Johanson & Associates Consulting

Val Johanson BSc, MSc Qual.

Submission to the Senate Community Affairs Legislation Committee Inquiry into the Therapeutic Goods Amendment Bill 2005

Background

Having established the Surveillance Unit in the Therapeutic Goods Administration in February 1991, acting as Head of Surveillance for four years under the Therapeutic Goods Act 1989, and subsequently managing the peak body for the natural healthcare industry in Australia until just over 12 months ago, I wish to respond to the Terms of Reference for the above inquiry and also raise some other general concerns relating to the proposed offences and penalties in this Amendment Bill.

Summary

The increased penalties and powers proposed in this Bill are considered to be:

- **total over regulation of small business in the low risk complementary medicines industry;**
- **unjustifiable based on the Pan matter for which we have not seen any evidence of any defective complementary medicine manufactured by Pan, despite the biggest recall of medicines in the world and for which ADRAC has determined certain causality for only two reversible adverse events linked with Pan- made products from 1600 products over an 18 month period;**
- **draconian and unwarranted legislative measures that will further force Australian business off shore,**
- **contrary to the Commonwealth's own Guide to "Framing Commonwealth Offences, Civil Penalties and Enforcement Powers" (February 2004) in setting the ratio of penalties for a corporate offender and an individual offender at double the ratio in the Crimes Act; and for proposing penalties via infringement notices up to 60 times that reflected in the Commonwealth Guide,**
- **imposing sanctions on the mostly Australian-run and Australian-owned complementary medicines industry that cannot be applied to the bigger, less safe, pharmaceutical industry, 75% of which operates off shore.**

The Australian Complementary Medicine industry is a low risk industry requiring appropriate regulation, appropriately interpreted and appropriately administered to ensure that Australians have freedom of choice of high quality, low risk products, and that the industry is viable and innovative in line with Australia's National Medicine Policy. Action taken in relation to Pan has turned an export oriented industry to an import industry and there is significant potential that further severe penalties will exacerbate this situation.

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia

Terms of Reference

To examine the provision of the Bill relating to new enforcement options for the TGA to:

a. 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);

b. ascertain if the Bill adequately accommodates differences between registrable and listable goods;

c. examine inequity implications for Australian based manufacturers due to the non-applicability of the civil penalty regime to foreign entities; and

d. 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. **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)**

1.1 In the Second Reading Speech for this Bill, the Hon Christopher Pyne states that "the main purpose of the amendments is to provide new alternative enforcement options to enable the 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. The amendments represent the government's determination to respond to deficiencies arising from the limited range of enforcement measures presently available to the TGA and are considered necessary to enable the TGA to adequately protect public health and safety. Existing options for dealing with breaches of regulatory requirements are restricted to either criminal prosecution or administrative sanctions such as withdrawing the sponsor's or manufacturer's right to continue marketing or manufacturing therapeutic goods. Resort to either of these options may not, in some circumstances, be appropriate or achieve the optimal regulatory outcome, given the time and resources taken to prosecute offenders and the possible need to maintain supply of products to the public because of their essential nature or the lack of available substitute products.

The following issues require consideration:

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia

1.1.1. Given that the regulatory action taken in relation to Pan Pharmaceuticals Ltd by the TGA in April 2003 under existing legislative provisions, was extremely effective in initiating the world's largest medicine recall in history and closing down the Pan manufacturing premises, it would appear that there are already sufficient measures and powers within the Therapeutic Goods Act 1989 to take appropriate action to achieve the desired regulatory outcome and to protect public health. It should be noted that this outcome was achieved even though it appears that there are no known incidents of death, serious injury or serious illness which was used as the justification for the regulatory action taken. ADRAC determined 'certain' causality of only two Adverse Event Reports linked with Pan manufactures products, both of which were reversible. The need for tightening up the sanctions and enforcement options is not therefore not clear, and is considered to be unjustified, particularly when these will impact most severely on the low risk complementary medicine industry.

1.1.2. Use of infringement notices are likely to lead to further intimidation of an industry sector which is already fearful of retribution as identified in the Evan's Review of the TGA's Consultative Processes.

