Australian Government

Department of Health and Ageing

SUBMISSION TO THE AUSTRALIAN SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE ON THE THERAPEUTIC GOODS AMENDMENT BILL 2005

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A: Executive Summary

The Therapeutic Goods Amendment Bill 2005 ('the Bill') was developed to provide the Therapeutic Goods Administration (TGA) with a new range of enforcement options.

It will enable the TGA to deal more effectively and efficiently with suppliers and manufacturers who place public health and safety at risk by failing to fully comply with regulatory requirements including product and manufacturing standards. It will also enable the regulator to better calibrate its response depending on the severity of the breach.

The Bill represents the Government's intention to address the problems associated with the limited options currently available to the TGA in exercising their enforcement role. In doing so it brings the penalties and sanctions framework for therapeutic products into alignment with the provisions of other Commonwealth legislation (including on matters relating to the environment, occupation health and safety and corporations). TGA's enforcement role is important to address and deter continuing serious breaches of regulatory requirements that can potentially expose the public to unacceptable risk of harm. The provisions of the Bill are intended to be a long term solution to the ongoing problems being uncovered by the TGA through increased enforcement activities.

There is no risk of a manufacturer receiving a major penalty for a minor breach of the legislation. The Bill will enable the TGA to respond to serious and dangerous practices with the appropriate force of the law, while also ensuring that minor breaches can be dealt with in a sensible manner. The Bill provides for appropriate checks and balances. For example, decisions to take matters before a court to pursue civil breaches may only be made following independent legal advice that there are legal grounds for doing so. In addition, the TGA is required to act as a model litigant, consistent with the Legal Services Directions issued by the Attorney General, and enforced by his Department. Decisions about whether or not breaches of the *Therapeutic Goods Act 1989* ("the Act") have occurred that warrant judicial sanction, and the form of that sanction, are decisions only a court can make, not the TGA.

The increased flexibility being afforded the regulator to encourage compliance should be a matter of comfort for the industry, as the potential for major disruptions to their manufacturing processes as a result of minor breaches is lessened.

The main focus of the Bill is to protect public health and safety, and in doing so increase consumer confidence in the therapeutic goods industry. The provisions of the Bill enable the regulator to take appropriate action, while also serving as a disincentive for inappropriate or unsafe practices.

B. Context

Therapeutic goods regulation in Australia

The *Therapeutic Goods Act 1989* ("the Act") is administered by the TGA, within the Department of Health and Ageing. The objective of the Act is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods.

Subject to certain exceptions, any product for which therapeutic claims are made must be either listed or registered in the Australian Register of Therapeutic Goods (ARTG), before it can be imported, manufactured or supplied in Australia. There were approximately 63,400 products on the ARTG at March 2005.

Australia's therapeutic goods regulatory framework is designed to protect public health and safety, while at the same time freeing industry from any unnecessary regulatory burden and minimising the cost of medicines regulation. A robust regulatory system allows the public access to safe therapies while contributing to the continued viability and growth of industry by creating confidence in, and acceptance of, Australian therapeutic goods, both domestically and overseas.

To ensure that therapeutic goods available in Australia are of an acceptable standard, the TGA has five main functions including:

- pre-market evaluation and approval of registered products intended for supply in Australia;
- development, maintenance and monitoring of standards for therapeutic goods;
- licensing of manufacturers in accordance with international standards of Good Manufacturing Practice;
- post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries; and
- the assessment of medicines for export.

