Authority to prescribe for privately practicing Nurse Practitioners in NSW

The NSW *Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 2008* regulate the prescription, supply, administration and use of Scheduled medicines, that is Schedule 2 and Schedule 3 medicines, restricted substances (Schedule 4) and drugs of addiction (Schedule 8).

Under s17A of the *Poisons and Therapeutic Goods Act 1966*, the Secretary of Health (or her delegate) can authorise nurse practitioners (NPs) to prescribe, possess, supply and/or use particular Scheduled medicines. The authority must be granted in writing.

In practice, the NSW Chief Nursing and Midwifery Officer (CNMO), as a delegate of the Secretary of Health, is responsible for authorising NPs to possess, use, supply or prescribe an Schedule 2 or Schedule 3 medicine, restricted substance or drug of addiction under s17A of the *Poisons and Therapeutic Goods Act 1966***.** The CNMO has historically authorised NPs in private practice on an individual basis.

In March 2020, the CNMO authorised NPs in NSW to possess, use, supply and/or prescribe any Schedule 2 and 3 medicine, restricted substance (Schedule 4) or drug of addiction (Schedule 8), where this is done in accordance with the NP's scope of practice. This authority includes all NPs working in NSW, whether working in the public or private sector.

This authorisation removes the need for privately practicing NPs to obtain written authorisation on an individual basis from the CNMO to possess, use, supply or prescribe a S2 or S3 medicine, restricted substance or drug of addiction.

NPs and their employers remain responsible for ensuring they practice in accordance with their scope of practice as defined by the Nursing and Midwifery Board of Australia, the Nurse Practitioner Standards for Practice and relevant legislation pertaining to their practice.

NOTE: Where NPs wish to prescribe or supply certain restricted substances and/or drugs of addiction, an additional authority from the Secretary of Health may be required. Further information regarding prescribing of these medicines can be found at: https://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/default.aspx
Prescribing of compounded and other unregistered medicines by NPs is generally discouraged.

Further information can be obtained by contacting Matt Lutze, Principal Advisor, Nursing Practice and Informatics, NSW Health Nursing and Midwifery Office:

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Issues around compounded and other unregistered medicines for nurse practitioners

Compounded medicines

A nurse practitioner (NP) could prescribe a compounded medicine only if such prescribing is within his/her scope of practice (as outlined by the Nursing and Midwifery Board of Australia - NMBA) and otherwise lawful (such as not an S8 medicine that requires prior authority).

A compounded medicine should only be considered where there is no registered medicine available and suitable for the patient's condition.

However issues of competency and scope of practice may arise.

The Pharmacy Board of Australia and Medical Board of Australia have issued a joint statement on compounded medicines.
https://www.medicalboard.gov.au/News/2017-11-24-media-release-joint-statement.aspx

Based on this guidance for medical practitioners, a NP needs to:

1. Be competent to assess whether the compounded medicine is safe and appropriate for the patient.

   This includes considering:
   - whether the substance(s) in the compounded medicine are suitable and approved for human use
   - whether there is sufficient evidence to support the intended use based on recognised therapeutic standards
   - whether the medicine will remain stable for the duration of use, and
   - the possibility of contamination of the medicine and the level of risk that contamination would present. E.g. the risk of contamination of injections and eye drops that should be sterile

2. Support patients to make an informed decision about their treatment by ensuring that they:
   - have been provided with information about the medicine which has been prescribed for compounding, and
   - understand that unlike medicines on the ARTG, compounded medicines have not been assessed by the TGA for efficacy, quality and safety.

The Therapeutic Goods Act 1989 sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The Therapeutic Goods Act 1989 (Cth) requires medicines to be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia, unless exempt.

Exemptions for pharmacists under the Therapeutic Goods Regulations 1990 Schedule 5 item 6, allow a pharmacist to extemporaneously prepare (compound) a medicine for human use provided the medicine is compounded for a particular person, for therapeutic application to that person.

A pharmacist must comply with the Pharmacy Board of Australia guidance on compounding. https://www.pharmacyboard.gov.au/codes-guidelines.aspx

Under the NSW Poisons and Therapeutic Goods Act 1966, an authority is required to prescribe and supply an unregistered Schedule 8 medicine that is a compounded medicine. A pharmacist may then supply a compounded Schedule 8 medicine on the prescription of the authorised prescriber.

Unregistered medicines

Generally, medicines used in Australia must be registered on the Australian Register of Therapeutic Goods (ARTG), unless exempted from registration, or approved for supply as an unregistered good, by the Therapeutic Goods Administration (TGA). Unregistered medicines are not assessed for quality, safety or efficacy by the TGA.

To prescribe an unregistered medicine, the prescriber must obtain an approval to supply an unregistered good issued under the Commonwealth's Therapeutic Goods Act 1989, under one of:

- Special Access Scheme, or
- Authorised Prescriber scheme, or
- Clinical Trial schemes.

The use of unregistered drugs should be considered experimental. Written informed consent from the patient is therefore required and any adverse events need to be reported to the Therapeutic Goods Administration.

It is a condition of the Special Access Scheme that the patient (or guardian) provides written informed consent. The patient must understand the nature of his/her condition (including its natural history) and have appropriate knowledge of the treatment options. Specifically, the patient must be informed about:

- the product not being approved in Australia and not assessed for quality, safety or efficacy by the TGA
- the possible benefits of treatment and any known risks and adverse effects
- the possibility of unknown risks and late adverse effects
- any available alternative treatments using registered products.

https://www.tga.gov.au/form/special-access-scheme

It is important for both the patient and prescriber to understand that the Australian Government does not accept responsibility for any adverse consequences of treatment, including any defects in the product related to manufacture.

Specific information about the unregistered drug may not be readily available, as information on the unregistered drug will not be in the Monthly Index of Medical Specialities (MIMS) and generally not listed in the Australian Medicines Handbook (AMH). If the drug is registered in another jurisdiction, product information may be available from the US Food and Drug Administration or the European Medicines Agency.
https://www.nps.org.au/australian-prescriber/articles/access-to-unregistered-drugs-in-australia

More information can be obtained from the TGA website.
https://www.tga.gov.au/accessing-unapproved-products