



New South Wales

# Medicines, Poisons and Therapeutic Goods Bill 2022

## Explanatory note

This explanatory note relates to this Bill as introduced into Parliament.

## Overview of Bill

The objects of this Bill are as follows—

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

## Outline of provisions

### Chapter 1 Preliminary

**Chapter 1** contains introductory and interpretative provisions.

## **Chapter 2 Regulation of supply, prescriptions and other activities**

**Chapter 2** deals with the following activities relating to scheduled substances and other therapeutic goods—

- (a) wholesale supply,
- (b) obtaining wholesale supply,
- (c) non-wholesale supply,
- (d) prescriptions,
- (e) clinical trials.

Chapter 2 also creates various offences that relate to scheduled substances and other therapeutic goods.

Chapter 2 contains regulation-making powers that may be considered Henry VIII provisions.

## **Chapter 3 Licences, approvals and other authorisations**

**Chapter 3** deals with the following kinds of authorisations under the proposed Act—

- (a) licences for wholesale supply and for obtaining wholesale supply of certain scheduled substances and other therapeutic goods,
- (b) approvals for the supply and prescription of certain scheduled substances and other therapeutic goods by health practitioners,
- (c) Opioid Treatment Program registrations,
- (d) authorities that relate to the *Drug Misuse and Trafficking Act 1985*.

## **Chapter 4 Application of Commonwealth therapeutic goods laws**

**Chapter 4** provides for the application in New South Wales of the *Therapeutic Goods Act 1989* of the Commonwealth, and regulations, orders, manufacturing principles, specifications, determinations, rules, delegations and other instruments in force under that Act, including in relation to offences against that Act.

## **Chapter 5 Investigation functions**

**Chapter 5** gives various powers to authorised officers in relation to information gathering, entering premises and seizure.

## **Chapter 6 Enforcement**

**Chapter 6** deals with the following matters—

- (a) the issue of compliance notices by the Secretary of the Ministry of Health (the *Health Secretary*),
- (b) the 5 tiers of penalties in the proposed Act,
- (c) proceedings for offences against the proposed Act, including evidentiary provisions,
- (d) the issue of penalty notices for offences against the proposed Act.

## **Chapter 7 Administration**

**Chapter 7** deals with the following matters—

- (a) the Regulatory Advisory Committee and the Clinical Advisory Committee,

- (b) authorised officers,
- (c) analysts and analyses,
- (d) public health risk authorisation orders made by the Health Secretary if there is a situation that presents a risk to the health or safety of humans or animals.

## Chapter 8 Miscellaneous

**Chapter 8** contains miscellaneous provisions.

### Schedule 1 Members and procedures of Advisory Committees

**Schedule 1** deals with the members and procedures of the Regulatory Advisory Committee and the Clinical Advisory Committee.

### Schedule 2 Savings, transitional and other provisions

**Schedule 2** contains savings, transitional and other provisions consequent on the enactment of the proposed Act.

### Schedule 3 Dictionary

**Schedule 3** defines words used in the proposed Act.

### Schedule 4 Amendment of Drug Misuse and Trafficking Act 1985 No 226

**Schedule 4** contains consequential amendments to the *Drug Misuse and Trafficking Act 1985*.

### Schedule 5 Amendment of other legislation

**Schedule 5** contains consequential amendments to various Acts and Regulations.

## Table of concordance

In this Table—

**PTGA** means the *Poisons and Therapeutic Goods Act 1966*.

**PTGR** means the *Poisons and Therapeutic Goods Regulation 2008*.

Provisions of the proposed Act	Corresponding provisions of PTGA and PTGR
ss 1–3	—
ss 4 and 5	s 4 PTGA
s 6	s 8 PTGA
ss 7–13	—
ss 14 and 15	ss 9 and 11 PTGA
ss 16 and 17	—
s 18	cl 134 PTGR
ss 19–27	—
ss 28–30	s 10 PTGA

<b>Provisions of the proposed Act</b>	<b>Corresponding provisions of PTGA and PTGR</b>
s 31	cll 49 and 99 PTGR
s 32	cll 49A and 99A PTGR
s 33	s 23 PTGA
ss 34 and 35	—
s 36	cll 32 and 77 PTGR
s 37	cll 33 and 78 PTGR
ss 38 and 39	—
s 40	cll 67 and 124 PTGR
s 41	—
s 42	s 36 PTGA
s 43	s 34 PTGA
s 44	s 36A PTGA
s 45	s 36B PTGA
s 46	s 36AA PTGA
s 47	s 12 PTGA
s 48	cll 64 and 108 PTGR
ss 49–51	s 18AA PTGA and cl 175 PTGR
ss 52 and 53	—
s 54	ss 18B, 18C and 18D PTGA
ss 55 and 56	—
ss 57–61	cll 160–163 and 165–168 PTGR
s 62	cll 164 and 169 PTGR
ss 63–66	cll 172 and 173 PTGR
s 67	—
ss 68–73	ss 28, 28A and 29 PTGA
ss 74 and 75	—
ss 76–81	s 17D PTGA
ss 82–85	—
s 86	ss 31 and 32 PTGA
s 87	ss 33, 33A, 33B, 33C and 33D PTGA
s 88	ss 33E and 33F PTGA
s 89	ss 33G and 33H PTGA
s 90	s 33I PTGA
s 91	s 33J PTGA
s 92	s 33L PTGA
ss 93–98	—
ss 99, 101, 103 and 104	s 43 PTGA

<b>Provisions of the proposed Act</b>	<b>Corresponding provisions of PTGA and PTGR</b>
s 100	s 43A PTGA
s 102	—
s 105	—
ss 106–111	cll 149–154 PTGR
s 112	s 43 PTGA
ss 113–117	—
s 118	s 36D PTGA
s 119	—
s 120	s 45 PTGA
ss 121–123	—
s 124	s 39 PTGA
s 125	s 40 PTGA
s 126	s 18A PTGA
s 127	s 6 PTGA
s 128	s 30 PTGA
s 129	s 30AA PTGA
s 130	ss 6A and 30A PTGA
ss 131–133	s 42 PTGA
s 134	s 43 PTGA
s 135	—
s 136	s 43 PTGA
s 137	s 37A PTGA
ss 138 and 139	s 37B PTGA
ss 140–142	—
s 143	s 37 PTGA
ss 144–146	—
s 147	s 45D PTGA
s 148	—
ss 149 and 150	s 45C PTGA
s 151	—
Schedule 1	Schedules 1 and 2 PTGA