TASMANIA

PHARMACY CONTROL AMENDMENT BILL 2016

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PHARMACY CONTROL AMENDMENT BILL 2016

(Brought in by the Minister for Health, the Honourable Michael Darrel Joseph Ferguson)

A BILL FOR

An Act to amend the Pharmacy Control Act 2001

Be it enacted by Her Excellency the Governor of Tasmania, by and with the advice and consent of the Legislative Council and House of Assembly, in Parliament assembled, as follows:

1. Short title

This Act may be cited as the *Pharmacy Control Amendment Act 2016*.

2. Commencement

This Act commences on a day to be proclaimed.

3. Principal Act

In this Act, the *Pharmacy Control Act 2001** is referred to as the Principal Act.

4. Long title amended

The long title of the Principal Act is amended by inserting "business" after "registration of pharmacy".

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^{*}No. 90 of 2001

5. Section 3 amended (Interpretation)

Section 3 of the Principal Act is amended as follows:

- (a) by inserting the following definition after the definition of *committee*:
 - eligible person means a person who holds an eligibility certificate;
- (b) by omitting "an eligibility certificate" from the definition of *eligibility* certificate and substituting "a certificate";
- (c) by inserting the following definition after the definition of *eligibility certificate*:
 - exempt person means a person who is exempt, under section 61D, from the requirement to apply for an eligibility certificate;
- (d) by inserting the following definitions after the definition of *inspection*:
 - interest in a pharmacy business see
 section 3B;
 - *lapsing date*, for a provision of this Act, means
 - (a) 30 June or, if another date is prescribed for the provision, that other date; or

- (b) if the Authority determines in respect of a particular person, pharmacy business business pharmacy premises that a date other than the date specified or prescribed under paragraph (a) this of definition should be the lapsing date for the provision, the other date so determined by Authority for that person business or those premises;
- (e) by inserting the following definition after the definition of *notice*:
 - owner, of a pharmacy business, means the person or persons for the time being holding an eligibility certificate and named in the certificate of registration for the relevant pharmacy business premises;
- (f) by omitting the definition of *pharmacy* business and substituting the following definition:

pharmacy business – see section 3A;

(g) by omitting the definition of *proprietary interest*;

- (h) by inserting the following definitions after the definition of *registration board*:
 - relevant pharmacy business, in relation to any pharmacy business premises, means the pharmacy business carried on in or from those premises;
 - relevant pharmacy business premises in relation to a pharmacy business, means the premises in or from which the business is carried on;
- (i) by omitting the definition of *responsible* occupier.

6. Sections 3A and 3B inserted

After section 3 of the Principal Act, the following sections are inserted in Part 1:

3A. Meaning of "pharmacy business"

- (1) In this section
 - dispensing, of narcotic substances or restricted substances, means preparing the narcotic substances or restricted substances for sale or supply to members of the public;
 - *preparing* includes packaging, labelling and recording.

- (2) In this section, the following expressions have the same meaning as they have in the *Poisons Act 1971*
 - (a) medicinal poison;
 - (b) narcotic substance;
 - (c) potent substance;
 - (d) restricted substance.
- (3) For the purposes of this Act, a business is a pharmacy business if it involves any or any combination of the following activities:
 - (a) 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;
 - (b) the sale or supply, by a pharmacist, of potent substances;
 - (c) 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.

(4) To avoid doubt, a business that is carried on by a person to whom section 27 of the *Poisons Act 1971* applies is not a pharmacy business for this Act.

3B. Meaning of "interest in a pharmacy business"

- (1) For the purposes of this Act, the expression *interest in a pharmacy business* means any legal or beneficial interest in the business, including an interest as
 - (a) a sole proprietor; or
 - (b) a partner; or
 - (c) a director, member or shareholder of a company as defined in the Corporations Act; or
 - (d) a trustee or beneficiary of, or unit holder in, a trust.
- (2) Without limiting the generality of subsection (1), a person will be taken to have an interest in a pharmacy business for the purposes of this Act if the person is party to an arrangement of a kind prescribed by the regulations.

