendment of this Act, the regulations and the NSW Poisons Schedules, including a proposal to make, alter or repeal the regulations;
(b) on other matters relating to scheduled substances, therapeutic goods or stock medicines;
(c) the scheduling of substances under the *Therapeutic Goods Act 1989* (Cth);
(d) other functions conferred or imposed on it by or under this Act or another Act.

Under the Draft MPTG Bill, it is proposed that the membership of the Regulatory Advisory Committee will be compromised of:

(a) persons who the Health Secretary considers have together, as far as practicable, qualifications and experience in the following areas:
    i. pharmacy, medical, dental, nursing and veterinary practice;
    ii. industrial use of scheduled substances, including in primary industry;
    iii. pharmacology;
    iv. toxicology;
    v. the manufacturing industry;
    vi. the development of medicines and the regulation of scheduled substances, including their registration as therapeutic goods under the Commonwealth *Therapeutic Goods Act 1989*;
    vii. assessing the risk of harm to persons, animals or the environment arising in connection with scheduled substances and therapeutic goods;
    viii. as a consumer of scheduled substances or therapeutic goods.
(b) a person nominated by the NSW Commissioner of Police.
(c) a person nominated by SafeWork NSW.
(d) a person with qualifications or experience of a kind prescribed by the regulations.

A skill-based membership of the Committee will assist in ensuring that Committee members are appropriately qualified before being appointed. Having members appointed by the Health Secretary,

rather than the Minister or Governor, is consistent with other similar committees in other legislation, such as the *Private Health Facilities Act 2007.*

9.2. Clinical Advisory Committee

The Draft MPTG Bill renames the Medical Committee to the Clinical Advisory Committee and updates its functions and membership.

The Medical Committee currently advises the Secretary on whether applications to prescribe or supply drugs of addiction (Schedule 8 substances) should be approved.

Like the Poisons Advisory Committee, certain positions on the Medical Committee must be filled by nominees of organisations, in this case being the Australian Medical Association and Royal Australasian College of Physicians.

The Draft MPTG Bill provides that the Committee must have at least 6 members appointed by the Health Secretary and each member must be a medical practitioner or nurse practitioner. Nurse practitioners have been included as they can be authorised to supply or prescribe Schedule 8 drugs of addiction and will have the requisite skill set to be able to advise the Health Secretary on approvals for Schedule 8 drugs of addiction.

Question 13
(a) Are the functions and membership composition of the Regulatory Advisory Committee appropriate? (b) Are the functions and membership composition of the Clinical Advisory Committee appropriate?

10. Regulation-making power

There are a range of regulation-making powers under the Draft MPTG Bill. In particular the Bill allows regulations to be made in relation to:

- Adding or removing Scheduled substances or therapeutic goods to which the Act applies;
- Adopting appendices of the National Poisons List;
- Prescribing persons, or classes of persons, who are permitted to supply, prescribe, or obtain a wholesale supply;
- The circumstances in which the Health Secretary can authorise activities regulated under the Act and Regulation;
- Persons who are exempted from the obligation to register under the OTP Registration scheme;
- The manufacture, compounding, supply, administration, possession, or use of goods and preparations;
- The issue of prescriptions for goods and prescribed therapeutic goods;
- Preparing, supplying, storing, packing, handling, carrying, and delivering Scheduled substances and other prescribed therapeutic goods;
- The calculation for the purposes of the NSW Poisons Schedules of percentages for liquid preparations;
- Records required to be kept for the purposes of activities relating to scheduled substances or other prescribed therapeutic goods, including the keeping of registers for the goods and preparations;
- Persons authorised to order or receive scheduled substances or other prescribed therapeutic goods on behalf of another person or body;
- The use of medical devices [within the meaning of the *Therapeutic Goods Act 1989* (Cth)], including restrictions, conditions, and offences;
- Licences, approvals, OTP registrations, and DMT authorities;
- Labelling, sampling, examining, testing, and analysing therapeutic goods;
- The quantities of Schedule 4D substances, or the determination of the quantities of Schedule 4D substances, for the purposes of a possession offence under the DMTA;
- The destruction of goods and preparations; and
- Reviews of decisions made by the Health Secretary under the Act or Regulations.

As previously noted, there will be a separate consultation process in relation to the regulation. However, at this stage the Ministry is seeking some broader feedback about the regulation-making powers.

