AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

# Therapeutic Goods Amendment Bill 2005

A submission to the

Senate Community Affairs Committee

by

Australian Self-Medication Industry

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## Executive Summary


- ASMI accepts the need for a robust but flexible and transparent sanctions regime to ensure consumers have access to safe, efficacious, quality medications.
- Thus we support the Bill in principle.
- ASMI is concerned, however, that the Bill (or, failing that, at least the Regulations) should include more detailed legislative provisions which would set down the way the system is intended to operate. Some matters are set out in the Implementation General Principles. But these are not intended to have the force of law.
- We would have preferred the Government to have commissioned a Regulatory Impact Statement. The costs to business — particularly in insurance premiums — could be significant.
- In quite a few respects, the arrangements as set out in the Bill or the General Principles vary from policies laid down by the Minister for Justice and/or Attorney-General's Department. The reasons for these departures have not been made clear. They should be.
- ASMI continues to have concerns about the meagre provisions in the Bill governing enforceable undertakings.

## This submission

Australian Self-Medication Industry (ASMI) represents the non-prescription medicines industry in Australia — both "over the counter" (OTC) and complementaries. This is a substantial Australian industry, with estimated annual turnover estimated at $A2.5bn.

Along with other industry associations in the medicines area, ASMI has received briefings about the Bill now before the Committee and associated administrative procedures. As appears below, we remain concerned about some aspects of this legislation.

## Objects of the Bill

One of the lessons of the Pan affair was that the existing enforcement processes lacked flexibility and sufficient regulatory reach. ASMI accepts the need for improvements of the kind typified in the Bill. **We believe that a robust, flexible scheme, administered sensibly and sensitively, will improve public health and safety.**

However, there is a need to ensure that the new legislation **will** be so administered. ASMI has been consulted about the proposed "General Principles" for its implementation and we assume that the Committee will be provided with a copy. These "General Principles", read with the provisions in the Bill, go some way to alleviate industry's concerns that the sanctions regime may be too heavy-handed, or applied selectively or secretively.

## The proposed sanctions regime

The present Act has a sanctions regime which creates a set of criminal offences. The main way to "deal with" anyone who infringes the regulatory code is to bring criminal proceedings against them. In the case of registration and listing of medicines, products can be de-registered or de-listed for breaches of approval conditions, without the presumption of the need for criminal offences to be proved. For the most part, however, the regulator faces the choice of criminal proceedings or little other sanction.

The present Bill will provide a wider range of sanctions:

- criminal sanctions (including some strict liability offences);
- a civil penalty regime;
- the issue of "infringement notices" and payment of fines to discharge them; and
- an option for sponsors to enter into enforceable undertakings.

With a wider range of sanctions available to the TGA, the expectation is that it will be able to administer a more calibrated approach to wrongdoing. Relatively less serious breaches of the regulatory regime can be nipped in the bud and future compliance more closely watched in cases where there has been such a breach.

However, if the regulator is to have the desired flexibility, it is clearly desirable for the TGA to be able to issue one search warrant, with evidence obtained available for use in a criminal prosecution or proceedings leading to a civil penalty.

## ASMI's concerns

ASMI notes that the Senate has referred four specific issues to the Committee and we have something to say about each below. In the broadest sense, we can say that our concerns are reflected in the issues the Senate has identified.

*Due process*

ASMI believes that elements of the new Bill may be open to administrative abuse. As well some things not in the Bill should be to avert that risk. This is not to say the new provisions will be abused; nor that the regulators intend to do so; ASMI accepts assurances from the TGA that its response will be careful and measured. But it is to say that such guarantees should be in the legislation itself. Some further checks and balances are needed in the Bill.

*Level of penalties*

Secondly, we do wonder whether some of the punishments actually do fit the crime. Some of the proposed pecuniary penalties seem very high, particularly for civil penalties (and we assume that infringement notices' fines would be similarly big). At Attachment 1, is a more detailed analysis of this and some related issues.

We are also concerned that, in several respects, the proposed sanctions regime departs from the principles and guidelines issued by the Attorney-General's Department in relation to these matters. Attachment 1 also identifies these issues.

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 that Department's reasons for having done so.

*Costs to industry*

Thirdly, ASMI has been concerned that no Regulatory Impact Statement (RIS) was commissioned by the Government.

It should not be assumed that the measures are costless. From an industry perspective, it is apparent that the new sanctions regime will involve rather more "plea bargaining" than the present, simpler, system. There are costs to industry implicit in this but their extent and nature are hard to predict when the Bill says so little about how the non-judicial sanctions will be administered and whether companies will have appeal rights.