7. Section 11 substituted

Section 11 of the Principal Act is repealed and the following section is substituted:

11. Guidelines

(1) The Authority may issue guidelines from time to time to provide practical guidance and direction to persons on the registration and renewal of registration of pharmacy business premises and other matters under this Act.

(2) The guidelines –

- (a) are to be written in plain language, follow a consistent style and format, and be as brief as possible consistent with their intended application; and
- (b) may be made so as to apply differently according to such matters, limitations or restrictions, whether as to time, location, circumstance or otherwise, as are specified in them; and
- (c) may confer responsibilities and discretionary responsibilities on the Authority; and
- (d) may not purport to impose sanctions for any failure to comply with them; and
- (e) may not contain provisions that are repugnant to the provisions of this or any other Act.

- (3) In the event that the provisions of any guideline are inconsistent with the provisions of any Act, the provisions of the Act always prevail.
- (4) The Authority may publish guidelines as it thinks fit having regard to their intended application.
- (5) No fee is chargeable or payable for issuing, supplying, obtaining or accessing a copy of any guidelines.
- (6) Guidelines are not
 - (a) statutory rules for the purposes of the *Rules Publication Act 1953*; or
 - (b) instruments of a legislative character for the purpose of the *Subordinate Legislation Act* 1992.
- (7) Guidelines are taken to be instruments to which section 22 of the *Acts Interpretation Act 1931* applies.

8. Section 58 amended (Interpretation)

Section 58 of the Principal Act is amended by omitting "responsible occupier" from paragraph (a) of the definition of *relevant party* and substituting "owner of the relevant pharmacy business".

9. Section 59A amended (Powers of Authority following inspection)

Section 59A of the Principal Act is amended by omitting subsection (2) and substituting the following subsection:

(2) If the Authority determines that action is required by the relevant party pursuant to subsection (1)(b), the Authority may direct the relevant party to carry out specified works or actions in relation to the pharmacy business premises and, if it considers it appropriate to do so in the circumstances, further direct the relevant party to close, and not trade from, the pharmacy business premises until those works or actions have been carried out.

10. Section 61A amended (Application of Part)

Section 61A(3) of the Principal Act is amended as follows:

- (a) by omitting the definition of *lapsing* date:
- (b) by omitting the definition of *related* party and substituting the following definition:

close relative, of a pharmacist, means –

(a) the spouse of the pharmacist; or

- (b) the son, daughter, grandson or granddaughter of the pharmacist; or
- (c) any child of the spouse of the pharmacist, of whom the pharmacist is not the natural parent; or
- (d) the father, stepfather, mother, or stepmother of the pharmacist; or
- (e) the brother, step-brother, sister or step-sister of the pharmacist;

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

Section 61B of the Principal Act is amended as follows:

- (a) by omitting from subsection (1) ", including a proprietary interest,";
- (b) by omitting from subsection (1) ", unless that person is exempt pursuant to section 61D" and substituting "(an *eligibility certificate*), unless the person is an exempt person";
- (c) by omitting from subsection (3) ", upon receipt of an application,";

- (d) by omitting from subsection (7) "earlier of –" and substituting "earlier of the following:";
- (e) by omitting paragraph (a) from subsection (7) and substituting the following paragraph:
 - (a) the lapsing date following its date of issue;
- (f) by omitting paragraph (c) from subsection (8) and substituting the following paragraph:
 - (c) the right to appeal the refusal.

12. Section 61C amended (Eligibility)

Section 61C of the Principal Act is amended as follows:

- (a) by omitting from subsection (1) ", including a proprietary interest, in a pharmacy business if" and substituting "in a pharmacy business if, and only if";
- (b) by omitting from subsection (1)(a) "that person" and substituting "in the case of a natural person, he or she";
- (c) by omitting from subsection (1)(c)(ii) "related party" first occurring and substituting "close relative";

- (d) by omitting from subsection (1)(c)(ii)(B) "related party" and substituting "close relative";
- (e) by omitting paragraph (b) from subsection (2) and substituting the following paragraphs:
 - (b) a close relative of a pharmacist;
 - (c) a trustee of another trust, each beneficiary or, if applicable, each unit holder of which is
 - (i) a pharmacist; or
 - (ii) a close relative of a pharmacist.

