

CLAUSE NOTES

Pharmacy Control Amendment Bill 2016

- Clause 1 **Short Title**
Provides that the Act will be cited as *Pharmacy Control Amendment Act 2016*
- Clause 2 **Commencement**
Provides for the Act to commence on a day to be proclaimed.
- Clause 3 **Principal Act**
Provides that, in the Bill, the *Pharmacy Control Act 2001* is referred to as the Principal Act.
- Clause 4 **Long Title amended**
This clause amends the long title of the Principal Act to clarify that the Act regulates pharmacy businesses and the registration of pharmacy business premises.
- Clause 5 **Section 3 amended (Interpretation)**
This clause amends section 3 of the Act to modify the way in which certain terms and phrases used in the Act are to be understood.
The clause:
- Simplifies the meaning of “eligible person” to mean a person who holds an eligibility certificate and applies the definition to the whole Act. Previously the definition was in section 71A of the Act and applied to the interpretation of Part 6A only. As it is also relevant to other Parts of the Act it has been moved to s3 Interpretation.
 - Simplifies the language to explain the meaning of “eligibility certificate” by deleting unnecessary words.
 - A new meaning is inserted for “exempt person” to assist legislative interpretation. This term means a person who may hold an interest in a pharmacy business, but due to the ownership structure of that particular pharmacy business or due to the ownership structure they operate under, they are not required to hold an eligibility certificate.

- The definition of “lapsing date” has been moved from Part 6A of the Act to section 3 Interpretation. The new meaning “lapsing date” has also been slightly amended. This term provides that provisions will lapse on 30 June unless another date is prescribed. The amendment also allows the Authority to specify a date on which certain provisions will lapse. This will allow the Authority to issue eligibility certificates in respect of a particular person, pharmacy business or pharmacy business premises for a specified period in certain circumstances; for example for a temporary pharmacy.
- Inserts a new meaning for “owner”. This meaning replaces the term used in the Act of “responsible occupier”. The change to the term “owner” places the responsibility for holding an eligibility certificate and being named in the certificate of registration for the business on the owner of that pharmacy business. This allows other parts of the Bill to place the responsibility to communicate with the Authority on the owners of pharmacy businesses.
- The meaning of “pharmacy business” is moved from this section to a new Section 3A.
- The meaning of “proprietary interest” is repealed. The reasons for the deletion is there was concern regarding the apparent difference between the meaning of “interest” and “proprietary interest” as only the latter phrase is defined and the terms were being used interchangeably. The meaning of interest in a pharmacy business held is now explained in the new Section 3B and has a consistent meaning throughout the Act.
- New meanings are inserted for “relevant pharmacy business” and “relevant pharmacy business premises”. This change differentiates the premises with the business conducted from it. If a premise is used to conduct a pharmacy business, it will be a pharmacy business premises for the purpose of the Act.
- The term “responsible occupier” is repealed and replaced with a definition for the term “owner”.

Clause 6

Sections 3A and 3B inserted

3A. Meaning of “pharmacy business”

This clause inserts or amends the meaning of “pharmacy business” used in the section to clarify.

- The term “dispensing” is inserted into section 3A. It provides that “dispensing” means preparing the narcotic or restricted substances for sale or supply to the public.
- A new term “preparing” is used in the explanation of the term “dispensing”. For the purpose of dispensing, “preparing” includes packaging, labelling or recording the substances.
- The clause clarifies that the terms “medicinal poison”, “narcotic substance”, “potent substance” and “restricted substance”, have the same meaning as in the *Poisons Act 1971*.
- A new meaning is inserted for “pharmacy business” which has been moved from Section 3. The clause now explains a pharmacy business as a business which involves any, or any combination of the following activities:
 - the compounding or dispensing, by a pharmacist, of narcotic substances and restricted substances on the prescription or lawful request of a medical practitioner or other health professional.
 - the sale or supply, by a pharmacist, of potent substances
 - the sale or supply, by a pharmacist or by an employee of that pharmacist under his or her supervision, of medicinal poisons that are in the possession, custody, or control of that or another pharmacist.
- Businesses that hold a licence to sell poisons under section 27 of the *Poisons Act 1971* are not pharmacy businesses within the meaning of that term in this Act.

