THERAPEUTIC GOODS AMENDMENT BILL 2005

THE INQUIRY

1.1 The Therapeutic Goods Amendment Bill 2005 (the Bill) was introduced into the House of Representatives on 17 August 2005. On 7 September 2005, the Senate, on the recommendation of the Selection of Bills Committee (Report No. 9 of 2005), referred the provisions of the Bill to the Committee for report.

1.2 In recommending the reference of the Bill to the Committee, the Selection of Bills Committee provided the following issues for consideration.

To examine the provisions of the Bill relating to new enforcement options for the Therapeutic Goods Administration (TGA) to:

- identify if the Bill provides sufficient detail on the scope of alleged breaches to which infringement notices may apply, on the use of alternatives to court proceedings, and the extent to which the processes of investigation of offences will be in line with procedural fairness (including the use of media during investigations and prosecutions);
- ascertain if the Bill adequately accommodates differences between registrable and listable goods;
- examine inequity implications for Australian based manufacturers due to the non-applicability of the civil penalty regime to foreign entities; and
- examine the need for ad hoc appeals mechanism against the imposition of an infringement notice and a fine under the civil penalties regime currently included in the Guidelines, to be included in the Regulations to preserve the appeal mechanism and prevent arbitrary variations and application.

1.3 The Committee considered the Bill at a public hearing on 13 October 2005. Details of the public hearing are referred to in Appendix 2. The Committee received 10 submissions relating to the Bill and 473 form letters. These are listed at Appendix 1. The submissions and Hansard transcript of evidence may be accessed through the Committee's website at http://www.aph.gov.au/senate_ca

1.4 The Parliamentary Library Bills Digest No 40 dated 5 September 2005 also discusses a number of issues relating to the Bill and may be accessed at http://www.aph.gov.au/library/pubs/bd/2005-06/06bd040.htm

THE BILL

1.5 The purpose of the Bill is to amend the *Therapeutic Goods Act 1989* (the Act) to better secure compliance with regulatory standards for therapeutic goods. The Bill introduces new enforcement options for the Therapeutic Goods Administration (TGA)

'to deal more effectively and efficiently with suppliers and manufacturers who may place public health and safety at risk by failing to fully comply with regulatory requirements including product and manufacturing standards'.[1] Briefly, the enforcement options proposed are:

- *tiered offence regime:* supplement a number of existing criminal offences with a tiered offences regime, which will include offences of strict liability and higher penalties for more culpable conduct resulting in harm or injury;
- *pre-disclosure notices:* require a defendant to provide a pre-disclosure notice of evidence in support of an exception to an offence relating to the importation, exportation, manufacture or supply of goods that are not included in the Australian Register of Therapeutic Goods (ARTG) prior to the defendant being committed for trial or prior to a hearing by a court of summary jurisdiction;
- *alternative verdicts:* provide for alternative verdicts for various tiered offences to the effect that if the jury acquits a person of an offence specifying an aggravating element, but is satisfied beyond reasonable doubt of facts that prove that the person is guilty of a lesser offence with no aggravating element, the jury may convict the person of the lesser offence;
- *civil penalty regime:* introduce a civil penalty regime for breaches of the Act;
- *infringement notices:* introduce infringement notices for strict liability offences under the Act and for breaches of civil penalty provisions;
- *enforceable undertakings:* introduce provisions for a person to provide enforceable undertakings to remedy breaches of regulatory requirements, or give undertakings not to engage in future conduct that would breach regulatory requirements;
- *extended geographical jurisdiction:* provides for certain offences to extend to conduct by an Australian citizen or body corporate outside Australia and for an offence to extend to conduct by an Australian resident outside Australia, where there is an equivalent offence in the laws of the local jurisdiction;
- *extension of body corporate liability:* extend the liability of a body corporate to executive officers who are directly involved in the day-to-day management of the company, if the body corporate commits an offence or contravenes a civil penalty provision under the Act;
- *warrant mechanism:* introduce a new warrant mechanism for the purposes of enabling investigations to take place in relation to civil penalty contraventions;
- *search warrant powers:* extend the powers of authorised persons under search warrants to allow for the securing of additional evidence; and

1 Parliamentary Secretary to the Minister for Health and Ageing, the Hon Christopher Pyne, *Second Reading Speech*, 17.8.05.