Facts about the therapeutic goods industry in Australia

- In 2003-04 the manufacturing sector of the Australian pharmaceuticals industry turned over around $7.8 billion (inclusive of over the counter products) and employed 15,000 people [1]
- About 155 firms are listed as suppliers to the Pharmaceutical Benefits Scheme[1]
- Sales of complementary medicines in Australia are estimated at around $1 billion a year[1]
- The Australian pharmaceuticals industry spent around $520 million on research and development in 2002-03[1]
- Pharmaceuticals are Australian's third largest manufactured export, with approximately $2.6 billion worth of product exported annually[1]
- The Australian Institute of Health and Welfare [2] estimates that in 2002-03, Australians spend in excess of $10 billion on pharmaceuticals. This includes:
  - $6.11 billion on benefit-paid pharmaceuticals (included in the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme); and
  - $3.89 billion on other pharmaceuticals, a category which includes unsubsidised prescription medicines, over the counter medicines, vitamins and minerals, some herbs and complementary medicines, and medical non-durables
- The estimate for the 2002-03 Australian Government contribution to total pharmaceuticals expenditure is over $5.1 billion[2]
- Estimates for sales of medical devices within Australia range from $2-3 billion dollars. Approximately 85-90% of these devices are imported. The domestic medical device industry also exports approximately $600 million worth of product annually [2] [3]
- The Australian medical devices and diagnostics industry employs around 10,000 people across about 1,100 companies [3]

C. Background to the Therapeutic Goods Amendment Bill

In response to the serious and wide-ranging breaches of critical regulatory requirements uncovered in relation to Pan Pharmaceuticals Ltd and suspension of their manufacturing licence in April 2003, amendments were made to the *Therapeutic Goods Act 1989* in May 2003. These changes were made to tighten up the regulatory requirements relating to compliance with standards, notification of adverse events in relation to therapeutic goods and to enable manufacturers of therapeutic goods to be more readily identifiable. As a result, the 2003 amendments to the Act also improved TGA's power to recover unsafe or substandard goods from the marketplace.

Pan Pharmaceutical Ltd

The Therapeutic Goods Administration (TGA) suspended the licence held by Pan Pharmaceuticals Limited to manufacture medicines for a period of six months from April 2003, because of serious concerns about the quality and safety of products manufactured by the company.

The suspension followed audits of the company's manufacturing premises, which revealed widespread and serious deficiencies and failures in the company's manufacturing and quality control procedures, including the systematic and deliberate manipulation of quality control test data. The licence was suspended in order to urgently address the safety and quality concerns posed by the multiple manufacturing breaches. Where the quality of a medicine cannot be certain, neither can the safety or effectiveness of that medicine.

Due to the serious and widespread nature of the manufacturing problems identified and following expert advice regarding potential risks, the TGA took the decision to recall all batches of medicines manufactured by Pan Pharmaceuticals Ltd since 1 May 2002 that were supplied to the Australian market.

219 products manufactured and supplied in Australia by Pan Pharmaceuticals Limited were identified for immediate recall. These products were cancelled from the Australian Register of Therapeutic Goods for quality and safety reasons. The company also had its approval to supply its range of export products (approximately 1650) cancelled.

Because of the very tight timeframe for effecting the amendments in May 2003, only selected offences, provisions or regulatory requirements that directly addressed high priority concerns were able to be amended.

As these amendments only focused on parts of the Act, irregularities and inconsistencies within the legislation resulted.

For example, as a consequence of the increases to penalty levels for only some of the offences contained in the 2003 amendments, a greater disparity in penalty levels under the Act resulted for offences of a similar kind in other parts of the Act. In addition, changes made expeditiously in May 2003 saw an increase in penalties for some offences for the pharmaceutical sector, while the same or similar offences for other sectors remained of a lower order.

An example of this is where subsection 35(2) was amended in May 2003 so that it now imposes a penalty of 1,000 penalty units and/or 12 months imprisonment, whereas the corresponding provision applicable to medical devices (refer to subsection 41MN(2)) was not amended at the time, and remained at 60 penalty units. Amendment is therefore appropriate to

make the penalty levels imposed under subsection 41MN(2) consistent with subsection 35(2), particularly where it relates to the same conduct.

This was an accepted and recognised consequence of the need to act swiftly to immediately redress problems with the Act, in the knowledge that the further amendment would rectify these inconsistencies.

In addition, existing options for dealing with breaches of regulatory requirements are restricted to either criminal prosecution or administrative action 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 they are essential for the treatment of some conditions or there is a lack of available substitute products.

An unacceptable level of non-compliance with important regulatory requirements continues to be uncovered by the TGA, particularly through increased unannounced audits of manufacturing premises. Non-compliance is not restricted to manufacturing problems.