3B. Meaning of “interest in a pharmacy business”

A new meaning is inserted for the term “interest in a pharmacy business”. This was necessary to make clear the ownership structures in which a pharmacy business can be held and to clarify the meaning of “interest” to make it easier to regulate the holding of an interest in a pharmacy business as pharmacy business structures are frequently becoming more complex. The clause

ensures that holding an interest in a pharmacy business means any legal or beneficial interest in the business, including an interest as a sole proprietor or a partner or a director, member or shareholder of a company or a trustee, beneficiary or unit holder in a trust.

A relevant safety net provision is added in this clause to ensure parties not covered under this section or in commercial structures can included by regulation as being able to hold an interest in pharmacy business.

Clause 7

Section 11 amended (Guidelines)

This clause amends the Act's provisions for Guidelines issued by the Authority by removing the previous provisions and inserting new ones.

The new section provides greater scope for the Authority to issue Guidelines necessary and appropriate to provide practical guidance and direction to pharmacists on the registration and renewal of the registration of a pharmacy business premises, as well as other matters under the Act. It will result in pharmacy businesses being provided additional practical support to meet their regulatory requirements. The Authority can choose whether or not to publish their Guidelines.

Clause 7 inserts Section 11(3) which makes it clear that if guidelines are inconsistent with the provisions of any Act, the provisions of the Act will prevail.

Clause 8

Section 58 amended (Interpretation)

This clause amends the meaning of "relevant party" by removing the term "responsible occupier" and replacing it with the phrase "the owner of the relevant pharmacy business". The definition of "responsible occupier" in section 3 is confusing and creates interpretation difficulties. The renaming of the term in the Act to "the owner of the relevant pharmacy business" makes the role of the position clear and clarifies that responsibility rests with the owner. The term "responsible occupier" has consequently been removed from the Act in clause 5 of this Bill.

Clause 9

Section 59A amended (Powers of Authority following inspection)

This clause repeals the previous section 59A(2) in favour of a new section 59A(2).

The clause clarifies the powers of the Authority following an inspection of the pharmacy business premises to carry out specified works or actions it considers appropriate.

It also gives the Authority the power to direct the relevant party to close and not trade from the pharmacy business premises until the required works or actions have been carried out.

Clause 10

Section 61A amended (Application of Part)

This clause omits the definition of 'lapsing date' as this is dealt with at Section 3.

This clause also omits the definition of 'related party' and replaces it with the term 'close relative' to better reflect the structure of modern families.

A 'close relative' for the purposes of this Act is a pharmacist's:

- Spouse
- Child or grandchild
- Parent or step-parent
- Sibling, including a step-sibling, or
- A child of the pharmacist's spouse, other than their own.

Clause 11

Section 61B amended (Applying to hold an interest in pharmacy business)

The references to how an interest in a pharmacy business can be held are amended to make clear the ownership structures a pharmacy business can be held. For example, to not allow specialised trust structures may create legal and commercial challenges for many pharmacy businesses. The clause also makes changes to make it consistent with associated minor amending provisions regarding "lapsing date" and "exempt person".

In summary, superfluous and ambiguous language is simplified without changing the intent of the original section.

Clause 12

Section 61C amended (Eligibility)

This clause simplifies language and clarifies that a person is to hold an interest in a pharmacy business if they meet the criteria set out in this section.

This clause amends Section 61C to:

- Ensure gender-neutral language
- Reflect that natural persons, partnerships and body corporate commercial structures can be 'eligible persons' under this section
- Clarify that the criteria of the section applies to all eligible persons
- Updates terms changed within previous clauses of this Bill.
- In the case of a body corporate, clarify that an eligible person to hold an interest in a pharmacy business includes a trustee of another trust, each beneficiary or unit holder of which is a pharmacist or a close relative of a pharmacist.