- *release of information:* allows for the release, to the public, of information about actions taken or decisions made under the Act or Regulations and the release, to Australian or international regulatory organisations of information relating to an offence or alleged offence or a contravention or an alleged contravention of a civil penalty provision involving therapeutic goods.

1.6 In addition, the Bill proposes minor amendments to certain advertising requirements; to include an amendment to section 61(3A) of the Act to correct a technical omission by including a reference to section 31AA; and amend section 56A to include an instrument of exemption issued under section 18A in the list of certificates that the Secretary may issue as evidence of certain matters.[2]

1.7 The Parliamentary Secretary to the Minister for Health and Ageing concluded that:

> With the new measures the TGA will be better placed to deter a company's continuing breaches of regulatory requirements before they become so serious that administrative action has to be taken that could put the company out of business.
>
> Deterring non-compliance by the industry as a whole is important in protecting consumers but it also creates a fairer environment for all players as law-abiding sponsors and manufacturers are not unfairly disadvantaged by their non-compliant competitors. Increased compliance also leads to greater credibility and attractiveness of marketed products.
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> The confidence of the community in the safety of therapeutic goods is of great importance. The observance of Australia's regulatory requirements for therapeutic goods by suppliers and manufacturers enhances the reputation of Australian industry. The provisions in the Bill represent appropriate measures to protect the interests of both the community and industry.[3]

ISSUES

The need for alternative options

1.8 The Bill provides for alternative options for dealing with non-compliance within existing regulatory requirements. The Australian Self-Medication Industry (ASMI) supported this approach and stated that:

> …the current regime allows for only criminal penalties, which clearly is inadequate and is extremely limited. The new amendment bill suggests that there will be a flexibility and a tiered system, which makes it far more appropriate and for the lower end of the risk spectrum it will therefore continue. Those more flexible, tiered penalties and sanctions will be more appropriate. We feel very strongly about not excluding listed – which includes most complementary medicines – from this new legislation. The

2 Explanatory Memorandum, pp.1-2.

3 Parliamentary Secretary to the Minister for Health and Ageing, the Hon Christopher Pyne, *Second Reading Speech*, 17.8.05.

> current legislation does not distinguish between the two, and we would not like the new legislation to make a distinction.[4]

ASMI noted that it did have some concerns about aspects of the Bill including the level of penalties.

1.9 The CEO of the Australasian College of Nutritional and Environmental Medicine did not see the need for stricter regulatory provisions and tougher penalties and stated:

> I feel that the TGA has been able to act adequately in dealing with Pan, …there have been a number of examples since the Pan incident where the TGA has used its muscle adequately, from what I can see. People who breach the law and do not provide safe and properly documented products need to be dealt with but I feel that what is there is adequate.[5]

1.10 Johanson and Associates noted that there are other effective administrative procedures that are currently under the Act, for example, cancellation of a product, recall procedures and cancellation of licences.[6]

Listable goods

1.11 Listable goods are considered to be a lower risk. Most complementary medicines are considered listed goods. Some witnesses commented that the complementary medicines industry is very safe and that the proposed changes are 'total over regulation of small business in the low risk complementary medicines industry'.[7]

1.12 ASMI stated that it believed that medicines offered for sale to the Australian public must conform to high standards of safety, quality and efficacy. In noted that the less risk that is deemed to be associated with the product, the less onerous are the rules relating to access, advertising, labelling and other aspects of presentation. ASMI stated:

> …the rules about quality and safety are the matters on which a regulatory regime should be enforcing sanctions. We do not see that there is any difference between ensuring the safety of the products made by Pan, for example, or those made by Pfizer, GlaxoSmithKlein. They should be safe. If they are not then those who have not made them safe are guilty and should be punished across the board in accordance with a regime which

4 *Committee Hansard* 13.10.05, p.3 (ASMI).

5 *Committee Hansard* 13.10.05, p.7 (Australian College of Nutritional and Environmental Medicine Inc).

