



Therapeutic Goods Amendment Regulation 2012 (No. 1)¹

Select Legislative Instrument 2012 No. 142

I, QUENTIN BRYCE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation under the *Therapeutic Goods Act 1989*.

Dated 28 June 2012

QUENTIN BRYCE
Governor-General

By Her Excellency's Command

CATHERINE KING
Parliamentary Secretary for Health and Ageing

1 Name of regulation

This regulation is the *Therapeutic Goods Amendment Regulation 2012 (No. 1)*.

2 Commencement

This regulation commences on the day after it is registered.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments

(section 3)

[1] Regulation 42ZCAA, before definition of *complaint*

insert

another authority includes the Therapeutic Goods Administration.

[2] Regulation 42ZCAJ, heading

substitute

42ZCAJ Dealing with complaint if court proceedings begun

[3] Subregulations 42ZCAJ (1) and (2)

omit

cannot

insert

must not

[4] After subregulation 42ZCAJ (2)

insert

- (3) However, subregulations (1) and (2) do not apply if the panel decides to deal with a complaint after taking into account the following matters:
- (a) whether either of the following would be unreasonably disadvantaged if the Panel were to deal with the complaint before the proceeding had been finally disposed of:
 - (i) the person making the complaint (if known to the Panel);
 - (ii) the person apparently responsible;
 - (b) whether the complaint could be referred to another authority under regulation 42ZCAGA;
 - (c) the public interest;
 - (d) any other matter the Panel thinks relevant.
- (4) If, after taking into account the matters mentioned in subregulation (3), the Panel decides to deal with a complaint, the Panel must give written notice of its decision to:
- (a) the person making the complaint (if known to the Panel); and
 - (b) the person apparently responsible.

[5] After subregulation 43AAE (3)

insert

Exemptions for financial years commencing 1 July 2009 and 1 July 2010

- (4) Subregulations (1), (2) and (3) are taken not to have applied to a person if:
- (a) an exemption was granted to the person under subregulation 43AAD (1) for a new entry in the Register based on the estimated turnover of a therapeutic good for either of the financial years commencing on 1 July 2009 or 1 July 2010; and

- (b) for either or both of the financial years mentioned in paragraph (a), the person did not give to the Secretary the information mentioned in paragraphs (1) (a) and (b) by the time mentioned in subregulation (1).
- (5) If subregulation (4) applies to a person, the Secretary may, by written notice given to the person, specify a date by which the person must provide the following information to the Secretary:
 - (a) details, in a form approved by the Secretary, of the actual turnover of the therapeutic good, for the financial year or financial years for which the person was required to give the Secretary the information mentioned in paragraphs (1) (a) and (b);
 - (b) a signed statement by an approved person, in a form approved by the Secretary, of the actual turnover of the therapeutic good for that financial year or those financial years.
- (6) A date specified in a notice mentioned in subregulation (5) must not be less than 2 months after the date of the notice.
- (7) If a person to whom subregulation (4) applies does not give the information mentioned in subregulation (5) to the Secretary by the date specified in the notice:
 - (a) the exemption is taken to be cancelled on the day after the date specified in the notice; and
 - (b) the person must pay the charge for which the exemption was granted within 2 months after the day specified in the notice.

[6] Subregulation 43AAF (1)

omit

43AAE (1),

insert

43AAE (1) or (5),

[7] Paragraph 43AAF (2) (b)

substitute

- (b) the person who receives the notice mentioned in paragraph (1) (b) must pay the charge for which the exemption has been granted:
- (i) if the exemption relates to a financial year other than the financial year commencing on 1 July 2009 or 1 July 2010—by 31 October of the following year; and
 - (ii) if the exemption relates to the financial year commencing on 1 July 2009 or 1 July 2010—within 2 months after the day specified in the notice.

[8] Schedule 1, item 26AA

substitute

26AA Australian Society for Bioregulatory Medicine Incorporated

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See www.comlaw.gov.au.