



Western Australia

Therapeutic Goods Law Application Act 2024

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Therapeutic Goods Law Application Act 2024

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Western Australia

Therapeutic Goods Law Application Act 2024

No. 19 of 2024

An Act —

- to apply the *Therapeutic Goods Act 1989* (Commonwealth) and legislative instruments under that Act as laws of the State; and
- to make consequential amendments to various other Acts; and
- for related purposes.

[Assented to 14 May 2024]

The Parliament of Western Australia enacts as follows:

Part 1 — Preliminary

1. Short title

This is the *Therapeutic Goods Law Application Act 2024*.

2. Commencement

This Act comes into operation as follows —

- (a) Part 1 — on the day on which this Act receives the Royal Assent;
- (b) the rest of the Act — on a day fixed by proclamation.

3. Terms used

- (1) In this Act —

amend includes replace;

amending Act means a Commonwealth Act that receives the Royal Assent on or after 27 November 2023 to the extent that it —

- (a) amends the *Therapeutic Goods Act 1989* (Commonwealth); or
- (b) makes or amends a therapeutic legislative instrument;

applied therapeutic goods law means the provisions that apply as a law of the State because of sections 5 and 10;

Commonwealth administrative laws means the following —

- (a) the *Administrative Appeals Tribunal Act 1975* (Commonwealth) (excluding Part IVA);
- (b) the *Freedom of Information Act 1982* (Commonwealth);
- (c) the *Ombudsman Act 1976* (Commonwealth);
- (d) the *Privacy Act 1988* (Commonwealth);
- (e) the legislative instruments in force under those Acts;

Commonwealth therapeutic goods law means —

- (a) the *Therapeutic Goods Act 1989* (Commonwealth); and

(b) the legislative instruments under that Act;

local regulations means the regulations made under section 26;

therapeutic legislative instrument means a regulation or other legislative instrument for the time being in force under the *Therapeutic Goods Act 1989* (Commonwealth).

- (2) If a term used in this Act is given a meaning in the *Therapeutic Goods Act 1989* (Commonwealth), it has the same meaning in this Act.

4. Act binds Crown

This Act binds the Crown in right of Western Australia and, so far as the legislative power of the Parliament permits, the Crown in all its other capacities.

Part 2 — Applying Commonwealth therapeutic goods law as State law

5. Application of Commonwealth therapeutic goods Act as State law

(1) In this section —

Commonwealth therapeutic goods Act means the *Therapeutic Goods Act 1989* (Commonwealth) as in force on 27 November 2023 as amended by —

- (a) a provision of a law of the Commonwealth that amends the *Therapeutic Goods Act 1989* (Commonwealth) that is made before 27 November 2023 but has not come into operation on or before 27 November 2023; and
- (b) each provision that —
 - (i) is in an amending Act that has effect for the purposes of this Part under section 7; and
 - (ii) has come into operation for the purposes of this Part under section 8.

(2) The Commonwealth therapeutic goods Act applies as a law of the State.

(3) The Commonwealth therapeutic goods Act applies under subsection (2) —

- (a) as modified by local regulations (if any) made for the purposes of section 15; and
- (b) as if it extended to matters in relation to which the State may make laws —
 - (i) whether or not the Commonwealth may make laws in relation to those matters; and
 - (ii) even though the terms of the Commonwealth therapeutic goods Act provides that it applies

only to specified matters with respect to which
the Commonwealth may make laws.

Note for this subsection:

For paragraph (b)(ii), the *Therapeutic Goods Act 1989*
(Commonwealth) section 6 sets out specified matters to which that Act
applies.

- (4) The provisions of the Commonwealth therapeutic goods Act that apply as a law of the State because of this section apply as a part of this Act.

6. Tabling amending Acts

An amending Act must be laid before each House of Parliament within 18 sitting days of the House after the day on which the Act receives the Royal Assent.

7. Disallowance of amending Acts

- (1) In this section —
- disallowance period*, in relation to a disallowance resolution of which notice is given in a House of Parliament, means the period of 30 sitting days of the House after the day on which the notice is given;
- disallowance resolution* means a resolution that an amending Act be disallowed;
- notice period*, in relation to an amending Act laid before a House of Parliament under section 6, means the period of 14 sitting days of the House after the day on which the amending Act is laid before it.
- (2) An amending Act has effect for the purposes of this Part if the amending Act is laid before each House of Parliament under section 6 and either —
- (a) no notice of a disallowance resolution is given in either House within the notice period; or

- (b) at least 1 notice of a disallowance resolution is given in a House within the notice period and, for each such notice, 1 of the following applies —
 - (i) the notice is withdrawn or discharged within the disallowance period;
 - (ii) the disallowance resolution is lost in the House or not agreed to within the disallowance period.
- (3) For the purposes of this section and section 6 —
 - (a) the period specified in section 6, a notice period or a disallowance period continues to run even though a House of Parliament is prorogued or dissolved or expires; and
 - (b) notice of a disallowance resolution given in a House of Parliament, or a motion that an amending Act be disallowed in the House, does not lapse even though the House is prorogued or dissolved or expires.