Clause 13

Section 61D amended (Exemptions)

This clause clarifies, by making a minor grammatical amendment, the requirement to apply for an eligibility certificate by omitting "applying" and replacing it with "the requirement to apply".

The term "or unit holder in" is added to subsection (b) to include unit holders as well as beneficiaries of a trust as exempt under this section.

Clause 14

Section 61E amended (Annual renewal of eligibility certificate)

This clause simplifies the language by removing an ambiguous phrase.

Clause 15

Section 61F inserted

This clause inserts a new section after section 61E in Part 5A to clarify who must hold an eligibility certificate.

61F. Persons are not required to hold more than one eligibility certificate

The Act's terminology is currently ambiguous regarding the scope of an Eligibility Certificate. This clause requires all owners of pharmacy businesses to hold an eligibility certificate. Owners will not be required to hold separate eligibility certificates for each pharmacy business they own unless their interest in those pharmacy business is held in different legal capacities (eg, a partnership or trust). An eligibility certificate will be required for

each interest held in a different legal capacity.

Clause 16 Section 62 amended (Offence for certain persons to hold interest in pharmacy business &c.)

This clause simplifies section 62 by removing unnecessary phrases without changing the intent of the original section.

Clause 17 Section 65 amended (Limitation on number of pharmacies in which person may have interest)

This clause repeals and replaces outdated terminology.

The clause is amended to make it clear that the pharmacy ownership limitation provisions also apply to beneficiaries and shareholders of trusts.

This clause also inserts a new paragraph to clarify that pharmacy business premises, exempt by the Authority from registration for a period not longer than 3 months under S.71J are not included in the four pharmacy business limit provided for under s.65. Eg. A temporary individual pharmacy business premises set up to conduct routine vaccinations.

Clause 18 Section 70A amended (Failure to notify Authority)

Clause 18 amends the meaning of the term 'relevant event'. It generally clarifies and applies gender neutral language to the existing section 70A which sets out certain events that pharmacists have an obligation to notify the Tasmanian Pharmacy Authority of which are indicative of unethical behaviour.

It also provides that a body corporate must also notify the Authority when:

- there is a change of membership; or
- there is a change to the particulars of the body corporate.

It also defines the meaning of a "scheduled substance" to refer to the national standard set by the Australian regulatory body.

Clause 19 Section 71A repealed

This clause repeals section 71A.

This section is no longer required as the definitions in this Part have been amended and moved to section 3 of the Act to aid interpretation for the entire Act, not just Part 6A.

- Clause 20** **Part 6A, Division 1: Heading inserted**
- This clause amends Part 6A by inserting the heading 'Division 1 – Preliminary' before section 71B to aid interpretation.
- Clause 21** **Part 6A, Division 2: Heading inserted**
- This clause amends Part 6A by inserting the heading 'Division 2 – Registration' after section 71B to aid the reader in the purpose of this Part.
- Clause 22** **Section 71E amended (Consideration of applications for registration of pharmacy business premises)**
- This clause repeals subsection 71E(2)(b) which requires the premises sought to be registered to be used solely for the purposes of a pharmacy. The subsection is superfluous and unnecessary.
- Clause 23** **Section 71F amended (Approval or refusal of applications)**
- The intent of the original clause remains. The clause replaces the previous section 71F(3)(c). When refusing an application to register a business premises the Authority is to give notice to the applicant of their right to appeal the refusal.
- Clause 24** **Section 71G amended (Nature of registration of pharmacy business premises)**
- This clause clarifies that the lapsing date of pharmacy business registration is related to the date upon which the notice takes effect.
- Clause 25** **Section 71H amended (Registration of pharmacy business premises may be cancelled or suspended)**
- This clause repeals outdated terms in favour of new terms brought in by this Bill.
- This clause makes clear:
- any failure to comply with action required by the Authority following an inspection of the premises under section 59A(1)(b), is grounds for cancellation or suspension of registration
 - responsibility rests with pharmacy business owners
 - the owner has a right to appeal any cancellation or

suspension of their registration

- cancellation takes effect when the Authority gives notice to the owner, or where a business is jointly owned, ideally all owners, but where this is not possible after making a reasonable attempt to do so, and it is unable to do so, it will be sufficient if at least one owner receives the notice. Cancellation may also take effect on a specified date in the notice.