Another aspect of costs to industry relates to proposed s. 54B which makes the "executive officer" of a company personally liable to be found guilty of an offence:

- where the company commits an offence;
- the officer knew the offence would be committed;
- the officer was in a position to influence the company about the offence;
- but failed to take reasonable steps to prevent the offence.

The definition of "executive officer" in proposed sub-s. 54B (5) is very wide and many people, including contractors, could be caught. Moreover, some of the offences concerned are deemed to be of strict liability.

It follows that many companies in the therapeutic goods industry — large or small — and even sole traders will have to meet new and increased insurance costs as a result of this very wide personal liability provision.

*Transparency*

Our fourth main concern reflects the issues identified in paras (a) and (d) of the Committee's terms of reference. These relate broadly to the issue of procedural fairness, access to appeals and transparency of the regulator's operations. Many in Australian business have only the benchmark of the ACCC's administration of the Trade Practices Act to go by. In that case, many have felt they were the victims of asymmetrical information and negotiation processes. This industry does not wish to find its members in the same situation with the TGA.

*Trans-Tasman Agency*

Finally, ASMI notes that the provisions of the Act as amended by this Bill will presumably last only until the proposed Trans-Tasman Agency is established under new and different legislation. We do not know whether the full range of sanctions, level of penalties, or limited transparency will be taken over in full into the new legislative regime, or whether other arrangements are in contemplation. That is because industry has not yet been consulted on the detailed legislative and administrative arrangements proposed for the new Agency.[1]

[1] The Agency is due to begin operations on 1 July 2006.

## The Committee's concerns

Against the background of these observations, ASMI offers the following views on each of the four issues referred to the Committee by the Senate.

### (a) and (d): Procedural fairness

ASMI agrees with what we understand to be the idea implicit in para (a). That is, that processes relating to **decisions** by the regulator to adopt a particular path of investigation and subsequent imposition of penalty(ies) should be:

- set out clearly in either the Act or in Regulations, rather than being left to implementation guidelines; and
- provide clear avenues of appeal **as of right** for persons being proceeded against by non-judicial processes.

We referred earlier to implementation guidelines relating to these matters. It is not clear whether these papers will meet the definition of a "Legislative Instrument" and therefore become subject to the procedures set down in the Legislative Instruments Act (including the possibility of whole or partial disallowance). ASMI believes they should be so classified. If that is the case, it would go some way to meet our concerns about the scope and nature of sanctions likely to be applied in a range of circumstances.

However, by itself, characterising the Guidelines as a Legislative Instrument will not provide for any greater degree of procedural fairness (including explicit rights of appeal). ASMI therefore supports the idea in para (d) that the Regulations should provide for these things. That is, they "should preserve the appeal mechanism and prevent arbitrary variations and application".

We understand that the Regulations have not yet been drafted, so all that is known about them is what the Explanatory Memorandum says is intended.[2]

There is no mention there of how any appeals mechanism might operate.

Specifically in relation to enforceable undertakings, we note that an undertaking can only be varied with the consent of the Secretary.[3] In the case of Australian Petroleum Pty Ltd v. ACCC[4] the Federal Court held that a decision by the Trade Practices Commission (as it then was) to refuse a request for variation of an enforceable undertaking given under s. 87B of the Trade Practices Act was a decision of an administrative character under an enactment. So it was subject to judicial review under the Administrative Decisions (Judicial Review) Act. This ruling provides some comfort that a decision of the Secretary under proposed s. 42YL will not be able to be withheld arbitrarily. It would be

[2] See Explanatory Memorandum, pp. 43-44.
[3] Proposed s. 42YL (2).
[4] (1997) 143 ALR 381.

better, however, if the Act were amended to make clear that such decisions are appealable and reviewable, as of right.

**(b): Listed and registered goods**

ASMI believes that medicines offered for sale to the Australian public must conform to high standards of safety, quality and efficacy. We believe that claims made for therapeutic goods must be able to be substantiated; anything less amounts to false and misleading advertising and is not in consumers' interests. Finally, we believe these principles must apply whether a product is a prescription, over-the-counter (OTC) or complementary medicine; or whether it is a registered or listed product.[5]

Clearly, some products are less risky to consumers than others. Likewise, a higher or lower dosage, or whether it is taken chronically or for short periods only, affects the level of risk attaching to a particular medicine. The rules about access to medicines — where and by whom they may be sold and in what size packs — do not exonerate sponsor companies from the need to observe legislation about quality, safety and efficacy of those medicines. The less risk that is deemed to be associated with a product, the less onerous are the rules relating to access, advertising, labelling and other aspects of presentation. But the same requirements for quality and safety apply across the board. Good Manufacturing Practice (GMP) is, and ought to be, incumbent on all. In ASMI's view, the new sanctions regime should not distinguish between the two classes of listed and registered medicines. There should be one law for all.