8. Commencement of provisions of amending Acts

- (1) If an amending Act has effect for the purposes of this Part under section 7(2), the Governor must declare that fact by proclamation as soon as practicable.
- (2) If a provision of the amending Act has come into operation in the Commonwealth before the proclamation is published —
 - (a) the proclamation must fix a day on which the provision comes into operation for the purposes of this Part, which must be on or after the day on which the proclamation is published; and
 - (b) the provision comes into operation for the purposes of this Part on that day.
- (3) If a provision of the amending Act has not come into operation in the Commonwealth before the proclamation is published, the provision comes into operation for the purposes of this Part when the provision comes into operation in the Commonwealth.

9. Tabling of amending Act taken to be publication for Standing Orders

- (1) In this section —
parliamentary committee means a committee established by either or both of the Houses of Parliament.
- (2) If a Standing Order of a House of Parliament provides that on the publication of an instrument under a written law the instrument is referred to a parliamentary committee for consideration, the laying of an amending Act before the House under section 6 is taken to be publication of the amending Act for the purposes of the Standing Order.
- (3) This section does not apply if the Standing Orders of the House provide specifically for an amending Act to be considered by a parliamentary committee.

10. Therapeutic legislative instruments

- (1) A therapeutic legislative instrument applies as a law of the State.
- (2) A therapeutic legislative instrument has effect for the purposes of its application under subsection (1) subject to —
- (a) any modifications made by local regulations for the purposes of section 15; and
 - (b) to the extent the therapeutic legislative instrument is made under the *Therapeutic Goods Act 1989* (Commonwealth) on or after 27 November 2023 — sections 11 and 13; and
 - (c) to the extent the therapeutic legislative instrument is made by a provision of an amending Act — subsection (3).

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- (3) A therapeutic legislative instrument, to the extent made by a provision of an amending Act, has effect for the purposes of its application under subsection (1) if —
- (a) the amending Act has effect for the purposes of this Part under section 7; and
 - (b) the provision has come into operation for the purposes of this Part under section 8.
- (4) The provisions of a therapeutic legislative instrument that apply as a law of the State because of this section apply as subsidiary legislation for the purposes of this Act.

Note for this section:

Under section 14, the *Interpretation Act 1984* does not apply to therapeutic legislative instruments that are subsidiary legislation for the purposes of this Act.

11. Therapeutic legislative instruments made under or for purposes of amending Act

- (1) This section applies to a provision of a therapeutic legislative instrument made under the *Therapeutic Goods Act 1989* (Commonwealth) if the provision is made under or for the purposes of —
- (a) a provision inserted into the *Therapeutic Goods Act 1989* (Commonwealth) by a provision of an amending Act; or
 - (b) a provision of the *Therapeutic Goods Act 1989* (Commonwealth) as amended by a provision of an amending Act.
- (2) The provision of the therapeutic legislative instrument does not have effect for the purposes of its application under section 10(1) until the later of —
- (a) the day on which the provision of the amending Act comes into operation for the purposes of this Part under section 8; and

- (b) the day on which the provision of the therapeutic legislative instrument comes into operation in the Commonwealth.
- (3) However, if the amending Act does not have effect for the purposes of this Part under section 7, the provision of the therapeutic legislative instrument does not have effect for the purposes of its application under section 10(1).

12. Publication of therapeutic legislative instruments

- (1) This section applies to a therapeutic legislative instrument made under the *Therapeutic Goods Act 1989* (Commonwealth) on or after 27 November 2023.
- (2) No later than 18 days after the day on which the therapeutic legislative instrument is made, 1 of the following must occur —
 - (a) the therapeutic legislative instrument is published in the *Gazette*;
 - (b) the therapeutic legislative instrument is published on the WA legislation website;
 - (c) notice is published in the *Gazette* —
 - (i) stating that the therapeutic legislative instrument is published on a website; and
 - (ii) stating the website on which the instrument is published.
- (3) For the purposes of subsection (2)(c), the website must be a website maintained by or on behalf of the State or the Commonwealth.