This clause also repeals paragraph (7), which required certificates of registration of pharmacy businesses to be returned to the Authority upon cancellation. The clause is redundant as certificates are sent electronically to the Authority.

Clause 26

Section 7II amended (Registration of pharmacy business premises may be relinquished)

This clause clarifies how registration of pharmacy business premises may be relinquished by the owners by repealing the existing subsection (1) and inserting new subsections (1) and (1A).

The new subsections allow for owners to relinquish registration at any time. To be effective, the owner must give notice to the Authority that they are relinquishing their registration. Where there is more than one owner, all owners must give notice to the Authority, either separately or jointly. This ensures that valuable business interests of pharmacy business owners who own a business jointly or in a partnership are protected.

The clause removes the ambiguity of subsection (2) of the Principal Act to remove ambiguity.

Subsection (3) is repealed and replaced with a new subsection (3) to stipulate that pharmacy businesses are not entitled to a refund when cancelling pharmacy business premise registration.

Clause 27

Section 7IJ amended (Premises exempt from registration requirements)

This clause inserts subsection (3A) which empowers the Authority to request such further information as it considers necessary when assessing an application for exemption from registration.

Clause 28

Section 7IK substituted (Annual renewal of registration)

This clause repeals Section 7IK and replaces it with a new section

71K. The new Section 71K removes and replaces redundant terms. This clause focuses on the renewal of the registration of the pharmacy business premises.

The requirements for renewal are:

- Registration must be renewed on or before it is time to renew.
- The application to renew must be on the approved form and lodged with the Authority. If a fee applies then that fee should be included with the application form as well as any other information the Authority may require.

This clause gives the power to the Authority to require information, waive fees or consider the application in the event that it has been lodged after the previous registration expired.

The Authority is given powers to renew or refuse the registration. Grounds for refusal to renew are set. They include:

- Where application is not on the approved form, lodged with the Authority or includes the relevant fee, or
- Where information required by the Authority has not been provided.
- Where the Authority reasonably believes the pharmacy business premises no longer meet the eligibility criteria.
- Where the Authority believes material facts in regards to the pharmacy business premises have changed since the original application.
- Or the application is made more than 30 days after the expiry of the previous registration.

This clause requires the Authority to notify the pharmacy business owner if they refuse to renew the business registration. The Authority must advise why the application was refused and that the applicant may appeal the decision.

This clause ensures that businesses that have applied for renewal of their registration within the required time period will remain registered until the Authority makes an assessment on their renewal application.

Clause 29

Part 6A, Division 3 inserted

This clause inserts a new Division into the Principal Act to clearly address alterations to pharmacy business premises:

Division 3 – Alterations

This clause inserts the following sections into the new division of the Principal Act:

Clause 30

71KA. Interpretation of Division

This clause inserts a new meaning for 'alteration' to include temporary or permanent alteration to any part of the pharmacy business premises which will affect or interfere with dispensing or storage of drugs or medicines, access or security arrangement to the pharmacy business premises or any other professional activities of the pharmacist.

71KB. Alterations to pharmacy business premises require approval

This clause is included to prohibit the owner of pharmacy businesses to allow any alterations to the premises without prior approval from the Authority.

A fine is prescribed for undertaking alterations without the Authority's permission.

Where the business has more than one owner, it is sufficient for one owner to request permission from the Authority on behalf of the business.

71KC. Applications for approval of alterations to pharmacy business premises

This clause sets out the requirements for seeking approval from the Authority for alterations to pharmacy business premises. It allows for the Authority to request further information it considers necessary and provides discretion to waive all or part of the application fee.

