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

Portfolio: Health
Introduced: House of Representatives, 12 December 2013

Summary of committee concerns

1.304 The committee considers that the bill engages fair trial rights. The committee seeks further information from the Minister for Health before forming a view on whether the bill is compatible with these rights.

Overview

1.305 This bill seeks to make a range of amendments to the *Therapeutic Goods Act 1989*. This includes amendments to:

- put beyond doubt that where regulatory action in relation to therapeutic goods is predicated on whether or not the goods comply with advertising requirements, those requirements include applicable provisions of the Therapeutic Goods Advertising Code (Schedule 1);
- 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);
- allow the Minister to make a legislative instrument determining that goods are not therapeutic goods for the purposes of the Act and to introduce a power for the Secretary to remove products from the Register that are not therapeutic goods, for the purpose of ensuring greater clarity and certainty (Schedule 3);
- remove inconsistencies relating to advertising offences in Division 3A of Part 5-1 (Schedule 4);
- make clearer the process by which the Secretary makes decisions to either register or not register goods, including the source of the Secretary's power to approve product information for medicines accepted for registration (Schedule 5);
- allow changes made by the Secretary to conditions of registration, listing or inclusion of therapeutic goods in the Register, and changes to conditions of manufacturing licences and conformity assessment certificates, to take effect earlier than is currently possible under the Act in certain circumstances (for example, where the sponsor or certificate or licence holder agrees to the earlier commencement) (Schedule 6);

- include a new power for the Secretary to cancel the registration or listing of goods where the presentation of listed therapeutic goods is unacceptable (for example if the presentation of a good is misleading or confusing as to the goods' content) or the presentation of registered therapeutic goods is not acceptable (encompassing a range of factors such as the consumer medicine information for the goods) (Schedule 7);
- provide a right of merits review where, under section 15(1) of the Act, the Secretary imposes conditions on the granting of her consent to the importing into, supplying in, or exporting from, Australia therapeutic goods (other than medical devices) that do not comply with an applicable standard (Schedule 8);
- make clear when a substituted decision of the Minister should be treated as a decision of the Secretary (Schedule 9);
- modify the definition of a 'kit' under the Act (Schedule 10);
- provide a minimum notice period of at least 20 working days before a cancellation of therapeutic goods from the Register takes effect (Schedule 12);
- revise publication provisions, including: allowing the Secretary the discretion to publish information about various regulatory decisions in the Gazette or on the Department's website (currently all provisions require publication in the Gazette only) and a new requirement to publish the particulars of any cancellation of registered or listed therapeutic goods by the Secretary (to bring in line with comparable requirements for cancellation of biologicals and medical devices from the Register) (Schedule 13);
- revise the commencement date of the time period within which a person other than a sponsor of a therapeutic good must make a request for merits review of a decision under the Act from the current requirement of 90 days after the decision first comes to the person's notice to 90 days of the earlier of when the decision is published or when the decision comes to the person's attention (Schedule 13);
- support the recent reclassification of medical devices that are hip, knee and shoulder joint replacement implants from Class IIb to the higher risk Class III classification and allow the Therapeutic Goods Administration sufficient time to identify and address the large number of Class III applications likely to be made (Schedule 14);
- allow the cancellation of the registration or listing of a product when the sponsor of the goods has failed to respond to a notice to provide information or documents and include a new defence of reasonable excuse to the offence of failing to comply with a notice to provide

information or documents about biologicals or medical devices (Schedule 15); and

- enable the holders of manufacturing licences and conformity assessment certificates and sponsors of medical devices who asked the Secretary to cancel their devices to request the reversal of that cancellation and new requirements to publish the details of the overturning of certain kinds of regulatory decisions.

Compatibility with human rights

Statement of compatibility

1.306 The bill is accompanied by a statement of compatibility that states that the bill 'contains one measure that appears to engage article 14(2) of the International Covenant on Civil and Political Rights'[1]. This refers to the right to be presumed innocent. The bill introduces a new strict liability offence for the making of false or misleading statements in connection with a request to vary an entry for a therapeutic good on the Register, where the use of the goods would likely result in harm or injury to any person.[2] The offence carries a maximum penalty of 2,000 penalty units (or $340,000).