13. Tabling and disallowance of therapeutic legislative instruments

- (1) This section applies to a therapeutic legislative instrument made under the *Therapeutic Goods Act 1989* (Commonwealth) on or after 27 November 2023.

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- (2) A therapeutic legislative instrument must be laid before each House of Parliament within 6 sitting days of the House after —
 - (a) if notice of the instrument’s publication is published under section 12(2)(c) — the day on which the notice is published; or
 - (b) otherwise — the day on which the instrument is published under section 12(2)(a) or (b).
- (3) A therapeutic legislative instrument ceases to have effect for the purposes of its application under section 10(1) if —
 - (a) the instrument is not published, or notice of its publication is not published, under section 12; or
 - (b) the instrument is not laid before each House of Parliament in accordance with subsection (2); or
 - (c) the instrument is laid before each House of Parliament in accordance with subsection (2) and —
 - (i) notice of a resolution to disallow the instrument is given in 1 of those Houses within 14 sitting days of the House after the instrument is laid before the House under subsection (2); and
 - (ii) the resolution to disallow the instrument is agreed to by the House.
- (4) A therapeutic legislative instrument that ceases to have effect under subsection (3) ceases to have effect at the end of the day on which the circumstance in subsection (3)(a), (b) or (c) occurs.
- (5) If a resolution is agreed to under subsection (3)(c), notice of the resolution must be published in the *Gazette* or on the WA legislation website within 21 days after the day on which the motion is passed.
- (6) If a therapeutic legislative instrument (the ***relevant instrument***) ceases to have effect under subsection (3), a therapeutic legislative instrument that was amended or repealed by the

relevant instrument revives, for the purposes of its application under section 10(1), on the day after the day on which the relevant instrument ceases to have effect.

- (7) For the purposes of this section —
- (a) the period specified in subsection (2) or (3)(c)(i) continues to run even though a House of Parliament is prorogued or dissolved or expires; and
 - (b) notice of a resolution to disallow a therapeutic legislative instrument given in a House of Parliament, or a motion that a therapeutic legislative instrument be disallowed in the House, does not lapse even though the House is prorogued or dissolved or expires.

14. Application of interpretation legislation to applied therapeutic goods law

- (1) In this section —

Commonwealth interpretation laws means —

- (a) the *Acts Interpretation Act 1901* (Commonwealth); and
- (b) another law of the Commonwealth that is relevant to the interpretation of a Commonwealth Act or legislative instrument.

Example for this definition:

Legislation Act 2003 (Commonwealth) section 13.

- (2) The *Interpretation Act 1984* does not apply to the applied therapeutic goods law.
- (3) The Commonwealth interpretation laws apply as laws of the State in relation to the interpretation of the applied therapeutic goods law and so apply as if the applied therapeutic goods law were a Commonwealth Act or were a legislative instrument under a Commonwealth Act, as the case requires.

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15. Local regulations may modify applied therapeutic goods law

The local regulations may modify the applied therapeutic goods law.

Part 3 — Functions and powers under applied therapeutic goods law

16. Commonwealth authorities and officers have functions under applied therapeutic goods law

A Commonwealth authority or Commonwealth officer referred to in the applied therapeutic goods law has the same functions and powers under the applied therapeutic goods law as they have under the Commonwealth therapeutic goods law, as that law applies to the Commonwealth.

17. Delegations under applied therapeutic goods law

Any delegation under the Commonwealth therapeutic goods law, as that law applies to the Commonwealth, is taken to extend to, and have effect for the purposes of, the corresponding provision of the applied therapeutic goods law.

Part 4 — Offences

18. Object of Part

- (1) The object of this Part is to further the purpose of this Act by providing for an offence against the applied therapeutic goods law to be treated as if it were an offence against a law of the Commonwealth.
- (2) The purposes for which an offence is to be treated as mentioned in subsection (1) include, but are not limited to —
 - (a) the investigation and prosecution of offences; and
 - (b) the arrest, custody, bail, trial and conviction of offenders or persons charged with offences; and
 - (c) proceedings relating to a matter referred to in paragraph (a) or (b); and
 - (d) appeals and reviews relating to criminal proceedings and to proceedings of the kind referred to in paragraph (c); and
 - (e) the sentencing, punishment and release of persons convicted of offences; and
 - (f) fines, penalties and forfeitures; and
 - (g) infringement notices in connection with offences; and
 - (h) liability to make reparation in connection with offences; and
 - (i) proceeds of crime; and
 - (j) spent convictions.
- (3) For the purposes of this Part, offences include contraventions for which a civil penalty may be imposed.