10.1. Restrictions on prescribing and supply

The Draft MPTG Bill provides for a regulation making power, which would enable the imposition of controls on the prescribing and supply of high-risk medicines (sections 12 and 13). The Draft MPTG Bill recognises that the ability of health practitioners to prescribe and supply certain medicines in certain circumstances needs to be restricted to protect public health and safety. For example, the controls on the prescribing and supply of Schedule 8 substances (such as fentanyl and oxycodone) will be strengthened to address the public harms associated with the misuse of these substances. The regulation-making power will also allow additional controls on the supply of certain Schedule 7 substances that have been found to be used for self-harm. Controls could include the imposition of licensing requirements on the retail supply of these substances, as recommended by the National Poisons Standard and by the Coroners Court.

10.2. Manufacture

The DMTA prohibits the manufacture of prohibited drugs unless the manufacturer is licensed or authorised under the PTGA Act or the *Poppy Industry Act 2016* or under an authority granted by the Health Secretary. However, the PTGA does not expressly regulate the manufacture of scheduled substances, other than Schedule 8 substances, as this is primarily the role of the Commonwealth. Rather, as the PTGA adopts the Commonwealth's *Therapeutic Goods Act 1989*, a person who has a licence to manufacture therapeutic goods issued under the *Therapeutic Goods Act 1989* is authorised, subject to certain additional restrictions in the PTGA (such as the requirement for a PTGA licence to manufacture a Schedule 8 substance). The Commonwealth's *Therapeutic Goods Act 1989* does not require all persons to obtain a manufacturing licence as some manufacturing may take place under exemptions from the licensing requirements.

The Draft MPTG Bill recognises that the regulation of the manufacture of therapeutic goods such as medicines is primarily the remit of the Commonwealth and will no longer require a Schedule 8 manufacturer to be licensed. Rather, the Draft MPTG Bill amends the DMTA to expressly recognise the Commonwealth manufacturing regime. Of course, a Commonwealth licensed manufacturer may only supply in and from NSW if licensed under the Draft MPTG Bill.

Some manufacturing, particularly where a Commonwealth licence is not required, can pose serious health and safety risks. Such manufacturing may include the compounding of medicines by pharmacists, medical practitioners, dentists, and veterinary practitioners. Risks associated with compounding have been identified, particularly in relation to the compounding of products required to be sterile, such as injectables, which may cause sepsis in patients. As such, the regulation-making power allows for regulations to be made in relation to manufacture activities. This means, that regulations may set controls in relation to compounding in order to address identified risks. Additionally, the regulation may include controls restricting the prescribing or supply of substances to be manufactured/compounded, which may be abused, misused, or trafficked into the illicit supply chain.

Question 15
Are there any other manufacturing activities that should be regulated under the Draft MPTG Bill?

10.3. Regulation of advanced therapies including biologicals

Evolving technological and scientific advances mean that advanced therapies, such as cell and gene therapies and viral vectors, are increasingly being researched and used in healthcare. The Draft MPTG Bill provides for a regulation making power to regulate therapeutic goods prescribed by the regulations, in addition to medicines and medical devices, including biologicals, should the need arise in the future to regulate newly developed advanced therapies in order to protect health and safety.

Question 17
Are there other goods that should be regulated under the Draft MPTG framework?

11. Summary

It is integral that the legislative framework regulating the supply of medicines, poisons, and therapeutic goods in NSW operates efficiently and effectively. The Draft MPTG Bill updates and modernises the existing PTGA and makes a range of changes to the existing legislative framework governing scheduled substances and therapeutic goods. The Draft MPTG Bill will:

- recognise modern business and clinical practices and be flexible enough to respond to future developments;
- reduce duplication and inconsistency with Commonwealth and other NSW Acts;
- facilitate efficient and effective administration and enforcement; and
- strengthen the ability to deal with health and safety risks through substance restriction orders and public health risk authorisation orders.

The Draft MPTG Bill seeks to ensure that there is a transparent framework governing the supply chain of scheduled substances and other therapeutic goods in a manner that ensures that people who need to access medicines and poisons can do so safely while the risk of substances being diverted in the criminal supply chain is minimised. The Draft MPTG Bill seeks to more clearly recognise the legislative interactions between Commonwealth and other NSW Acts. The provisions of the Draft MPTG Bill create mechanisms to recognise contemporary and evolving prescribing practices, such as electronic prescribing and online authorisations.

Scheduled substances are used in a range of industries and are vital in many health and veterinary products. The regulation of medicines underpins the entire NSW health system. The Draft MPTG Bill creates a new legislative framework that will create greater transparency, regulate proportionate to risk, more closely align with the recommendations of the National Poisons Standard, and create efficiencies for the supply chain for scheduled substances across NSW. Importantly, in the exercise of functions under the Bill, the protection of the health and safety of the public is the paramount consideration.