1.307 The statement of compatibility sets out the rationale and justification for the new offence and concludes that the offence is a reasonable, necessary and proportionate limitation on the right to be presumed innocent.

Committee view on compatibility

Right to a fair trial – presumption of innocence

1.308 Article 14(2) of the International Covenant on Civil and Political Rights (ICCPR) protects the right to be presumed innocent until proven guilty according to law. Generally, consistency with the presumption of innocence requires the prosecution to prove each element of a criminal offence beyond reasonable doubt. An offence provision which requires the defendant to carry an evidential or legal burden of proof with regard to the existence of some fact will engage the presumption of innocence because a defendant's failure to discharge the burden of proof may permit their conviction despite reasonable doubt as to their guilt. Similarly, strict liability offences engage the presumption of innocence because they allow for the imposition of criminal liability without the need to prove fault.

1.309 However, reverse burden and strict liability offences will not necessarily be inconsistent with the presumption of innocence provided that they are within reasonable limits which take into account the importance of the objective being

1 Statement of compatibility, p 5.

2 See item 1 of Schedule 11 to the bill.

sought and maintain the defendant's right to a defence. In other words, such offences must be reasonable, necessary and proportionate to that aim.

1.310 The statement of compatibility sets out the following reasons for why it is necessary to impose strict liability in relation to this offence:

- requests to vary an entry on the Register can relate to serious safety issues, such as adding a warning in connection with the use of medicine, and the provision of false or misleading information that is relied upon by the Secretary to make a decision could have serious consequences for public health;
- such requests can require a significant amount of data to satisfy the Secretary that the variation does not involve a reduction in the quality, safety or efficacy of the goods and there is a particular level of dependence on the accuracy of the information as the information is often only known to the sponsor; and
- the proposed offence will form part of a tiered approach under the Act to offending conduct relating to the provision of false or misleading information where the information is relied upon to inform regulatory decision-making and is likely to cause harm or injury, and it is considered appropriate and necessary for deterrence purposes to include a criminal sanction for non-compliance regardless of any mental element as part of this framework.[3]

1.311 The statement of compatibility also notes that there is no period of imprisonment applicable and that the maximum penalty of 2000 penalty units reflects the seriousness of the conduct addressed, namely in circumstances where use of the goods would likely result in harm or injury to a person.

1.312 The committee notes that the bill contains a number of other measures which also engage the right to be presumed innocent and which are not addressed in the statement of compatibility.[4]

1.313 Currently, the Act provides a strict liability offence for providing false or misleading information in response to a notice to provide information or documents regarding therapeutic goods by a person in relation to whom a medicine is listed under section 26A of the Act, where the use of the goods may lead to harm or injury to a person.[5] The offence carries a maximum penalty of 2000 penalty units (or $340,000). The bill expands the scope of the current offence to apply to any person issued a notice and who provides information or documents, not just persons in

3 Statement of compatibility, pp 6-7.

4 Items 5 and 6 of Schedule 2 to the bill and items 2 and 3 of Schedule 4 to the bill.

5 *Therapeutic Goods Act 1989*, s 31(5B).

relation to whom a medicine is listed under the Act.[6] According to the explanatory memorandum, such persons may include, for example, applicants or sponsors seeking to register their goods in the Register.[7]

1.314 The bill also amends an existing offence in the Act for publishing or broadcasting an advertisement about therapeutic goods that contain a prohibited representation,[8] by including an additional element so that the offence will only apply where the use of the prohibited representation has not been permitted under the Act.[9] The bill imposes strict liability in relation to this new element of the offence.[10]

1.315 The bill also extends the operation of a defence to an existing offence under the Act relating to publishing or broadcasting an advertisement containing a restricted representation which has not been approved, where the advertisement in question has been made by, or on behalf of, the Commonwealth.[11] According to the explanatory memorandum, this will ensure consistency with other like offences, in relation to which the defence currently applies.[12] A defendant will bear an evidential burden in relation to this defence.[13]

1.316 The committee considers that the application of strict liability and the use of a reverse burden as proposed by the bill are unlikely to raise issues of incompatibility with article 14(2) of the ICCPR. In particular, in relation to the new and expanded offences criminalising the provision of false and misleading information, the committee considers the offences apply in a regulatory context, in an area where activities can have serious consequences for public health and safety. While the penalties of 2000 penalty units are high, they may nevertheless be considered justifiable, given that the offences are directed at preventing the provision of information which would likely lead to harm or injury to a person and given the need for strong deterrent measures to protect the public from exposure to therapeutic goods that have been approved for continued supply on the basis of false or misleading information.