6 *Committee Hansard* 13.10.05, p.8 (Johanson & Associates Consulting).

7 *Submission* 6, p.1 (Johanson & Associates Consulting); see also *Submissions* 3 p.1 (Name Withheld); 10, p.1 (Blackmores Ltd).

> applies equally and without difference. Therapeutic goods should be regulated without difference. That is our position.[8]

1.13 The Department of Health and Ageing (DoHA) commented:

> …any medicine can cause harm. We are not talking about the fact that many complementary medicines may be regarded as low risk in a regulatory sense but, if a low-risk medicine is contaminated – intentionally or otherwise – and those chemicals are then introduced into the body, they can cause substantial harm. In that sense, in terms of regulation and breaches, we do not differentiate between listed medicines and registered medicines.[9]

1.14 Johanson and Associates stated that the amendments will 'unfairly target the complementary medicine industry as 75% of all pharmaceutical products are manufactured overseas'.[10]

1.15 DoHA noted that although Australia's sanctions regime can not extend beyond its borders, provisions exist which enable the TGA to prevent substandard products for being imported into Australia, or if already imported, to be removed from the market. For example, the TGA may refuse registration or listing in the ARTG, cancel an existing registration or listing, impose conditions in relation to goods included in the ARTG, and to require information in relation to manufacturing procedures. The Department concluded:

> Those powers go a considerable way to providing balance in the legislation in terms of the treatment of overseas based manufacturers versus those in Australia, and in terms of the ability of the TGA as regulator to respond effectively and appropriately to inadequacies in the manufacturing processes of overseas based manufacturers importing into or supplying therapeutic goods in Australia.[11]

Impact on industry

1.16 Witnesses commented that compliance costs will increase and impact adversely on small business.[12] In addition, witnesses stated that the change to the regulatory environment had led manufacturers of complementary medicines to move off shore and as a result the once self-supplied market had become an import-supplied market.[13]

1.17 Johanson and Associates stated that:

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8 *Committee Hansard* 13.10.05, p.2; *Submission* 1 p.5 (ASMI).

9 *Committee Hansard* 13.10.05, p.10 (DoHA); see also *Submission* 5, pp.38-41 (DoHA).

10 *Submission* 6, p.7 (Johanson & Associates Consulting).

11 *Submission* 5, pp.42-45 (DoHA).

12 *Submissions* 3, p.2 (Name Withheld); 4, p.1 (MIAA).

13 *Submission* 3, p.2 (Name Withheld).

> These new sanctions and penalties will increase the rapid move off shore of Australian companies manufacturing complementary medicines, further impeding the growth of the industry. This will result in consumers importing greater quantities of less regulated products of unknown safety and quality for their own personal use so does not benefit either industry or consumers.[14]

1.18 ASMI however commented that the manufacturers in Australia that are ASMI's members 'have not suffered any loss of business because of the Pan affair. There was a market blip; you would have to expect that' but sales had recovered. It went on to state that ' if you obey the law, have a candid and sensible relationship with the TGA and the inspectors and observe good manufacturing practice, you can run an effective business within this regime'.[15]

1.19 DoHA responded that there will not be a greater burden on industry as there are existing sanctions under the Therapeutic Goods Act and the proposed legislation provides for a greater array of options with those sanctions providing more flexibility rather than an increased burden to the industry.[16]

1.20 The Department also noted that deterring non-compliance by industry would not only protect consumers but would also create a fairer environment for all players as law-abiding sponsors and ensure that manufacturers are not unfairly disadvantaged by their non-compliant competitors. As many sponsors of therapeutic goods subcontract the manufacture of their product to third parties, the failure of the third party manufacturers to comply with regulatory measures can in turn impact adversely on the viability and reputation of these sponsors' businesses. The Department concluded that 'increased compliance also leads to greater credibility and attractiveness of marketed products'.[17]

1.21 Witnesses also stated that given the potential impact on industry development in Australia, a regulatory impact statement should have been mandatory.[18]

Level of penalties

1.22 The Bill introduces a civil penalties regime for breaches of the Act. The Department noted that 'civil penalties are expected to be more effective in deterring and preventing non-compliance with regulatory requirements by body corporates, who represent the bulk of those regulated under the Act and regulations'.[19]

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14 *Submission* 6, p.6 (Johanson & Associates Consulting).

