

Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013

Portfolio: Health

Introduced: House of Representatives, 12 December 2013

Purpose

2.5 The Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 (the bill) seeks to make a range of amendments to the *Therapeutic Goods Act 1989* (the Act).

2.6 The bill would introduce a new offence and civil penalty provision for providing false or misleading information in relation to a request to vary an existing entry on the Register for therapeutic goods and extend the application of existing offence and civil penalty provisions for providing false or misleading information in response to a request for information about registered therapeutic goods and devices (Schedules 2 and 11). Further amendments are outlined in the committee's *Second Report of the 44th Parliament*.

Background

2.7 The committee reported on the bill in its *Second Report of the 44th Parliament*.

2.8 The bill was passed by the Parliament and received Royal Assent on 28 February 2014.

Committee view on compatibility

Right to a fair trial and fair hearing

Civil Penalties

2.9 The committee sought clarification from the Minister for Health as to whether the proposed amendments to insert a new civil penalty provision and to expand the scope of an existing civil penalty provision were consistent with the right to a fair trial in article 14 of the ICCPR. In particular, the committee requested the following information:

- an assessment of the provisions against the three criteria set out in its Interim Practice Note 2, relating to (i) the domestic classification; (ii) the nature or purpose of the penalty; and (iii) the severity of the penalty; and

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- whether particular protections, such as the presumption of innocence, the prohibition against double jeopardy and the privilege against self-incrimination, would apply to the relevant enforcement proceedings.

Assistant Minister's response

These measures are clearly described in the Bill as being civil penalties and are plainly distinguishable from the corresponding criminal offences in the Bill or the Act [*Therapeutic Goods Act 1989*] relating to the same conduct.

The penalties are consistent with the regime throughout the Act of having civil penalties as an alternative to criminal offences for a range of behaviour that breaches important regulatory requirements.

Although the maximum levels of these penalties may appear high, this reflects the relative size and nature of the therapeutic goods industry, in particular the presence of large multi-national companies.

It is important the Act contain a strong deterrent against providing false or misleading information to the TGA in relation to the carrying out of its functions. If the TGA were to rely upon information that is false or misleading to approve a request to vary an entry in the Register for a therapeutic good, or to come to a view that a product continued to be safe for use by consumers, there could potentially be serious consequences for public health.

[...]

These civil penalties are also not aimed at the public at large, but rather are only relevant for specific groups, namely (in the case of new section 9H) sponsors of therapeutic goods that are entered on the Register and (in the case of the expanded section 31AAA of the Act) sponsors of registered or listed goods, applicants for registration or listing and persons in relation to whom therapeutic goods were registered or listed in the previous five years.

[...]

In addition, neither of the above measures carries any sanction of imprisonment for non-payment. Section 42YD of the Act makes it clear if the Federal Court orders a person to pay a civil penalty, the Commonwealth may enforce the order as if it were a judgment of the Court - i.e. as a debt owed to the Commonwealth.

With these issues in mind, these civil penalties would not seem likely to be 'criminal' for the purposes of human rights law.

As such, the question in relation to the application of particular protections, such as the presumption of innocence, would not appear to arise in these circumstances.

It is important to note the Act protects a person from being required to pay a civil penalty if they have already been convicted of an offence

relating to the same conduct, and prohibits criminal proceedings from being started if an order has been made against the person in civil penalty proceedings for the same conduct. Any civil penalty proceedings will be stayed if criminal proceedings relating to the same conduct are, or already have been, started.

The Act also makes it clear that any evidence given by a person in civil penalty proceedings (whether or not any order was made by the court in those proceedings) will not be admissible in criminal proceedings involving the same conduct.¹

Committee response

2.10 The committee thanks the Assistant Minister for Health for her response and has concluded its examination of this bill.

1 See Appendix 2, Letter from Senator the Hon Fiona Nash, Assistant Minister for Health, to Senator Dean Smith, 14 March 2014, pp 1-3.