19. Application of Commonwealth criminal laws to offences against applied therapeutic goods law

- (1) In this section —
relevant Commonwealth criminal law means a law of the Commonwealth relating to a purpose referred to in section 18(2).
- (2) The relevant Commonwealth criminal laws apply as laws of the State in relation to an offence against the applied therapeutic goods law as if the applied therapeutic goods law were a law of the Commonwealth and not a law of the State.
- (3) For the purposes of a law of the State, an offence against the applied therapeutic goods law —
- (a) is taken to be an offence against the laws of the Commonwealth in the same way as if the applied therapeutic goods law were a law of the Commonwealth; and
 - (b) is taken not to be an offence against the laws of the State.
- (4) Subsection (3) has effect for the purposes of a law of the State except as provided by the local regulations.

20. Functions and powers conferred on Commonwealth authorities and officers relating to offences

- (1) A Commonwealth law applying because of section 19 that confers on a Commonwealth authority or Commonwealth officer a function or power in relation to an offence against the Commonwealth therapeutic goods law also confers on the authority or officer the same function or power in relation to an offence against the corresponding provision of the applied therapeutic goods law.
- (2) In performing a function or exercising a power conferred by this section, the Commonwealth authority or Commonwealth officer

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must act as nearly as practicable as the authority or officer would act in performing or exercising the same function or power in relation to an offence against the corresponding provision of the Commonwealth therapeutic goods law.

21. No double jeopardy for offences against applied therapeutic goods law

- (1) Subsection (2) applies if —
 - (a) an act or omission is both an offence against the applied therapeutic goods law and an offence against the corresponding provision of the Commonwealth therapeutic goods law; and
 - (b) an offender has been punished for that offence under the corresponding provision of the Commonwealth therapeutic goods law.
- (2) The offender is not liable to be punished for the offence under the applied therapeutic goods law.

Part 5 — Commonwealth administrative laws

22. Application of Commonwealth administrative laws to applied therapeutic goods law

- (1) The Commonwealth administrative laws apply as laws of the State to any matter arising in relation to the applied therapeutic goods law as if the applied therapeutic goods law were a law of the Commonwealth and not a law of the State.
- (2) For the purposes of a law of the State, a matter arising in relation to the applied therapeutic goods law —
 - (a) is taken to be a matter arising in relation to laws of the Commonwealth in the same way as if the applied therapeutic goods law were a law of the Commonwealth; and
 - (b) is taken not to be a matter arising in relation to laws of the State.
- (3) Subsection (2) has effect for the purposes of a law of the State except as provided by the local regulations.
- (4) A provision of a Commonwealth administrative law applying because of this section that purports to confer jurisdiction on a federal court is taken not to have that effect.
- (5) For the purposes of this section, a reference in a provision of the *Administrative Appeals Tribunal Act 1975* (Commonwealth) (as that provision applies as a law of the State) to the whole or any part of Part IVA of that Act is taken to be a reference to the whole or part of that Part as it has effect as a law of the Commonwealth.

23. Functions and powers conferred on Commonwealth authorities and officers

- (1) A Commonwealth administrative law applying because of section 22 that confers on a Commonwealth authority or Commonwealth officer a function or power also confers on the

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authority or officer the same function or power in relation to a matter arising in relation to the applied therapeutic goods law.

- (2) In performing a function or exercising a power conferred by this section, the Commonwealth authority or Commonwealth officer must act as nearly as practicable as the authority or officer would act in performing or exercising the same function or power under the Commonwealth administrative law.

Part 6 — Miscellaneous

24. Fees payable under applied therapeutic goods law

The Commonwealth may retain fees paid to, or recovered by, the Commonwealth, a Commonwealth authority or Commonwealth officer in respect of the performance or exercise of functions or powers conferred on them by the applied therapeutic goods law.

25. Reference in Commonwealth law to provision of another law

For the purposes of sections 19 and 22, a reference in a Commonwealth law to a provision of that or another Commonwealth law is taken to be a reference to that provision as applying because of those sections.

26. Local regulations

The Governor may make regulations prescribing matters —

- (a) required or permitted by this Act to be prescribed; or
- (b) necessary or convenient to be prescribed for giving effect to this Act or the applied therapeutic goods law.

Part 7 — Transitional provisions

27. Term used: commencement day

In this Part —

commencement day means the day on which this section comes into operation.