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6 Items 5 and 6 of Schedule 2 of the bill.

7 Explanatory memorandum, p 16.

8 *Therapeutic Goods Act 1989*, s 42DL(1)(a).

9 Item 1 of Schedule 4 of the bill. Under section 42DK(2) of the *Therapeutic Goods Act 1989*, the Secretary may permit the use of a prohibited representation, including on the label of goods or in information included in the package in which goods are contained.

10 Item 2 of Schedule 4 of the bill.

11 Section 42DL(3)(a) of the Therapeutic Goods Act, amended by item 3 of Schedule 4 of the bill.

12 Explanatory memorandum, pp 25-26.

13 See note accompanying section 42DM(3) of the *Therapeutic Goods Act 1989*.

1.317 However, the committee emphasises its expectation, as set out in its Practice Note 1, that statements of compatibility should include sufficient detail of relevant provisions in a bill which impact on human rights to enable the committee to assess their compatibility. This includes identifying and providing justification where the existing application of strict liability or the reversal of a burden of proof is expanded by a bill.

Right to a fair trial - civil penalties

1.318 The bill proposes to introduce a new civil penalty provision for false statements in connection with a request to vary an entry on the Register in relation to therapeutic goods.[14] The penalty provision carries a maximum penalty of 5000 penalty units ($850,000) for an individual and 50,000 penalty units ($8.5 million) for a body corporate. According to the explanatory memorandum, the purpose of the provision is to introduce a corresponding civil penalty provision to the new criminal offences for false statements in requests for variation of entries in the Register that are proposed by the bill (including the proposed new strict liability offence described above).[15]

1.319 The bill also expands the operation of an existing civil penalty provision. Currently, the Act sets out a civil penalty provision for providing false or misleading information in relation to medicines listed under section 26A of the Act.[16] The civil penalty provision carries a maximum penalty of 5000 penalty units ($850,000) for an individual and 50,000 penalty units ($8.5 million) for a body corporate. The bill seeks to expand the operation of this provision so that it applies to any person who is issued a notice and who provides information or documents, not just persons in relation to whom a medicine is listed under the Act.[17] According to the explanatory memorandum, this mirrors the change made by the bill to the corresponding criminal offence under the Act (as described above).[18]

1.320 As our predecessor committee has noted on multiple occasions, where a penalty is described as civil under national or domestic law, it may nonetheless be classified as 'criminal' for the purposes of Australia's human rights obligations because of its purpose, character or severity. As a consequence, the specific criminal process guarantees set out in article 14 of the ICCPR may apply to such penalties and proceedings to enforce them.

1.321 The committee set out in its Interim Practice Note 2 the expectation that statements of compatibility should provide an assessment as to whether civil penalty

14 New section 9H at item 1 of Schedule 11 to the bill.

15 Explanatory Memorandum, p 47.

16 *Therapeutic Goods Act 1989*, s 31AAA.

17 Item 9 of Schedule 2 to the bill.

18 Explanatory memorandum, p 16.

provisions in bills are likely to be 'criminal' for the purposes of article 14 of the ICCPR and if so, whether sufficient provision has been made to guarantee their compliance with the relevant criminal process rights provided for under the ICCPR. These issues are neither identified nor addressed in the statement of compatibility accompanying this bill. The committee notes that the civil penalties introduced or expanded on by the bill involve the application of quite significant pecuniary penalties to individuals.

1.322 The committee intends to write to the Minister for Health to seek clarification as to whether the proposed amendments to insert a new civil penalty provision and to expand the scope of an existing civil penalty provision are consistent with the right to a fair trial in article 14 of the ICCPR. In particular, the committee requests 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**
- **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.**