1.1.3. The views of the Australian Law Reform Commission (Report of the Australian Law Reform Commission, "Principled Regulation, Federal Civil and Administrative Penalties in Australia", Dec. 2002, p12.6*) that "Infringement notices are also attractive for regulators as they allow offences to be officially "noticed" and penalised without the need to prove any of the elements of the offence to the relevant standard.....This results in an "opt-in" process where the criminal burden of proof will only need to be met by the prosecution if the person to whom the notice is issued elects to contest the offence in court."*

1.1.4. Disadvantages of infringement notice schemes as identified in the above report are significant :

- *Lack of court scrutiny;*
- *Risk that innocent people will pay the amount specified in the notice to avoid the expense of contesting proceedings;*
- *Payment reflects a presumption of guilt;*
- *Insufficient safeguards to prevent abuse;*
- *Possibility of discriminatory enforcement against vulnerable members of the community;*
- *Possibility of "net-widening", i.e. automatic issue of an infringement notice which would otherwise have been dealt with by a caution or warning.*

1.1.5. While the time and resources required for prosecution are recognised and acknowledged, in cases of identified and proven public safety issues, the appropriate course of action would seem to be to withdraw the products of concern. The current legislative provisions under Sections 40 and 41 were successfully used to immediately suspend Pan's licence and cancel relevant products from the from the ARTG under Section 30. Similar action has been subsequently taken against 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.

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia

1.1.6. The issue of "the possible need to maintain supply of products to the public because of their essential nature or the lack of available substitute products" is not clear, given that the rationale is that of protecting the public from unsafe products. Is it suggested here that these products may continue to be supplied?

1.2 The proposal for infringement notices should be examined carefully to ensure that they are in accord with the Commonwealth Guide which proposes various limitations on their use including:

- for relatively minor offences as serious offences should be determined in court and should not be capable of being excused by an administrative assessment
- where a high volume of contraventions is expected
- where a penalty must be imposed immediately to be effective
- should only apply to strict or absolute liability offences where the offences should not require proof of fault
- should only apply to … offences [which] carry physical elements on which an enforcement officer can make a reliable assessment of guilt or innocence
- 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.

1.2.1 The "draft General Principles" for the Bill propose fines up to 500 penalty units for a natural person and 5000 penalty units for a body corporate based on for infringement notices" - i.e., increases of up to 60 times on what the Commonwealth Guide would allow.

1.2.2 Attachment A to the "draft General Principles", explaining the "Risk Multiplier" and "tiered fine system" work appear to propose 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.

1.2.3 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.

1.3. The bill extends the circumstances in which the TGA is authorised to release information it holds in relation to therapeutic goods. The bill specifically permits the public release of information relating to any regulatory decisions and actions taken under the act and regulations. In addition, the bill also authorises the release of information relating to a breach or an alleged breach of the act or regulations involving therapeutic goods to Australian and overseas regulatory agencies. This extra capacity to disseminate such information will assist in improving the TGA's ability to protect public health and safety.

1.3.1. The need for this provision is questioned, given that this information was disseminated widely in both Australia and overseas in relation to the Pan recall, including use of the media. This also raises the issue of whether the information that was disseminated at that

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia

time was permitted under existing regulatory provisions, noting that the export market of Australian product has virtually been decimated as a result of this action- again with no known serious adverse events resulting from any of the Pan made product.

2. ascertain if the Bill adequately accommodates differences between registrable and listable goods

2.1 The bill extends the liability of a body corporate to executive officers who are directly involved in its day-to-day management if the body corporate commits an offence or contravenes a civil penalty provision. This measure ensures that executive officers who are in a position to prevent a contravention by the body corporate will be deemed liable for the contravention if they fail to take reasonable steps to do so.

2.2.1 The extension of liability to executive officers will exacerbate further the difficulties currently being experienced in identifying and appointing appropriately qualified executives to senior positions in the complementary medicines industry and again encourage companies to move off shore where they are not subject to such draconian measures.

2.2.2 As the industry is unaware of any evidence to demonstrate that any complementary medicine manufactured by Pan was defective, it does not seem appropriate to use the Pan matter as the justification for introducing further draconian penalties and powers which will inevitably impact on the low risk complementary medicine market- in particular listable complementary medicines.

2.2.3 It is considered that a case has not been made to justify the introduction of these severe penalties to low risk listable complementary medicines and there does not appear to be any mechanism to differentiate between low risk listables and higher risk registerable products. .