15 *Committee Hansard* 13.10.05, p.4 (ASMI).

16 *Committee Hansard* 13.10.05, p.10 (DoHA).

17 *Submission* 5, pp.6-7 (DoHA).

18 *Submissions* 4, p.1 (MIAA); see also *Submission* 1, p.2 (ASMI).

19 *Submission* 5, p.10 (DoHA).

1.23 Witnesses commented that the level of proposed penalties, particularly for civil penalties, is very high.[20] It was stated that the penalties regime departs from the Commonwealth guidelines. Johanson and Associates commented that breaches of the Therapeutic Goods Act will carry double the financial penalty for treason, terrorism or genocide.[21] It also stated:

> It is of considerable concern that the intent of the Bill appears to provide for significantly higher pecuniary penalties to be imposed by infringement notices that is detailed in the Commonwealth Guide, raising again the justification for such draconian measures in a low risk environment as the complementary medicines industry.[22]

1.24 The Australian Self-Medication Industry (ASMI) stated:

> ASMI has been advised by those responsible for preparation of the Bill that the Attorney-General's Department has consented to the proposed departures from its guidelines. However, we have not been told what were the Department's reasons for having done so.[23]

1.25 DoHA indicated that the civil penalty provisions generally allow for higher penalty levels than those imposed under criminal offences. It stated that there was a deterrence aspect to the level of penalties and that 'the higher penalties imposed under the Bill make it clear, for example, that cost-cutting measures employed by companies may not necessarily pay off'.[24] The Department also noted that many of the companies in the therapeutic goods industry are large and 'maximum penalties therefore should be set at a meaningful level to achieve the objective of effective deterrence for non compliant activity'.[25] DoHA added that the highest tiered offences can only be made out where the non-compliance has resulted, or will result, in harm or injury to a person and that:

> The high pecuniary penalty reflects that these offences are directed at corporations standing to make profits, rather than individuals who are able to be incarcerated.[26]

1.26 In addition, the Department stated that the legislation incorporates maximum amounts and 'at the end of the day a court would decide on the appropriate level of fines'.[27]

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20 *Submissions* 1, pp.2, 7 (ASMI); 2 p.1 (Mr M Browning).

21 *Submission* 6, p.6 (Johanson & Associates Consulting); see also *Committee Hansard* 13.10.05, p.1 (ASMI).

22 *Submission* 6, p.4 (Johanson & Associates Consulting).

23 *Submission* 1, p.2 (ASMI).

24 *Submission* 5, p.10 (DoHA). See also Additional Information 24.10.05, p.2 (DoHA).

25 *Submission* 5, p.11 (DoHA).

26 *Submission* 5, Additional Information, 24.10.05, p.3 (DoHA).

27 *Committee Hansard* 13.10.05, p.11 (DoHA).

1.27 The Department also commented that there are a number of checks and balances enshrined in the legislation: before the TGA commences an action it needs to access independent legal advice to ensure that the action is likely to have a successful outcome, and generally 'that there is no prospect of a major penalty for a minor breach'.[28]

1.28 The Attorney-General's Department indicated that it had supported the departure from the guidelines because :

> …the impact on public health, the fact that you are dealing with commercial conduct and the fact that so much of this conduct is by corporations. It really is something different from traditional Commonwealth criminal law…but it is becoming more common for the Commonwealth to regulate this sort of conduct.[29]

The Attorney-General's Department also noted that the Commonwealth had recently announced that there would be a review of Commonwealth penalties. [30]

Infringement notices

1.29 Witnesses commented on the introduction of an infringement notices regime by regulation. Johanson and Associates pointed to disadvantages of the use of infringement notices including lack of court scrutiny, payment reflects a presumption of guilt and the risk of innocent people paying the amount specified in the notice to avoid the expense of contesting proceedings. Johanson and Associates went on to state that the current provisions in the Act have been used successfully against both Pan Pharmaceuticals and other manufacturers 'indicating that there is provision within existing legislation to adequately address any potential public health issues and raising the question of the need for imposing further penalties and powers'.[31]

1.30 The Department stated that the use of infringement notices 'will allow appropriate enforcement action to be taken where readily assessable elements of a breach are identified and the infringement may appropriately be dealt with expeditiously without proceeding to a court hearing'.[32] The Department also stated that:

> Compliance with an infringement notice is not to be taken as an admission of any contravention of the Act. If complied with in relation to an offence, the person will not be prosecuted for the relevant offence and the person will not be taken to have been convicted of that offence.[33]

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28 *Committee Hansard* 13.10.05, pp.13-14, 15 (DoHA).