ASMI therefore does not support the idea implicit in para (b).

**(c): Local vs. foreign entities**

It is not clear to us what this para intends to imply. Whether therapeutic goods are produced in Australia, or imported, and whether the company is Australian or foreign-owned, the law recognises the "sponsor" as the responsible person or entity "in relation to therapeutic goods". The sponsor is defined in s3. of the Act as follows:

> "sponsor, in relation to therapeutic goods, means:
> (a) a person who exports, or arranges the exportation of, the goods from Australia; or
> (b) a person who imports, or arranges the importation of, the goods into Australia; or
> (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);
> but does not include a person who:
> (d) exports, imports or manufactures the goods; or
> (e) arranges the exportation, importation or manufacture of the goods;

[5] Prescription medicines must be registered, as must OTC's which are scheduled S2 or S3 in the *Standard for Uniform Scheduling of Drugs and Poisons*. Other OTC's and most complementaries are listable.

> on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia."

It is the sponsor who may commit breaches of the Act or Regulations which attract the various sanctions provisions in the Bill.

We would also invite the Committee's attention to item 6 of Schedule 1 to the Bill. It specifically applies extended geographical jurisdiction (Category B) to the operation of key sections of the Act.

The drafting of para (c) would appear to suggest that "Australian-based manufacturers" are to be treated inequitably compared with "foreign entities". We can see no substance for such an apprehension.

## Conclusions

While ASMI supports the Bill in principle, we consider that it is capable of some improvements. In particular, we recommend that:

- the penalties regime be brought more into line with the Attorney-General's Guidelines;
- rights of appeal and review, especially in relation to enforceable undertakings, be provided for explicitly in the Bill; and
- search warrant provisions be amended so that the regulators do not have to choose, at the start of their investigation, between eventual criminal or civil proceedings.

To some extent, we support the ides implicit in paras (a) and (d) of the Committee's terms of reference. We consider, however, that the ideas set out in (b) and (c) have no substance.

In relation to the proposed Trans-Tasman Joint Agency, ASMI is not in a position to envisage how (or indeed whether) the sanctions regime as amended by the provisions of this Bill will be carried forward when the Agency begins operations on 1 July 2006.

## Attachment 1

### Therapeutic Goods Amendment Bill 2005

The Therapeutic Goods Amendment Bill 2005 ("the Bill") was introduced into the Commonwealth Parliament on 17 August 2004. It introduces additional means for punishing offending behaviour of civil penalties, infringement notices and enforceable undertakings, in addition to criminal prosecutions. In addition, ASMI has been provided with a draft supporting document to the Bill - "Therapeutic Goods Amendment Bill 2005 - General Principles" ("draft General Principles").

**Penalty increases**

The Bill also substantially increases penalties. An example is for importing or supplying therapeutic goods that do not conform with a standard applicable to the goods. The existing section 14 imposes a maximum penalty of 12 months or 1,000 penalty units. (For a corporate offender, the penalty is five times the penalty units, i.e. 5000 penalty units). Under the new s14(1) (which applies where the goods are, put loosely, dangerous) that will go to 5 years and 4,000 penalty units – 20,000 penalty units for a corporate offender. (A penalty unit is $110, so 20,000 penalty units = $2.2m).

The civil penalties are even higher. What appears to be an identical offence to the existing s14(1) is found in the new civil penalty provision - s14A(1) - and the maximum penalty is 50,000 penalty units for a corporate offender – so a fine of $5.5m.

Additionally, the ratio in the new s14A between penalties for a corporate offender and an individual offender is 10:1. Under the general standard in the Crimes Act[6], the ratio is 5:1.

In February 2004, by authority of the Minister for Justice and Customs, "A Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers" ("the Commonwealth Guide") was issued.

The Commonwealth Guide says that use of other than the Crimes Act ratio is not considered desirable[7]. There is no indication why the Bill sets the ratio at 10:1.

