

Therapeutic Goods Law Application Bill 2023

EXPLANATORY MEMORANDUM

The *Therapeutic Goods Law Application Bill 2023* (the Bill) provides for an Act to apply the *Therapeutic Goods Act 1989* (Cth) (the Commonwealth Act) as a law of Western Australia, and to make consequential amendments to various other Acts which reference the Commonwealth Act.

The Commonwealth Act sets out the legal requirements for the import, export, manufacture, and supply of all therapeutic goods in Australia with extensive requirements for registration as well as regulating other aspects including advertising, labelling, and product appearance.

The Commonwealth Act currently extends to all corporations operating within WA or inter-state and to any sole traders in WA who operate inter-state. However due to constitutional limitations, the Commonwealth Act does not apply to those manufacturers who do not trade as corporations or who are not engaged in trade outside WA. The adoption of the Commonwealth Act will effectively extend the authority of the Act over sole traders only operating within the WA state boundaries and will require them to comply with national standards.

This Bill provides for the tabling and disallowance of future amendments made to the Commonwealth Act, as well as subsidiary legislation. This provides an efficient mechanism to apply the Commonwealth Act whilst still maintaining the oversight of the Western Australian Parliament.

There are three Henry VIII clauses in this Bill and each has been identified and justified.

The Bill is set out in eight Parts as described below.

PRELIMINARY

Clause 1 **Short title**

The Act will be called the *Therapeutic Goods Law Application Act 2023*.

Clause 2 **Commencement**

This clause provides for the commencement of the Act. Part 1 comes into operation on the day on which the Act receives the Royal Assent. The rest of the Act will commence by proclamation. Part 8 Division 1 amends a section of the *Human Tissue and Transplant Act 1982* that is yet to be commenced. As a result commencement of Part 8 Division 1 will happen when that section is commenced.

Clause 3 **Terms used**

This clause defines terms used in the Act. Key definitions include:

- amending Act - a Commonwealth Act made on or after this Bill that receives Royal Assent, and which amends the Commonwealth Act.
- applied therapeutic goods law – means the provisions of the Commonwealth Act that apply due to sections 5 and 10 of this Act.
- therapeutic legislative instrument – subsidiary legislation made under the Commonwealth Act in force now and in the future which can include regulations, determinations, orders, and other instruments.

Clause 4 Act binds the Crown

This clause provides for the Act to bind the Crown.

Part 2 Applying Commonwealth therapeutic goods Law as State law

Clause 5 Application of Commonwealth therapeutic goods Act as State law

This clause applies the Commonwealth Act, as in force on Monday 27 November 2023, as a law of WA.

It also provides that the Commonwealth Act applies as a law of the State despite the Commonwealth not having the constitutional power to make those laws and despite the Commonwealth Act stating that it only applies to matters for which the Commonwealth can make laws. This provides for the removal of any constitutional limitations that might otherwise affect this Act.

Clause 6 Tabling amending Acts

Clause 7 requires an amending Act to 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.

The tabling requirement ensures that any amendments to the Commonwealth Act will be subject to scrutiny by the Western Australian Parliament before coming into effect in WA.

Clause 7 Disallowance of amending Acts

This clause sets out the process by which an amending Act is subject to oversight and potential disallowance by the WA Parliament.

An amending Act does not apply in WA until it has been tabled under section 6 and passed both Houses without a disallowance motion being passed during the notice period of 14 sitting days, and subsequently endorsed.

A notice of a disallowance motion may be provided within the 14 sitting day notice period. Following this, the disallowance motion must be dealt with 30 sitting days by the House.

Clause 8 Commencement of provisions of amending Acts

This clause clarifies when an amending Act commences in WA. If an amending Act has effect under section 7, the Governor must declare this by proclamation.

If an amending Act by the Commonwealth is in operation prior to the publication of the proclamation, the proclamation must specify when that provision comes into operation in WA. Otherwise, an amending provision comes into operation in WA when it comes into operation in the Commonwealth.

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

This clause provides that the laying of an amending Act before a House under section 6 is taken to be publication of the amending Act for the purposes of a Standing Order of the House which provides for referral of an instrument to a parliamentary committee on publication of the instrument.

This provides an extra layer of scrutiny of Commonwealth amending laws and ensures Western Australian Parliament's sovereignty and law-making powers are maintained.

Clause 10 Therapeutic legislative instruments

Clause 11 provides that existing therapeutic legislative instruments (subsidiary legislation including but not limited to regulations) apply in WA on the commencement day of this Act.

It also provides that future therapeutic legislative instruments made under future amending Acts have effect in WA.

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

This clause provides that therapeutic legislative instruments made under a provision of an amending Act only apply as subsidiary legislation in WA under clause 10 of this Act if the amending Act has not been disallowed and has commenced.

If a valid notice of disallowance is passed under section 7, the amending Act will not apply in WA, and therefore any dependent therapeutic legislative instrument will also not have effect.

