Statement of Public Interest

Medicines, Poisons and Therapeutic Goods Bill 2022

Need: Why is the policy needed based on factual evidence and stakeholder input?

The introduction of the Medicines, Poisons and Therapeutic Goods Bill 2022 ('the Bill') follows an extensive review of the *Poisons and Therapeutic Goods Act 1966* ('the Act').

The Act governs the supply chain for medicines and poisons ('scheduled substances') and therapeutic goods in NSW. It is over 55 years old, is no longer fit for purpose, and has not kept pace with contemporary healthcare and business frameworks. Therefore, the Bill seeks to repeal and remake the Act.

Scheduled substances and therapeutic goods are vital in many health and veterinary products and used in research and industry. However, there are dangers associated with their use and some scheduled substances are liable to be diverted for criminal purposes. The regulation of scheduled substances must balance the need to allow access for legitimate uses and the need to restrict access to protect health and safety. The Bill seeks to do this by setting out who is authorised to wholesale supply, non-wholesale supply, issue prescriptions, and obtain wholesale supplies of scheduled substances and prescribed therapeutic goods.

The Bill has been developed with input from members of the public and stakeholders, which was received during a public consultation process involving a discussion paper and exposure bill.

Objectives: What is the policy's objective couched in terms of the public interest?

The objective of the Bill is to create a framework governing the supply-chain of scheduled substances and therapeutic goods in NSW in order to ensure appropriate and safe supply while protecting the health and safety of the public. These products are vital to the healthcare, veterinary, and other industries; however, there are dangers associated with certain scheduled substances which, depending on the substance, can be harmful to health, addictive, or deadly. Further, some substances, such as Schedule 8 drugs of addiction, are liable to be diverted for criminal purposes.

As such, while it is necessary to ensure that appropriate persons and organisations have access to certain substances, there also needs to be safeguards in place to mitigate the risks of harm and criminal diversion.

The Act is over 55 years old and is outdated and requires a complete rewrite to bring it up to date with modern drafting techniques, reflect contemporary and safe business practices, have a robust enforcement regime, and integrate it with other Commonwealth and NSW legislation that regulates scheduled substances and therapeutic goods. In achieving this, the Bill makes clear that the paramount consideration of the Bill is the protection of public health and safety. Further objects of the Bill include:

- regulating activities involving scheduled substances and other prescribed therapeutic goods, by providing, for example, that only specified health practitioners (such as a doctor or nurse practitioner) can prescribe prescription-only medication, to protect public health and safety;

- using the national Poisons Standard as the basis for classifying and regulating certain substances. This ensures greater alignment across States and Territories in the regulation of these products in the interests of national consistency;

- authorising certain activities involving scheduled substances and other prescribed therapeutic goods, including when the activities are prohibited under another law. For example, while the *Drug Misuse and Trafficking Act 1985* (NSW) creates offences relating to the supply and administration of *prohibited drugs*, the Bill enables health practitioners such as doctors to supply and administer these substances in the course of the treatment of a patient; and

- providing for effective administration and enforcement mechanisms in relation to scheduled substances and other prescribed therapeutic goods. In particular, the Bill will moderninse enforcement tools, including by allowing for on-the-spot fines and compliance notices, and will increase penalties to create closer alignment with equivalent offences in other Australian States and Territories.

Options: What alternative policies and mechanisms were considered in advance of the bill?

The changes in the Bill can only be achieved through legislative amendment.

Analysis: What were the pros/cons and benefits/costs of each option considered?

The Act is no longer fit for purpose and requires significant updating. It is one of the oldest in the Health portfolio and can be difficult to understand and apply in practice. The Bill has not kept pace with contemporary healthcare and business models. Updates to the framework governing the supply chain for scheduled substances and therapeutic goods in the Bill seek to ensure that the regulation of the supply chain for medicines and poisons in NSW is current, effective, and is flexible and responsive given new insights from the COVID-19 pandemic and recent natural disasters.

Pathway: What are the timetable and steps for the policy's rollout and who will administer it?

All of the provisions of the Bill will commence on proclamation. NSW Health will generally be responsible for oversight of the implementation of the Bill, and will further consult and work with key impacted persons, groups, and industry ahead of commencement. Before the Bill can commence, regulations must be developed. The regulations will be the subject of a separate public consultation process.

Consultation: Were the views of affected stakeholders sought and considered in making the policy?

There has been extensive consultation with stakeholders. In April 2022, as part of the review of the Act, the Ministry of Health released a consultation draft bill and discussion paper and invited submissions from any interested parties. Over 80 submissions were received, including from health and professional bodies, industry groups, the Medical Services Committee, the Pharmacy Guild, the Pharmaceutical Society of Australia, healthcare regulators and members of the community. The Ministry of Health also held targeted meetings with impacted industries, including with public and private healthcare bodies; health professional councils and colleges, healthcare regulators; government stakeholders, including the NSW Police Force, the Department of Communities and Justice, the Department of Primary Industries, and the Environmental Protection Agency; and associations such as the Nurses and Midwives Association and the Australian Medical Association.