Further, the Commonwealth Guide says that the appropriate penalty units for individuals should be the maximum period of imprisonment (in months) multiplied by 5[8]. Under the new s14(1) that would result in a maximum fine of 300 penalty units (for an individual). The new s14(1) prescribes 4,000. The Commonwealth Guide notes that the fine equivalent for life imprisonment is 2000 penalty units for an individual[9]. The Commonwealth Guide notes that life imprisonment applies to treason, certain war crimes

[6] s. 4B(2)
[7] Page 37
[8] Page 37
[9] Page 38

such as genocide and certain terrorist acts. So a breach of s14(1) carries twice the financial penalty for treason, terrorism and genocide.

## Civil Penalties

The Bill seems to allow the same offence to be dealt with criminally or by civil penalty. We are not aware of previous instances where that can be done. The Commonwealth Guide seems to envisage that matters should be dealt with either by criminal prosecution or by civil penalties and not by both[10] - although it is implicit in the Commonwealth Guide that there may be overlap between the two.

It is considered that criminal offences should apply to more serious conduct than where civil penalties apply. In the Bill no such distinction seems to be drawn. The criminal offences and civil penalties seem to cover the same conduct.

The Commonwealth Guide says:

> "The inclusion of a civil penalty provision in Commonwealth legislation is most likely to be appropriate and effective where each[11] of the following circumstances is present:
>
> - Criminal punishment not merited. Contraventions of the law involving serious moral culpability should only be pursued by criminal prosecution.
>
> …
>
> - Civil penalties have traditionally been directed against corporate or white collar wrongdoing where imprisonment is either not available (because the wrongdoing (sic.) is a corporate entity) or imprisonment is an inappropriate sanction. In these cases, the financial disincentive that civil penalties provide is most likely to be useful and effective."[12]

The approach taken in the Bill and the "draft General Principles" seems to be out of step with the above principles. The "draft General Principles", to the extent they are specific, refer to the following justifications for using civil penalties rather than criminal prosecutions:

1. "… where criminal culpability is absent but serious breaches of critical regulatory requirements has occurred civil action rather than criminal prosecution may be more appropriate."

[10] Pages 56-57 at 7.2
[11] Emphasis added
[12] Pages 56-57 at 7.2

*That justification is not found in the Commonwealth Guidelines. We understand, however, that the TGA will not take CP proceedings without having first obtained independent legal advice.*

*The Bill's civil penalty provisions cover very much the same ground and have very much the same elements as its criminal provision. In the same paragraph as is quoted above calls, the draft General Principles "Proceedings versus Criminal Prosecutions" observes that the Bill contains "parallel civil penalty and criminal offence provisions in relation to substantially the same conduct."*

2. "…civil penalties are often more appropriate for sanctioning corporate wrongdoing [than criminal prosecution]."
   *In context, that seems to be a similar but broader proposition than the Commonwealth Guidelines' argument that civil penalties may be appropriate where imprisonment is either not available (because the wrongdoing is a corporate entity) or imprisonment is an inappropriate sanction.*

3. "Higher pecuniary penalties, which is the main feature of civil sanctions, may also be a more effective deterrent for regulating commercial activities".
   *That is a bold assertion which we do not consider to be of either general or wide acceptance, and is not found in the Commonwealth Guidelines.*

**Infringement notices**

The Bill creates the ability to introduce an infringement notices regime by regulations. Such regulations should be closely scrutinised when they become available to ensure that they accord with the Commonwealth Guide.

The Commonwealth Guide has an extended discussion of infringement notices[13]. It proposes various limitations on their use, some of which are reflected in the draft General Principles. The limitations that the Commonwealth Guide proposes are:

1. "An infringement notice scheme may be employed for relatively minor offences"[14] "Serious offences should be determined in court and should not be capable of being excused by an administrative assessment."[15]
   *Although the draft General Principles do not envisage that infringement notices will be used in the most serious cases, the document does not articulate that they will only be used for relatively minor offences, nor that they will not be used in serious cases.*

[13] Pages 45-55
[14] Page 45 at 6.2
[15] Page 46 at 6.2

2. "An infringement notice scheme may be employed … where a high volume of contraventions is expected"[16] … "The administrative apparatus required to set up an infringement notice scheme will only be warranted in high volume contexts."[17]

   *There is no discussion in the draft General Principle of the expected volume of infringement notices. However, the TGA has told ASMI that these would be rare cases only.*

3. "An infringement notice scheme may be employed … where a penalty must be imposed immediately to be effective."[18]