Clause 12 Publication of therapeutic legislative instruments

This clause requires that any future therapeutic legislative instruments made on or after the commencement date of this Act must be published in Western Australia in some form within 18 days after it is made.

The clause also provides various publication options for future therapeutic legislative instruments. The Commonwealth creates a wide variety of therapeutic legislative instruments, and the preferred publication approach may

change depending on the instrument. Publication of subsidiary legislation, like the therapeutic legislative instruments, is a requirement of the *Interpretation Act 1984 (WA)*.

Clause 13 Tabling and disallowance of therapeutic legislative instruments

This clause sets out the requirements for future therapeutic legislative instruments to be subject to be tabled and subject to oversight by the WA Parliament.

Therapeutic legislative instruments, made after the commencement of this Act, have effect immediately when made by the Commonwealth.

Therapeutic legislative instruments must be tabled to the WA Parliament within 6 sitting days of publication as outlined in clause 12. Notice of a resolution to disallow the instrument must be given within 14 sitting days of the House.

Therapeutic legislative instruments will cease to have effect if one of the following occurs:

- they are not published as required by clause 12; or
- they are not tabled within 6 sitting days to the WA Parliament after publication, or
- they are tabled within 6 sitting days and notice of a resolution to disallow is given and agreed to by a House.

If a therapeutic legislative instrument cease to have effect, the previous provisions that were in place prior to that therapeutic legislative instrument are revived.

Clause 14 Application of interpretation legislation to this Act and applied therapeutic goods Law

This clause provides that the *Interpretation Act 1984* does not apply to the WA applied therapeutic goods law, instead the *Commonwealth Acts Interpretation Act 1901* applies.

Clause 15 Local regulations may modify applied therapeutic goods law

This is a Henry VIII clause and is identified as such as per the requirements of the Standing Committee on Uniform Legislation. It provides for local regulations (as provided in Clause 26) may modify the applied therapeutic goods law, which includes the Act as well as subsidiary legislation.

This power has been provided to allow for any future necessary refinements to this Commonwealth Law that might be deemed necessary to ensure its appropriate application within Western Australia. Each State and Territory that has adopted the Commonwealth Law has included a similar power to ensure a local adaptive mechanism

Parliamentary oversight is maintained by the provisions of this Act that require tabling of all subsidiary legislation to Parliament.

Part 3 Functions and powers under applied therapeutic goods law

Part 3 provides for consistency of operation of the powers and functions by relevant Authorities and officers under the Commonwealth Act.

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

This clause ensures that any authority or person, including the Commonwealth Secretary or the Department administering the Commonwealth Act, has the same functions and powers in Western Australia

Clause 17 Delegations under applied therapeutic goods law

This clause ensures that any delegations under the Commonwealth Act also apply for the purpose of the WA applied law provisions.

Part 4 — Offences

Part 4 deals with offences and the application of Commonwealth criminal law to the applied therapeutic goods law. This ensures seamless operation regardless of the underlying constitutional framework.

Clause 18 Object of Part

Part 4 provides for a uniform compliance regime for therapeutic goods with offences treated as an offence against the law of the Commonwealth. A range of purposes are listed to be treated as under Commonwealth law, including investigation, prosecution, legal proceedings, fines, penalties, and infringements.

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

This clause provides that relevant Commonwealth criminal laws apply to any purposes listed in clause 18 and that any offences are offences against Commonwealth law and not State law.

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

Clause 20 provides that a Commonwealth authority or officer continues to have all functions or powers provided by Commonwealth criminal laws in regards any offence and must perform them as such.

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

This clause provides that a person is punished for an offence against the Commonwealth Act, then that person cannot be punished for the same offence under the applied therapeutics good law.

Part 5 — Commonwealth administrative laws

Part 5 deals with the application of Commonwealth administrative laws to the operation of the applied therapeutic goods law. This ensures seamless operation regardless of the underlying constitutional framework.

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

This clause provides that Commonwealth administrative laws (as defined in section 3) apply to the operation and application of the Commonwealth Act and any therapeutic goods instruments.

An exception is provided in 22(4) to provide that no Commonwealth administrative law can confer jurisdiction of a federal court of this applied law.

Clause 22(5) is based on model national application Bill developed and agreed by the Australasian Parliamentary Counsels Committee in 2012. It ensures appropriate review rights under the applied therapeutic goods law are the same as the Commonwealth Act.

Clause 23 Functions and powers conferred on Commonwealth authorities and officers

This clause provides that any powers or functions provided to Commonwealth officers or authorities by virtue of a Commonwealth administrative law, have effect in the application of the Commonwealth Act and the applied therapeutic goods law WA.

Any officer or authority exercising these functions or powers for the purposes of the Commonwealth Act must do so in the same manner as if exercising the power under the Commonwealth administrative law.

Part 6 — Miscellaneous

Clause 24 Fees payable under applied therapeutics goods law

Clause 24 allows that the Commonwealth may retain any fees paid or recovered within WA as allowed under the applied therapeutic goods law.