13. Section 61D amended (Exemptions)

Section 61D of the Principal Act is amended as follows:

- (a) by omitting "applying" and substituting "the requirement to apply";
- (b) by inserting in paragraph (b) "or unit holder in" after "beneficiary of".

14. Section 61E amended (Annual renewal of eligibility certificate)

Section 61E(7) of the Principal Act is amended by omitting paragraph (c) and substituting the following paragraph:

(c) the right to appeal the refusal.

15. Section 61F inserted

After section 61E of the Principal Act, the following section is inserted in Part 5A:

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

- (1) Subject to section 65, an eligibility certificate has effect for multiple pharmacy businesses and, accordingly, a person who holds an interest in more than one pharmacy business is not required to hold more than the one eligibility certificate in respect of those interests.
- (2) However, subsection (1) applies only if, and only to the extent that, the person holds the various interests in the same legal capacity.

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

Section 62(1) of the Principal Act is amended as follows:

- (a) by omitting ", including a proprietary interest,";
- (b) by omitting paragraph (b) and substituting the following paragraph:
 - (b) the person is an exempt person.

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

Section 65 of the Principal Act is amended as follows:

- (a) by omitting from subsection (1) ", hold an interest, including a proprietary interest" and substituting "or as a trustee, beneficiary or unit holder of a trust, hold an interest";
- (b) by omitting "premises." from the definition of *pharmacy business* in subsection (2) and substituting "premises;";
- (c) by inserting the following definition after the definition of *pharmacy business* in subsection (2):
 - premises does not include individual premises that are the subject of an exemption under section 71J that has been granted for a period not exceeding 3 months.

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

Section 70A(1) of the Principal Act is amended by omitting the definition of *relevant event* and substituting the following definitions:

relevant event, in relation to a person, means –

- (a) for an individual
 - (i) his or her registration as a pharmacist under the Health Practitioner Regulation National Law (Tasmania) is suspended or cancelled or made subject to a condition or another restriction; or
 - (ii) he or she is charged, whether in this State or elsewhere, with an offence punishable by imprisonment for a term of 12 months or longer; or
 - (iii) he or she is convicted of, or is the subject of a finding of guilt for, an offence, whether in this State or elsewhere, punishable by imprisonment; and
- (b) for a body corporate, there is a change to the membership or

particulars of the body corporate; and

- (c) for any person
 - (i) the person's authority under a law of a State or Territory to obtain, possess, sell or supply a scheduled medicine or a class of scheduled medicines is cancelled or restricted; or
 - (ii) there is a change of trustees, beneficiaries or, if applicable, unit holders of a trust in which the person has any legal or equitable interest, being a trust that holds an interest in a pharmacy business in this State;

included for the time being in Schedule 2, 3, 4 or 8 to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) produced by the Australian Committee for Chemicals Scheduling (AACS), being a committee of the regulatory body known as the Therapeutic Goods Administration (TGA), which is a part of the Commonwealth Government Department

responsible for the administration of the *Therapeutic Goods Act 1989*;

19. Section 71A repealed

Section 71A of the Principal Act is repealed.

20. Part 6A, Division 1: Heading inserted

Part 6A of the Principal Act is amended by inserting the following heading before section 71B:

Division 1 – Preliminary

21. Part 6A, Division 2: Heading inserted

Part 6A of the Principal Act is amended by inserting the following heading after section 71B:

Division 2 – Registration

22. Section 71E amended (Consideration of applications for registration of pharmacy business premises)

Section 71E(2) of the Principal Act is amended by omitting paragraph (b).

23. Section 71F amended (Approval or refusal of applications)

Section 71F(3) of the Principal Act is amended by omitting paragraph (c) and substituting the following paragraph:

(c) the right to appeal the refusal.

24. Section 71G amended (Nature of registration of pharmacy business premises)

Section 71G(1) of the Principal Act is amended by inserting "following the date on which it takes effect" after "date".