   *There is no discussion in the draft General Principles of this criterion.*

4. "An infringement notice scheme should only apply to strict or absolute liability offences."[19] "The offences should not require proof of fault".[20]

   *Presumably the Commonwealth Guide uses such terms as "strict liability", "absolute liability" and "proof of fault" in the same sense as the Commonwealth's Criminal Code. It does not seem to be the case that all the provisions referred to in the draft General Principles apparently in the context of proposals to issue infringement notices are strict liability offences in that sense. While the referred to offences do not articulate required mental elements, the Criminal Code itself would require proof of one of the fault elements of intention, recklessness, knowledge or intention.*[21]

5. "An infringement notice scheme should only apply to … offences [which] carry physical elements on which an enforcement officer can make a reliable assessment of guilt or innocence."[22] "[This assessment needs to turn on] straightforward and objective criteria rather than on complex legal distinctions. … the physical elements giving rise to a notice should be readily capable of assessment by an enforcement officer."[23]

   *The draft General Principles refers to this criterion, but does not say that infringement notices will only be used for offences where an enforcement officer can make a reliable assessment of guilt or innocence, turning on straightforward and objective criteria rather than on complex legal distinctions.*

6. "Infringement notice penalty … must equal 1/5 of offence maximum … and should not exceed 12 penalty units for a natural person or 60 penalty units for a body corporate."[24]

   *The draft General Principles envisages fines up to 500 penalty units for a natural person and 5000 penalty units for a body corporate based on for*

[16] Page 45 at 6.2
[17] Page 46 at 6.2
[18] Page 45 at 6.2
[19] Page 45 at 6.2
[20] Page 46 at 6.2
[21] Criminal Code sections 3.2(b) and 5.1(1)
[22] Page 45 at 6.2
[23] Page 46 at 6.2
[24] Page 46 at 6.2

*infringement notices" - i.e., increases of up to 60 times on what the Commonwealth Guide would allow.*

*However the draft General Principles seems to be envisaging an even stronger regime than that. It is unclearly drafted, but Attachment A to the draft General Principles, explaining how the "Risk Multiplier" and "tiered fine system" would work[25], seems cause for alarm. Attachment A seems to envisage that, where a court could impose a fine of $5000 on an individual and $50,000 on a corporation, the TGA via an infringement notice could impose fines of $55,000 and $550,000 respectively. That puts the Commonwealth Guide's maxima even more "in the shade".*

*There are also other problems with the "Risk Multiplier"/"tiered fine system" if we understand it correctly. It would give enormous, unaccountable discretion to the TGA. We know of no precedent for it or anything like it.*

*Further confusion is added because the draft General Principles envisages that infringement notices will be issued instead of both criminal offences and civil penalty provisions. As noted above, the same conduct may be subject to proceedings under either the criminal or the civil penalty provision. Different penalty provisions apply to the two procedures. That anomaly is further complicated if the TGA has a discretion to choose which one it will issue an infringement notices in the stead of.*

*Taking the example used above of section 14(1) and the identical s14A(1). If the TGA decided to issue an infringement notice on the basis of section 14(1), the fine would be $88,000 for an individual and $440,000 for a corporation.*

*If the TGA decided to issue an infringement notice on the basis of section 14A(1), without the "Risk Multiplier"/"tiered fine system", the fine for identical conduct would be $55,000 for an individual and $550,000 for a corporation.*

*As we read the "Risk Multiplier"/"tiered fine system", that could go as high as $605,000 for an individual and $6,050,000 for a corporation. This is the proposed penalty for one (in the words of the Commonwealth Guide) relatively minor offence!*

**Enforceable undertakings**

These are an unusual weapon proposed to be added to the TGA's armoury by the Bill. To date, the main use of enforceable undertakings in Australia has been under the Trade

[25] Attachment A seems not to be consistent with the body of the "draft General Principles". The general body contains formulae that involve dividing the civil penalty by one fifth or one tenth and then multiplying by a fraction of 0.25, 0.5 or 1.0 However Attachment A seems to disregard the need to divide by one fifth or one tenth; it also multiplies the civil penalty – not by a fraction – but by multiples of up to 11.

Practices Act and its State and Territory equivalents and under corporations law, by ASIC, although their use appears to be spreading.

In the trade practices and corporations law contexts, concern has been expressed that the ACCC/ASIC etc have on occasions "blackmailed" companies into giving enforceable undertakings under threat of proceeding instead for civil penalties. If the TGA's armoury is to include, in respect of the same conduct, not only civil penalties but also infringement notices and criminal prosecution, that risk is all the greater.