3. examine inequity implications for Australian based manufacturers due to the non-applicability of the civil penalty regime to foreign entities

3.1 The bill introduces a parallel civil penalty regime for breaches of the act to allow for an alternative and quicker process for dealing with a wide range of legislative breaches. Civil penalties are expected to be more effective in deterring and preventing noncompliance with regulatory requirements by body corporates, who represent the bulk of those regulated under the Therapeutic Goods Act 1989 and regulations.

Higher penalty levels attach to civil penalties because they are designed to provide adequate incentives, especially in relation to well-resourced corporate entities, for deterring breaches of regulatory requirements under the act. The inclusion of alternative civil penalties and criminal offences is an effective strategy that has worked well under other Commonwealth legislation.

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia

Issues identified are:
3.1.1 The non-applicability of the civil penalty regime to foreign entitles creates an unlevel playing field, particularly as this would apply to the majority of higher risk pharmaceutical products- 75% of which are manufactured overseas.

3.1.2 The justification of civil penalties as a means of enabling faster response to dealing with legislative breaches cannot be sustained given that they cannot be applied to foreign entities. In cases where the civil penalty regime cannot be applied, other existing measures would have to be pursued. As 75% of higher risk pharmaceutical products are manufactured off shore it appears that the level of penalty is not directly proportional to the risk involved. It can be argued that enforcement action and penalty regimes for the higher risk products are less able to be pursued in the case of the majority of pharmaceutical products than those being proposed for the low risk products being manufactured in Australia.

3.1.3 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 wither industry or consumers.

3.1.4 The new proposed penalties of 4,000 penalty units is double that noted in the Commonwealth Guide as equivalent to life imprisonment (2000 penalty units for an individual)which applies to treason, certain war crimes such as genocide and certain terrorist acts. It is therefore proposed that breaches of the Therapeutic Goods Act will carry double the financial penalty for treason, terrorism and genocide. Given that there are only four or five deaths associated with complementary medicines in Australia, over a 25 year period, and most of these are questionable causality, it is difficult to justify the imposition of such severe penalties on what is surely an extremely low risk industry.

3.1.5 The Bill seems to propose that the same offence can be dealt with criminally or by civil penalty, when the Commonwealth Guide indicates that matters should be dealt with either by criminal prosecution or by civil penalties but not by both although it is recognised that there may be some overlap. It is considered that criminal offences should apply to more serious conduct than where civil penalties apply but these does not appear to be and distinction in the Bill as criminal offences and civil penalties seem to cover the same conduct. The proposals in the Bill appear to be out of step with the Commonwealth Guide.

4. **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.**

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia

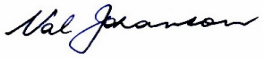
4.1 The explanatory memorandum states that "The test for the strict liability offences is an objective test, where the conduct/use of the goods "is likely to result in harm or injury to any person," and that "The word likely used in this context is an objective test where it is reasonably likely that harm or injury would occur."

4.1.1 The Pan recall of 1600 products was based on the TGA advice that this action was necessary to "prevent imminent risk of death, serious illness or serious injury, and was retrospective for a 12 month period. It is of note that there had been just one Adverse Event Report considered by ADRAC to be certain causality to a Pan made product during the 10 months prior to the recall and that this was a reversible allergic type reaction. It would appear essential therefore that clear criteria are required to assist determination of what is "likely to result in harm or injury".

4.1.2 These amendments will unfairly target the complementary medicine industry as 75% of all pharmaceutical products are manufactured overseas. As company Executives will be liable under these amendments it will become increasingly difficult if not impossible to appoint well qualified executives who are willing to take this risk, particularly as the Bill effectively reverses the onus of proof and treats the executive as guilty until proven innocent.

4.1.3 There is concern that with the introduction of civil penalties, there is the potential to be punished twice for the same act i.e double jeopardy. The Bill seems explicitly to envisage that a person might be the subject of both criminal proceedings and civil penalty proceedings over the same conduct – see proposed section 42YG, even though 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.

4.1.4 It is considered essential that the appeals mechanisms be included in the Regulations to provide clarity, certainty and consistency in the interpretation and application of these sanctions.



Val Johanson
Prinicpal Conultant
5 October 2005

Mobile: 0412887857 PO Box 137
Phone: +61 2 62350180 Calwell ACT 2905
Email: val@nhm.johanson.com.au Australia