Clause 25 Reference in Commonwealth law to provision of another law

Clause 25 provides that in relation to clause 19 and 22 (Commonwealth criminal and administrative laws), if a Commonwealth law refers to another Commonwealth law (whether within the same or a different Act) this is to be a reference to that law as applying in Western Australia.

Clause 26 Local regulations

This is a Henry VIII clause and is identified as such as per the requirements of the Standing Committee on Uniform Legislation.

Clause 26 provides a broad power for the Governor to make regulations in respect any matter required or permitted by this Act, or as needed to give effect to the applied therapeutic goods Law.

This power has been provided to allow for any future necessary refinements to this Commonwealth Law that might be deemed necessary to ensure its appropriate application within Western Australia. Each State and Territory that has adopted the Commonwealth Law has included a similar power to ensure a local adaptive mechanism.

Along with the disallowance and tabling provisions, this clause will support maintenance of WA sovereignty. All regulations made under the applied therapeutic goods law must also be tabled with Parliament and reviewed by the Joint Standing Committee on Delegated Legislation. This provides an additional measure of oversight to ensure no inappropriate application of this extended power.

The local regulations power is also referenced in Clause 31.

Part 7 — Transitional provisions

Part 7 provides for a range of transitional matters necessary for the efficient operation of the applied therapeutic goods law.

Clause 27 Terms used: commencement day

This clause defines this term as this date is when the various transitional provisions commence for a period limited to two years.

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

This Bill applies the national law as in force on Monday 27 November 2023. Clause 28 provides that any amending acts receiving royal assent after that day but before the commencement of this Act, are subject to the tabling and disallowance provisions of sections 7 through 9. However, they are treated as if Royal assent was received on Act commencement. This means they have 18 days to be tabled from the commencement of this Act.

Clause 29 Therapeutic legislative instruments made on or after Monday 27 November 2023 but before Act commencement day

This clause applies similar requirements as clause 28 to any therapeutic legislative instruments made after Monday 27 November 2023.

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

Clause 30 provides any existing sole traders dealing with therapeutic goods, who are not currently subject to the requirements of the Commonwealth Act, with two years in which they can continue their previously lawful behaviour. At the end of the transitional period, they must thereafter comply with the

requirements of the applied therapeutic goods law. This provides time for sole traders to make any necessary structural adjustments to their operations.

Clause 31 Transitional regulation-making power

This is a Henry VIII clause and is identified as such as per the requirements of the Standing Committee on Uniform Legislation.

Clause 31 provides the ability to make any necessary regulations to deal with transitional matters. The ability to make transitional regulations would exist for two years from commencement of this Act. Because it is a local regulation power, as per Clause 26, transitional regulations may be made that affect the operation of the applied therapeutic goods law.

This power has been provided to allow for any future necessary refinements to the applied therapeutics goods law that might be deemed necessary specifically during the transition period of 2 years that applies from commencement day of this Act.

All regulations made under the applied therapeutic goods law must be tabled with Parliament and reviewed by the Joint Standing Committee on Delegated Legislation. This provides an additional measure of oversight to ensure no inappropriate application of this extended power.

Transitional regulations could not affect or remove a right of a person or impose a liability that has effect prior to the publication date of that regulation. In effect, it can not create a retrospective effect.

Part 8 — Consequential amendments

Part 8 provides for necessary minor technical amendments to several Western Australian Acts which reference the Commonwealth Act.

Clause 32 Act amended

This clause provides for minor technical amendments to the *Human Tissue and Transplant Act 1982* as described below.

Clause 33 Section 29A amended

Section 29A prohibits the unauthorised trading in tissue, where one of the forms of authorised trading can be under the Commonwealth Act.

This clause amends the reference to the Commonwealth Act to include the applied therapeutic goods law to ensure no legislative gap. There is no substantive effect on the operation of the Act or any functions within it.

Clause 34 Act amended

This clause provides for minor technical amendments to the *Medicines and Poisons Act 2014* as described below.

Clause 35 Section 3 amended

This clause amends the reference to the Commonwealth Act to include the applied therapeutic goods law to ensure no legislative gap.

Clause 36 Section 12 amended

This clause amends the definition of an 'appropriate licence' to include the applied therapeutic goods law and ensure no legislative gap.

Clause 37 Section 28 amended

Section 28 lists the Commonwealth Act as one of several Acts where a contravention against those Acts is grounds for taking disciplinary action against a health professional under the *Medicines and Poisons Act 2014*.

This clause amends the reference to the Commonwealth Act to include the applied therapeutic goods law to ensure no legislative gap.

Clause 38 Section 60 amended

Section 60 lists the Commonwealth Act as one of several Acts where a contravention against those Acts is grounds for taking disciplinary action against a licensee or permit holder under the *Medicines and Poisons Act 2014*.

This clause amends the reference to the Commonwealth Act to include the applied therapeutic goods law to ensure no legislative gap.