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. They can be undertakings to do or not to do a very wide range of things. Accordingly the new s42YL allows the undertaking to be "in connection with a matter in relation to which the Secretary has a power or function under this Act or the regulations"[26]. That is a very wide range.

Because of these and other issues the Australian Law Reform Commission in its "Principled Regulation" report in 2003 recommended that there should be clearly articulated legislative parameters guiding the scope of undertakings.[27] The Bill does not seem to do that. Nor does it appear that the scope of Regulations proposed under s. 42YK will cover this issue.

**Muddles with double jeopardy**

An important legal principle is that a person should not be in jeopardy of conviction more than once for the same act[28]. With the Bill's introduction of civil penalties, there is the potential to be punished twice for the same act. The Bill makes some attempt to deal with this – see ss 42YF – 42YH. Its effect is that you cannot be subject to a civil penalty if you have already been convicted of the offence and you cannot be convicted if you have already been subjected to a civil penalty.

But the double jeopardy rule goes further. And in our view the Bill should go further: if you have been the subject of criminal proceedings (and won) you should not be liable to subsequent civil penalty or infringement notice for the same conduct. And vice versa, no matter whether the civil penalty proceedings, the criminal prosecution or the infringement notice comes first.

But the Bill seems explicitly to envisage that a person might be subject to double jeopardy – subject to of both criminal proceedings and civil penalty proceedings over the same conduct – see proposed section 42YG.

The Commonwealth Guide supports the above approach of preventing double jeopardy[29].

[26] s. 42YL(1)
[27] Para 16.79
[28] See *Crimes Act 1914* (Cth) s4C
[29] Page 52 at 6.7 and page 54 at 6.8

**Protection from self incrimination and legal professional privilege**

The last part of the note to the new section 31C is misleading because the section referred to there (s31F) only protects an individual defendant from self incrimination. It does not protect a corporate defendant.

Of even greater concern is s42YE empowering the Secretary to require the production of information if she suspects that the information is relevant to a civil penalty provision. Despite s42YE(3), that requirement seems to override legal professional privilege. It also seems to completely override the privilege against self incrimination. There appears to be nothing preventing the use of such information even in criminal proceedings. Contrast the existing s41JC.

**Requirement that defendant gives 21 days' notice of certain defences**

This requirement in s41MIA and elsewhere is unusual and contrary to the general approach taken in criminal proceedings.

**"Ancillary" liability**

The new s54B(1) sets out the circumstances when an "executive officer" of a body corporate commits an offence, viz.: such officer will be guilty of the offence:

1. where the body corporate commits an offence; and
2. the officer knew the office would be committed; and
3. the officer was in a position to influence the body corporate in relation to the commission of the act; and
4. the officer failed to take reasonable steps to prevent the commission of the offence.

A similar regime will apply to "executive officer" responsibility re civil penalty provisions (the new s54B(3)).

The definition of "executive officer" (the new s54B(5)), catches any one "who is concerned in, or takes part in, the management of the body". That potentially could pick up the company secretary, the managing director and the Chief Operating Officer. But it could also pick up more junior employees in the line where the breach occurred – for example a production line manager or a shift manager.

The amendments seem designed to prevent a sole trader from being able to escape liability by saying their contractors let them down – many of the offences are of strict or absolute liability.

Very small players might be incorporated or they might be unincorporated. If the sole trader is incorporated, s54B would apply. The person behind the company could be

liable if the company committed an offence – but only if s/he knew the offence would be committed and failed to take reasonable steps to prevent it. (It would be hard for the proprietor to argue that s/he was not in a position to influence the body corporate in relation to the commission of the act).

The penalties on these people are very heavy – they are the same as for an individual who breaches the provision in question – upwards of half a million dollars in some cases – and long periods of imprisonment.

**Direct and primary liability**

In addition to liability as above, which arises because the person is involved in an offence by the company, individuals in companies could also be prosecuted because they have directly breached such provisions as making false statements. One of numerous examples is the proposed s21A. The proposed s21A makes it an offence to make false statements in certifying such things as that medicine is eligible for listing, is safe, has acceptable presentation and conforms to applicable standards. That is expressed to be an offence of strict liability – meaning that it will not be a defence to show that you had a mistaken but unreasonable belief in the truth of the certification.

An officer – however junior – or a consultant – who certifies such matters for the purposes of the Therapeutic Goods Administration, is potentially personally liable to very large penalties if s/he gets it wrong.