NSW Health

Pharmaceutical Services newsletter

August 2026

Chief Pharmacist's message

Welcome to the September edition of the Pharmaceutical Services newsletter, your source for updates and practical guidance on the regulation of medicines, poisons and therapeutic goods in NSW.

A key focus of this edition is the **new Medicines, Poisons and Therapeutic Goods legislative framework, which will commence on 5 November 2026.** Replacing legislation that has been in place for almost 60 years, the new framework has been designed to better reflect modern healthcare practices while maintaining strong safeguards for public health and safety.

The new legislation will:

- improve clarity and consistency
- support modern healthcare delivery models
- better align with other legislative frameworks
- maintain strong safeguards for public health and safety.

While many regulatory requirements will remain unchanged, there are important updates that practitioners, authorised persons and industry stakeholders should be aware of. In this edition, we highlight some key changes and provide links to resources to help you prepare for implementation.

Thank you for your ongoing commitment to the safe and quality use of medicines in NSW.

David Ng

Chief Pharmacist, NSW Ministry of Health

New medicine and poisons supply laws apply from 5 November 2026

From **5 November 2026**, the supply of medicines and poisons in NSW will be regulated under the new *Medicines, Poisons and Therapeutic Goods Act 2022* and its supporting Regulation.

The new laws will introduce changes for health practitioners who prescribe, supply, dispense and administer medicines, as well as individuals, businesses, organisations and institutions that obtain or supply medicines or poisons.

Resources are available on our website to help health practitioners, authorised persons, and industry understand the changes and prepare for implementation. Reviewing the information relevant to your practice or business now will help minimise disruption to patient care and business operations.

NSW Health is committed to supporting stakeholders and industry throughout this transition.

Click here to access resources on the new legislation

Terminology changes for scheduled substances

The Medicines, Poisons and Therapeutic Goods legislation introduces a number of updated terms for scheduled medicines.

While **most regulatory requirements remain unchanged**, the updated terminology aligns more closely with commonly understood terms and provides greater clarity for medicines subject to additional controls.

Key terminology changes include the introduction of the terms **nominated Schedule 4 medicines**, **Schedule 4D substances**, and a consistent reference to **Schedule 8 substances**.

Understanding these changes will help practitioners and industry apply legislative requirements correctly and navigate the transition to the new framework.

Nominated Schedule 4 medicines

Nominated Schedule 4 medicines is the new term for medicines previously referred to as **certain restricted substances or clause 37 medicines**. These medicines are subject to additional regulatory controls due to the significant risks associated with their use.

The regulatory requirements are largely unchanged.

Treatment must continue to be initiated by appropriately qualified specialists, and other prescribers continuing treatment under specialist care will require NSW Health approval unless an exemption applies.

Examples of these medicines include the oral retinoids (isotretinoin and acitretin), fertility medicines (clomifene and follitropins), prostaglandins (dinoprost), and others such as thalidomide and lenalidomide.

and lenalidomide.

A key change for prescribers and pharmacists is that prescriptions for nominated Schedule 4 medicines will no longer need to include a clause 37(4)(b) statement or approval number.

Learn more about Nominated S4 medicines here

Schedule 4D substances

Schedule 4D (S4D) substances is the term now used consistently in the new legislation instead of the previous terms:

- **prescribed restricted substances**
- **special restricted substances** or **Schedule 4 Appendix B (S4B) substances.** These are specifically referred to in the new legislation as **Schedule 4D substance that is an anabolic-androgenic steroidal substance**.

S4D substances and medicines are those that require additional controls because of their potential for abuse, misuse or diversion. They are listed in the new Regulation and can also be found here. S4Ds must be stored as outlined in the Medicines Storage Standards.

Key change for S4D prescriptions - Under the new legislation:

- prescriptions for Schedule 4D medicines will be valid for 12 months, compared to the current 6 months.
- Repeat paper prescriptions for dispensed S4D anabolic-androgenic steroidal medicines may be given back to the patient to have dispensed in a pharmacy of their choice.