29 *Committee Hansard* 13.10.05, pp.11-12 (A-Gs).

30 *Committee Hansard* 13.10.05, p.12 (A-Gs).

31 *Submission* 6, p.3 (Johanson & Associates Consulting).

32 *Submission* 5, p.8, see also pp.32-35 (DoHA).

33 *Submission* 5, Additional Information, 20.10.05, p.1 (DoHA).

1.31 No appeal provisions are proposed for the issue of an infringement notice 'as appeal mechanisms are usually appropriate for a review of a regulatory decision that binds another party'.[34] Those receiving an infringement notice may elect to pay but are under no obligation to do so.

1.32 DoHA concluded that an infringement notice is 'intended to penalise, and deter, future breaches' and that 'action will only be commenced where there is evidence to support an action, as determined by independent legal advice, and judicial sanction is warranted given the nature of non-compliance'.[35]

Enforceable undertakings

1.33 ASMI described the introduction of enforceable undertakings as 'unusual'. ASMI stated that ' by their nature, enforceable undertakings are more prone to abuse than other means of enforcement because there is no real limit on the undertakings that can be extracted. They can be about a very wide range of matters'.[36]

1.34 ASMI stated that rights of appeal and review, especially for enforceable undertakings, be provided for explicitly in the Bill.[37] It stated that:

> But we do not see why there should not be an appeal on the merits about an enforceable undertaking because there is a lot of angst in business, and has been for some many years now, with the way in which enforceable undertakings are – how shall I put it? – extracted from participants or proponents of matters before the ACCC. We would prefer that this legislation made it clear that industry comes to this matter as an equal party and does have access to objective processes rather than merely me talking to one of my friends in the department on behalf of the client, and hoping they will see it my way. It is a question of objective criteria rather than internal assurances.[38]

1.35 DoHA stated that enforceable undertakings are a form of administrative resolution based on voluntary undertakings that may be given by the person concerned as an alternative to regulatory action. Where an undertaking is breached, the TGA may seek enforcement of the undertaking by the Federal Court. The TGA will not have the power to compel a sponsor or manufacturer to give an enforceable undertaking.

1.36 The Department also indicted that court enforceable undertakings 'are intended as an option only where the TGA believes that a resolution based on enforceable undertakings offers the best solution to ensure that no further breaches

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34 *Submission* 5, Additional Information, 20.10.05, p.2 (DoHA).

35 *Submission* 5, p.8 (DoHA).

36 *Submission* 1, pp.11-12 (ASMI).

37 *Submission* 1, p.6 (ASMI).

38 *Committee Hansard* 13.10.05, p.3 (ASMI).

will occur or that the breach will be appropriately remedied'.[39] This may occur where, for example, a deficiency in a manufacturing process needs to be rectified by a manufacturer whose general manufacturing ability is not in question.[40]

1.37 The Department concluded:

> …one of the principal aspects of the new arrangement is to enable the regulator to better calibrate the response, depending on the nature and severity of the breach. That is why there are new aspects, including enforceable undertakings, infringement notices and a range of other things. I do not want the senators to be of the view that the sole goal of the bill is deterrence. It is also about being able to calibrate the response more appropriately.[41]

Recommendation

The Committee reports to the Senate that it has considered the Therapeutic Goods Amendment Bill 2005 and recommends that the Bill be passed without amendment.

Senator Gary Humphries
Chairman

November 2005

39 *Submission* 5, p.36 (DoHA).

40 *Submission* 5, p.9 (DoHA).

41 *Committee Hansard* 13.10.05, p.17 (DoHA).