25. Section 71H amended (Registration of pharmacy business premises may be cancelled or suspended)

Section 71H of the Principal Act is amended as follows:

- (a) by omitting paragraph (c) from subsection (1) and substituting the following paragraph:
 - (c) there has been, in respect of the premises, a failure to comply with a decision of the Authority made pursuant to section 59A(1)(b) within the time specified in a notice under section 59A(1) or, if no time is specified, within a time that the Authority considers reasonable.

- (b) by omitting from subsection (3) "responsible occupier of the premises" and substituting "owner of the relevant pharmacy business";
- (c) by omitting paragraph (d) from subsection (3) and substituting the following paragraph:
 - (d) the right to appeal the cancellation or suspension.
- (d) by omitting subsection (4) and substituting the following subsections:
 - (4) The cancellation takes effect when the notice under subsection (3) is given to the owner of the relevant pharmacy business premises or on such later date as is specified in the notice.
 - (4A) Where the relevant pharmacy business is jointly owned, the Authority is to give each of the owners notice under subsection (3) but if, after making a reasonable attempt, it is unable to do so, subsection (4) still applies provided at least one of the owners has been given the notice.
- (e) by omitting from subsection (6) "responsible occupier of the premises" and substituting "owner of the relevant pharmacy business";

- (f) by omitting subsection (7).
- 26. Section 71I amended (Registration of pharmacy business premises may be relinquished)

Section 71I of the Principal Act is amended as follows:

- (a) by omitting subsection (1) and substituting the following subsections:
 - (1) The registration of pharmacy business premises may be relinquished at any time.
 - (1A) To effect the relinquishment, the owner of the relevant pharmacy business or, if it is jointly owned, each of the owners jointly or severally is to give an appropriate notice to the Authority.
- (b) by omitting from subsection (2) "the notice" and substituting "notice in accordance with subsection (1A)";
- (c) by omitting subsection (3) and substituting the following subsection:
 - (3) No entitlement to a refund of registration or other fees arises by reason of the relinquishment of registration.

27. Section 71J amended (Premises exempt from registration requirements)

Section 71J of the Principal Act is amended by inserting after subsection (3) the following subsection:

(3A) The Authority may require an applicant for an exemption to provide such further information or evidence as it considers necessary in order to consider the application.

28. Section 71K substituted

Section 71K of the Principal Act is repealed and the following section is substituted:

71K. Annual renewal of registration

- (1) The registration of pharmacy business premises is from time to time renewable.
- (2) To effect the renewal, the owner of the relevant pharmacy business is to lodge an application with the Authority on or before the lapsing date.
- (3) The application is to be
 - (a) in an approved form; and
 - (b) lodged with the Authority; and
 - (c) accompanied by the prescribed renewal fee, if any; and

- (d) supported by such information or evidence as the Authority requires.
- (4) The Authority may require the applicant to provide such further information or evidence as it considers necessary in order to consider the application.
- (5) The Authority may waive all or part of the renewal fee.
- (6) If for any reason the application is not lodged on or before the lapsing date, the Authority may still consider the application if it is
 - (a) lodged no later than 30 days after the lapsing date; and
 - (b) accompanied by, in addition to the renewal fee, the prescribed late fee.
- (7) The Authority, after considering the application may
 - (a) renew the registration; or
 - (b) refuse to renew the registration.
- (8) The Authority may refuse to renew the registration if
 - (a) the applicant fails to comply with subsection (3) or (4); or

- (b) the Authority reasonably believes that the pharmacy business premises no longer meet the criteria for eligibility having regard to the matters set out in section 71E(3); or
- (c) the Authority is satisfied that material facts or matters relied upon in support of the original application, including, in the case of a body corporate, details of its membership, have changed; or
- (d) the application is made more than 30 days after the lapsing date.
- (9) If the Authority refuses to renew the registration, it is to give the applicant notice of
 - (a) the refusal; and
 - (b) the reason for the refusal; and
 - (c) the right to appeal the refusal.
- (10) If the application is made on or before the lapsing date or within 30 days after the lapsing date, the registration of the pharmacy business premises is taken to continue until the earlier of the following:
 - (a) the date upon which the Authority renews the registration;

(b) the date upon which the Authority gives a notice under subsection (9).