28. Amending Acts enacted on or after 27 November 2023 but before commencement day

If an amending Act receives the Royal Assent on or after 27 November 2023 but before commencement day, sections 6 to 8 apply to the amending Act as if it received the Royal Assent on commencement day.

29. Therapeutic legislative instruments made on or after 27 November 2023 but before commencement day

If a therapeutic legislative instrument is made on or after 27 November 2023 but before commencement day, section 12(2) applies as if the therapeutic legislative instrument were made on commencement day.

30. Liability of persons acting lawfully before commencement of applied therapeutic goods law as law of State

- (1) This section applies if a person —
 - (a) dealt with or used therapeutic goods immediately before commencement day in a manner (the *transitioned conduct*) that was not unlawful; and
 - (b) would, but for this section, contravene a provision of the applied therapeutic goods law by engaging in the transitioned conduct on commencement day.
- (2) For the period of 2 years beginning on commencement day, the person —
 - (a) may engage in the transitioned conduct; and

- (b) does not contravene a provision of the applied therapeutic goods law by engaging in the transitioned conduct.

31. Transitional regulation-making power

- (1) In this section —
publication day, in relation to transitional regulations, means the day on which the transitional regulations are published in accordance with the *Interpretation Act 1984* section 41(1)(a);
transitional regulations means local regulations made for the purposes of subsection (2).
- (2) Local regulations may deal with matters of a transitional, savings or application nature arising in connection with the enactment of this Act.
- (3) Transitional regulations cannot be made after the end of the period of 2 years beginning on commencement day.
- (4) If transitional regulations provide that a state of affairs is taken to have existed, or not to have existed, on and from a day that is earlier than publication day, but not earlier than commencement day, the regulations have effect according to their terms.
- (5) If transitional regulations contain a provision referred to in subsection (4), the provision does not operate so as to —
 - (a) affect, in a manner prejudicial to any person (other than the State or an authority of the State), the rights of that person existing before publication day; or
 - (b) impose liabilities on any person (other than the State or an authority of the State) in respect of anything done or omitted to be done before publication day.

Part 8 — Consequential amendments

Division 1 — *Human Tissue and Transplant Act 1982* amended

32. Act amended

This Division amends the *Human Tissue and Transplant Act 1982*.

33. Section 29A amended

- (1) In section 29A(1) insert in alphabetical order:

TG law provision means —

- (a) a TGA provision; or
- (b) a provision or portion of the applied therapeutic goods law as defined in the *Therapeutic Goods Law Application Act 2024* section 3(1).

- (2) In section 29A(1) in the definition of ***TGA provision*** delete “Act.” and insert:

Act;

- (3) In section 29A(4):

- (a) in paragraph (d)(i) delete “TGA provision; and” and insert:

TG law provision; and

- (b) in paragraph (d)(ii) delete “TGA provision” and insert:

TG law provision

Division 2 — Medicines and Poisons Act 2014 amended

34. Act amended

This Division amends the *Medicines and Poisons Act 2014*.

35. Section 3 amended

In section 3 insert in alphabetical order:

therapeutic goods law means —

- (a) the *Therapeutic Goods Act 1989* (Commonwealth); or
- (b) the applied therapeutic goods law as defined in the *Therapeutic Goods Law Application Act 2024* section 3(1);

36. Section 12 amended

In section 12 in the definition of *appropriate licence* paragraph (e) delete “the *Therapeutic Goods Act 1989* (Commonwealth);” and insert:

a therapeutic goods law;

37. Section 28 amended

Delete section 28(1)(a)(v) and insert:

- (v) a therapeutic goods law;

38. Section 60 amended

Delete section 60(1)(a)(v) and insert:

(v) a therapeutic goods law;

=====

Defined terms

[This is a list of terms defined and the provisions where they are defined.

The list is not part of the law.]

Defined term	Provision(s)
amend.....	3(1)
amending Act.....	3(1)
applied therapeutic goods law.....	3(1)
commencement day	27
Commonwealth administrative laws.....	3(1)
Commonwealth interpretation laws.....	14(1)
Commonwealth therapeutic goods Act.....	5(1)
Commonwealth therapeutic goods law.....	3(1)
disallowance period.....	7(1)
disallowance resolution.....	7(1)
local regulations.....	3(1)
notice period.....	7(1)
parliamentary committee.....	9(1)
publication day.....	31(1)
relevant Commonwealth criminal law.....	19(1)
relevant instrument.....	13(6)
therapeutic legislative instrument.....	3(1)
transitional regulations.....	31(1)
transitioned conduct.....	30(1)

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