

## **Division 3A—Therapeutic goods advertisements for which an approval is not required**

### **42DKA Application of Division**

This Division applies to advertisements about therapeutic goods other than advertisements for which an approval is required under Part 2 of the *Therapeutic Goods Regulations 1990*.

### **42DKB Certain representations not to be published or broadcast**

- (1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to the person apparently responsible for publishing or broadcasting the advertisement, prevent that person from publishing or broadcasting, or causing to be published or broadcast, an advertisement containing that representation (whether express or implied) about those goods.
- (2) A notice under subsection (1) is not a legislative instrument.

### **42DL Advertising offences**

- (1) A person must not publish or broadcast an advertisement about therapeutic goods:
  - (a) that contains a prohibited representation (whether in express terms or by necessary implication) about those goods; or
  - (b) that does not contain a required representation about those goods; or
  - (c) that contains a restricted representation, about those goods, the use of which has not been approved under subsection 42DF(1) or permitted under subsection 42DK(1); or
  - (d) that is in contravention of a notice referred to in section 42DKB that was given to the person; or
  - (e) that contains:
    - (i) a reference to the Act other than in a statement of the registration number, listing number or device number of the goods; or

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- (ii) a statement suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than a statement of their availability as a pharmaceutical benefit or a statement authorised or required by a government or government authority (including a foreign government or foreign government authority); or
- (f) that contains a statement referring to goods, or substances or preparations containing goods, included in Schedule 3, 4 or 8 to the current Poisons Standard, other than a statement authorised or required by a government or government authority (including a foreign government or foreign government authority); or
- (g) that are not entered in the Register; or
- (h) if the goods are therapeutic goods, or come within a class of therapeutic goods, that:
  - (i) are exempt goods or exempt devices prescribed in the regulations for the purposes of this provision; or
  - (ii) have been approved under subsection 19(1) or section 41HB of this Act for importation into, exportation from, or supply within, Australia.

Penalty: 60 penalty units.

- (2) For the purposes of an offence against subsection (1), strict liability applies to the following physical elements:
  - (a) that the use of a restricted representation, as referred to in paragraph (1)(c), has not been approved under subsection 42DF(1) or permitted under subsection 42DK(1);
  - (b) that the notice referred to in paragraph (1)(d) is a notice referred to in section 42DKB;
  - (c) that goods, substances or preparations referred to in paragraph (1)(f) are included in Schedule 3, 4 or 8 to the current Poisons Standard;
  - (d) that the therapeutic goods, or class of therapeutic goods, referred to in paragraph (1)(h):
    - (i) are exempt goods or exempt devices prescribed in the regulations made for the purposes of subparagraph (1)(h)(i); or

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- (ii) have been approved under subsection 19(1) or section 41HB of the Act for importation into, exportation from or supply within, Australia.
- (3) It is a defence to a prosecution under subsection (1) if:
  - (a) in relation to an advertisement mentioned in paragraph (1)(a) or (f)—the advertisement is made by, or on behalf of, the Commonwealth; and
  - (b) in relation to an advertisement mentioned in paragraph (1)(f)—the goods, substances or preparations are mentioned in Appendix H of the current Poisons Standard; and
  - (c) in relation to goods mentioned in paragraph (1)(g)—the goods are exempt goods or exempt devices other than goods of a kind mentioned in paragraph (1)(h).

**Note:** A defendant bears an evidential burden in relation to the matters mentioned in subsection (3) (see section 13.3 of the *Criminal Code*).

**42DM Compliance with Code**

- (1) A person is guilty of an offence if:
  - (a) the person publishes or broadcasts an advertisement about therapeutic goods; and
  - (b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

**Penalty:** 60 penalty units.

- (2) An offence against this section is an offence of strict liability.