29. Part 6A, Division 3: Heading inserted

Part 6A of the Principal Act is amended by inserting the following heading after section 71K:

Division 3 – Alterations

30. Sections 71KA, 71KB, 71KC, 71KD and 71KE inserted

Before section 71L of the Principal Act, the following sections are inserted in Division 3:

71KA. Interpretation of Division

In this Division –

alteration, to pharmacy business premises, means any alteration, whether permanent or temporary, that is likely to affect or interfere with –

- (a) the dispensing of medicines or drugs on the premises; or
- (b) the storage of medicines or drugs on the premises; or

- (c) access to the premises; or
- (d) the security arrangements for the premises or any part thereof; or
- (e) the professional activities of the pharmacist.

71KB. Alterations to pharmacy business premises require approval

(1) The owner of a pharmacy business must not cause or allow an alteration to be made to the relevant pharmacy business premises unless the alteration has been approved by the Authority.

Penalty: Fine not exceeding 20 penalty units.

(2) If a pharmacy business is owned by 2 or more persons jointly, the obligation of those persons under subsection (1) is joint and several but the discharge of that obligation by one owner also discharges the corresponding obligation of each other owner.

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

(1) An application for an approval under section 71KB is to be –

- (a) in an approved form; and
- (b) signed by the owner of the relevant pharmacy business or, if it is jointly owned, at least one of the owners; and
- (c) lodged with the Authority; and
- (d) accompanied by the prescribed fee, if any; and
- (e) accompanied by such information or evidence as the Authority requires.
- (2) The Authority may require the applicant to provide such further information or evidence as it considers necessary in order to consider the application.
- (3) The authority may waive all or part of the fee.

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

- (1) The Authority, after considering an application for an approval under section 71KB, may
 - (a) grant the application subject to any conditions that the Authority thinks fit to impose; or
 - (b) refuse the application.

- (2) However, the Authority must not grant the application unless it is satisfied that, the pharmacy business premises, as proposed to be altered
 - (a) will be suitable to be used for the purposes of a pharmacy business; and
 - (b) will not be
 - (i) located wholly or partly within a supermarket; or
 - (ii) capable of being entered from within a supermarket; or
 - (iii) capable of being used to gain entry to a supermarket.
- (3) The matters that the Authority may have regard to for the purposes of subsection (2)(a) include the matters referred to in section 71E(3).

71KE. Approval or refusal of applications

- (1) As soon as practicable after granting an application for an approval under section 71KB the Authority is to give the applicant notice of
 - (a) the approval; and
 - (b) the date of the approval; and

- (c) if applicable, the conditions of the approval; and
- (d) if paragraph (c) applies, the right to appeal the conditions of the approval.
- (2) As soon as practicable after refusing an application for an approval under section 71KB, the Authority is to give the applicant notice of
 - (a) the refusal; and
 - (b) the date of the refusal; and
 - (c) the reasons for the refusal; and
 - (d) the right to appeal the refusal.

31. Part 6A, Division 4: Heading inserted

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

Division 4 – Registration notices

32. Sections 71KF and 71KG inserted

Before section 71L of the Principal Act, the following sections are inserted in Division 4:

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

(1) In this section –

- appropriate notice, of the occurrence of an event, means a notice advising, and setting out full particulars, of the event;
- disruptive event, in relation to pharmacy business premises, means
 - (a) a fire, flood or other damaging event that prevents, or is likely to prevent, a pharmacy business being carried on in or from the premises for an extended period; or
 - (b) an interruption to the supply of electricity, gas, water or another service to the premises that lasts, or is likely to last, for an extended period; or
 - (c) an event prescribed by the regulations;

extended period means a period exceeding 3 days.

(2) The owner of a pharmacy business must give the Authority appropriate notice of the occurrence of a disruptive event in relation to the relevant pharmacy business premises within 7 days after that occurrence.

Penalty: Fine not exceeding 2 penalty units.

- (3) If a pharmacy business is owned by 2 or more persons jointly, the obligation of those persons under subsection (2) is joint and several but the discharge of that obligation by one owner also discharges the corresponding obligation of each other owner.
- (4) A person who gives the Authority notice of the occurrence of a disruptive event under subsection (2) must, on written request, give the Authority any further information it may require concerning the disruptive event.