71KD. Consideration of application for approval of alteration to pharmacy business premises

This clause provides for the Authority to grant or refuse an application to alter a pharmacy business premises. It provides parameters for approval to ensure alterations will be suitable for the purposes of a pharmacy and the pharmacy will not be located within a supermarket or provide access to the premises directly

from or to a supermarket.

This clause guides the Authority on matters to consider when granting approval for alterations. These matters include consideration of whether alterations will affect the requirements for that pharmacy's business premises registration under s 71E(3).

71KE. Approval or refusal of applications

This clause requires the Authority to give the applicant notice as soon as practicable of the approval of the application and associated details of that approval.

Where the application is refused, the Authority must provide notice to the applicant as soon as practical of that refusal, the date, reasons and the applicant's right to appeal the refusal.

Clause 31

Part 6A, Division 4: Heading inserted

Part 6A of the Principal Act is amended by inserting a new heading before section 71L:

Division 4 – Registration notices

Clause 32

Sections 71KF and 71KG inserted

This clause inserts new sections into the new Division 4.

71KF. Notice of events disruptive to registered pharmacy business premises

This clause inserts meanings for the following new terms:

'appropriate notice' is a notice that advises and sets out full particulars of an event.

'disruptive event' is an unforeseen event that directly affects the business and its ability to carry on its business activities. Examples are specified in the definition.

'extended period' is to be longer than three days.

This clause requires that the owner, or one of the owners, where there is more than one, of a pharmacy business provide the Authority with notice of a disruptive event within 7 days of that event. A fine is prescribed for failure to notify the Authority of such an event.

The Authority may request further information about the event

from the owner who gave notice. A fine is prescribed for failure to provide any further information requested.

71KG. Notice of important events relevant to registration of pharmacy business premises

This clause inserts meanings for the following new terms:

'appropriate notice' – means a notice advising and setting out full particulars of any event.

'major change' – means any changes to leasehold arrangements. Examples are in the definition.

This clause requires the owner, or one of the owners where the business is owned jointly, of the pharmacy business to notify the Authority within 14 days of any change when the business is abandoned, wound up due to retirement or incapacity, when the interests in the business change, either legally or otherwise, any major change is made to leasehold arrangements or when a prescribed event occurs.

A fine not exceeding 2 penalty units is prescribed for owners for failure to provide appropriate notice to the Authority.

The Authority may request further information regarding the event from the owner who gave notice. This clause prescribes a fine not exceeding 2 penalty units for failure to provide further information as requested.

Clause 33

Part 6A, Division 5: Heading inserted

Part 6A of the Principal Act is amended by inserting a new heading before section 71L to logically divide up related information:

Division 5 – Register

Clause 34

Section 71L amended (Register)

This clause repeals paragraph (2)(a) and inserts a new paragraph (2)(a) which requires the Authority to record the name of the owner, or owners of the pharmacy business premises.

Clause 35

Section 73 amended (Information requirements)

The term 'corporate provider' is repealed as it is redundant.

This clause inserts a new term 'information' to mean documents,

access to documents and copies of documents.

This clause inserts a new subsection (1A) to require the owner of a pharmacy business to give to the Authority any relevant information it may require.

This clause repeals the current subsection (2) and inserts a new subsection (2) to clarify that where a business is owned as a body corporate, partnership or trust, the owners may be required to provide relevant information on the ownership structure.

Redundant terms are repealed and replaced with updated terms to provide clarity.

This clause makes clear that where a business is owned by more than one person, the obligations of this section apply to all owners however, it will be sufficient for one owner to give appropriate notice to discharge the correspondence obligation on other owners in respect to that notice.

Clause 36 **Section 74 amended (Service of documents)**

This clause repeals references which allow documents to be provided by facsimile.

Clause 37 **Repeal of Act**

This clause provides for the *Pharmacy Control Amendment Act 2016* to be repealed 365 days from the day it commences.