View information on S4D medicines under the new laws here

Schedule 8 medicines

The term **Schedule 8 (S8) substances** is now consistently used across the legislation instead of the older term **drugs of addiction.**

You may encounter the terms **controlled drugs** and **drugs of dependence** in other jurisdictions and publications. The medicines included in S8, and the controls that apply to them, remain the same.

S8 medicines are subject to strict legislative controls because of their high potential for misuse, abuse and dependence.

Common examples include, but are not limited to, opioid analgesics, ketamine, flunitrazepam, alprazolam, psychostimulants. A full list is available in the Poisons Standard.

Storage of S8 substances must comply with the Medicines Storage Standards.

Additional requirements continue to apply to S8 medicines, including:

- Monitoring through SafeScript NSW to support safe prescribing and dispensing.
- **NSW Health approval** for certain Schedule 8 medicines. Information about medicine approvals is available here.

More information about Schedule 8 medicines is available here

---

Other substance-related terminology changes

The following terms continue to be used under the new legislation:

- A '**scheduled substance**' is a medicine or chemical that is classified under the Poisons Standard. Substances and chemicals are assigned to Schedules 2 to 10 according to their level of risk, which determines the controls on their manufacture, supply, storage, use and disposal to ensure safe handling and use.
- A '**prohibited drug**' is a substance listed in Schedule 1 of the Drug Misuse and Trafficking Act 1985 (NSW), (DMTA), or an analogue of the listed substance.
- A '**prohibited plant**' is a growing cannabis, coca or opium plant, as defined in the DMTA.

The following term is **new** under the MPTG legislation:

- A '**prohibited scheduled substance**' is a Schedule 4D, Schedule 8, or a Schedule 9 substance that is not a 'prohibited drug'.

Prepare now

NSW Health encourages practitioners, authorised persons and industry stakeholders to review the guidance relevant to their practice or business before **5 November 2026**. Early preparation will help support a smooth transition and minimise disruption to patient care and business operations.

Access all resources on the new legislation

Other NSW Health news

Future Health Podcast: What's next for healthcare?

The NSW Health **Future Health Podcast** explores emerging trends that may shape the future of healthcare and the health workforce. The recently released Series 8 ***Beyond Health: Ideas Changing Our World***, features discussions with experts in AI, neuroscience, strategy and futures thinking.

Whether you're interested in innovation, leadership or the evolving role of technology in healthcare, this series of podcasts offers thought-provoking insights into the future of health.

Listen to podcast on *Beyond Health: Ideas Changing Our World* here

Every conversation counts: Supporting immunisation in pharmacy practice

Healthcare providers play an important role in shaping patient attitudes towards vaccinations. As pharmacists are taking on an expanding role in vaccine delivery, access to evidence-based vaccine communication support is vital.

Research shows patients want health professionals to proactively discuss vaccination, provide timely and locally relevant information, and offer regular reminders. By having the right tools and information, pharmacist immunisers can confidently address questions and concerns and support informed decision making.

Pharmacists help improve access to vaccination and can now administer vaccines for more than 20 diseases to eligible people in NSW. They are encouraged to make immunisation a routine part of pharmacy practice and proactively initiate conversations about immunisation.

A range of resources are available to support vaccine conversations.

Access resources to support vaccine conversations here

We care what you think

The Pharmaceutical Services newsletter aims to keep you updated about your regulatory responsibilities as a NSW health practitioner, licence holder or authority holder.

To help us improve our service to you, we would appreciate it if you could take 2-4 minutes to complete our anonymous survey. Your feedback can shape the content and timing of our newsletter for future editions.

Share this newsletter

Share this newsletter – Forward to a colleague and encourage them to subscribe to updates from the NSW Health Pharmaceutical Services Unit.

NSW Ministry of Health

We acknowledge the Traditional Custodians of the lands where we work and live. We celebrate the diversity of Aboriginal peoples and their ongoing cultures and connections to the lands and waters of NSW and pay our respects to Elders both past and present.

health.nsw.gov.au/pharmaceutical