Penalty: Fine not exceeding 2 penalty units.

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

(1) In this section –

appropriate notice, of the occurrence of an event, means a notice advising, and setting out full particulars, of the event;

major change, to leasehold arrangements, means –

(a) a transfer or assignment of the lease; or

- (b) a change to the term of the lease (including the extension of term or renewal options, if any); or
- (c) a change to the way in which the rent is calculated; or
- (d) the expiration of the lease; or
- (e) a change to the obligations of the parties for and in respect of the condition or maintenance of the premises leased.
- (2) The owner of a pharmacy business must give the Authority appropriate notice within 14 days if
 - (a) the person, or all persons, carrying on the pharmacy business abandon it; or
 - (b) the pharmacy business is, because of the retirement or physical incapacity of any person, or for any other reason, wound up; or
 - (c) there is a change in respect of any interests held in the relevant pharmacy business premises, whether as to the identity or number of the interest holders.

- the quantum, apportionment or legal nature of the interests or otherwise; or
- (d) where the pharmacy business occupies the relevant pharmacy business premises under lease, there is a major change to the leasehold arrangements; or
- (e) a prescribed event relevant to the registration of the relevant pharmacy business premises occurs.

Penalty: Fine not exceeding 2 penalty units.

- (3) If a pharmacy business is owned by 2 or more persons jointly, the obligation of those persons under subsection (2) is joint and several but the discharge of that obligation by one owner also discharges the corresponding obligation of each other owner.
- (4) A person who gives the Authority notice of the occurrence of an event under subsection (2) must, on written request, give the Authority any further information it may require concerning the event.

Penalty: Fine not exceeding 2 penalty units.

33. Part 6A, Division 5: Heading inserted

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

Division 5 – Register

34. Section 71L amended (Register)

Section 71L(2) of the Principal Act is amended by omitting paragraph (a) and substituting the following paragraph:

(a) the name of the owner of the relevant pharmacy business or, if it is jointly owned, each of the owners;

35. Section 73 amended (Information requirements)

Section 73 of the Principal Act is amended as follows:

(a) by omitting the definition of *corporate* provider from subsection (1) and substituting the following definition:

information includes documents,
 access to documents and copies
 of documents;

(b) by inserting the following subsection after subsection (1):

- (1A) The Authority, by notice, may require the owner of a pharmacy business to give it
 - (a) any information about the pharmacy business or the conduct of the pharmacy business; or
 - (b) any other relevant information.
- (c) by omitting subsection (2) and substituting the following subsection:
 - (2) Without limiting its generality, under subsection (1A) the owner of a pharmacy business may be required to give the Authority
 - (a) in the case of a body corporate
 - (i) any relevant information about its membership, shareholdings, officers or employees; and
 - (ii) any other relevant information about its structure, management or operations; and

- (iii) a copy of its replaceable rules or constitution; and
- (b) in the case of a partnership, a copy of the partnership deed; and
- (c) in the case of a person whose interest in the pharmacy business is held in trust
 - (i) a copy of the trust deed; and
 - (ii) relevant information about the trustees or beneficiaries of or, if applicable, unit holders in the trust.
- (d) by omitting from subsection (3) "A corporate provider" and substituting "The owner of a pharmacy business";
- (e) by inserting the following subsection after subsection (3):
 - (4) If a pharmacy business is owned by 2 or more persons jointly, the obligation of those persons under subsection (3) in respect of a notice is joint and several but the

discharge of that obligation by one owner in respect of the notice also discharges the corresponding obligation of each other owner in respect of the same notice.

36. Section 74 amended (Service of documents)

Section 74 of the Principal Act is amended as follows:

- (a) by omitting paragraph (b) from subsection (1);
- (b) by omitting subparagraph (iii) from subsection (2)(a);
- (c) by omitting subparagraph (ii) from subsection (2)(b).

37. Repeal of Act

This Act is repealed on the three hundred and sixty fifth day from the day on which it commences.