There are a number of instances where post market surveillance by the TGA has revealed ongoing problems with product compliance, ranging from a product contaminated with pathogens known to cause gangrene, to serious deficiencies in quality control systems.

The number and nature of breaches (in particular, manufacturing breaches) detected and their seriousness suggest that the current sanctions are inadequate in deterring non-compliance with important regulatory requirements designed to protect public health and safety.

D. The Amendment Bill

The Bill does not introduce new regulatory requirements for industry. The Bill provides for alternative options for dealing with non-compliance within existing regulatory requirements. The expanded range of enforcement mechanisms under the Bill provides a more flexible approach to securing compliance within the regulatory scheme. The introduction of civil penalties means that non-compliant persons can be fined rather than prosecuted in appropriate circumstances. In a number of cases this may be TGA's preferred course of action unless the conduct has the characteristic of criminality and is likely to cause or has caused harm or injury to consumers. The level of fines applicable in a particular case will be determined by a court, and will reflect the court's assessment of the seriousness of the conduct in question. The payment of fines rather than conviction is likely to be preferable to many persons in view of the adverse consequences on a person following a conviction.

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 action has to be taken that could put the company out of business.

Deterring non-compliance by the industry as a whole is important, not only in protecting consumers, but also in creating a fairer environment for all players as law-abiding sponsors and ensuring that manufacturers are not unfairly disadvantaged by their non-compliant competitors. Many sponsors of therapeutic goods subcontract the manufacture of their products to third parties, and a failure of these third party manufacturers to comply with regulatory measures can in turn impact adversely on the viability and reputation of these sponsors' businesses. This was

the case with Pan Pharmaceuticals who manufactured for a number of other companies. Increased compliance also leads to greater credibility and attractiveness of marketed products. Achieving a high level of compliance with the regulatory scheme for therapeutic goods in Australia will continue to advantage the industry as well as afford greater protection for consumers, and this is in the interest of government, the industry and the public.

Consultation

The Bill was drafted taking into account the document "A Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers" ("the Commonwealth Guide") issued by authority of the Minister for Justice and Customs. It should also be noted that the Attorney-General's Department was involved in the design and drafting of the Bill. Agreement was also obtained from the Minister for Justice and Customs in relation to the new enforcement measures proposed in the Bill and the increases in offence penalty levels.

Before proceeding with the bill the TGA consulted with the Office of Regulatory Review, which determined that a Regulation Impact Statement (RIS) was not required as the legislation did not impose additional regulatory requirements, and that the main purpose of the Bill is to enhance or refine enforcement mechanisms in the Act.

A draft of the proposed amendments to the Act was released to industry for comments in March 2005, along with an explanatory document outlining the rationale for the provisions of the Bill.

A number of organisations received verbal briefing to further explain the rationale and provision of the intended legislation. The groups included Medicines Australia; Complementary Healthcare Council of Australia (CHC); Australian Self Medication Association (ASMI); Generic Manufacturers Industry Association of Australia; the Medical Industry Association of Australia and Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD). These meetings enabled Departmental officials to fully understand any issues raised by industry.

In response to the concerns raised by industry, that the Bill did not provide enough detail on the way in which the TGA would go about administering the new regime, a series of draft guidelines were prepared. These guidelines covered:

- the difference in approach for civil and criminal proceedings;
- the issuing of infringement notices;
- the use of enforceable undertakings; and
- the use of media releases to inform the public about regulatory actions taken.

These guidelines were provided to industry in August. The TGA has had a series of meetings with industry to discuss the guidelines.

Attachment 1 to this submission is a copy of the draft guidelines.

Attachment 2 provides a schedule of the consultation meetings that have been held with industry groups to date.

While many of the concerns of industry were able to be addressed and resolved, there remain several areas of concern to the industry. These matters are summarised below.

Attachment 3 to this submission provides detailed responses to the specific issues for consideration as identified by the Senate Committee.

Attachment 4 to this submission provides a summary of the Frequently Asked Questions associated with the consultations.

Infringement notices

The Bill introduces infringement notices for strict liability offences and for conduct that is subject to the new civil penalty regime. 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. An infringement notice is intended to penalise, and deter, future breaches. If payment is made within the time permitted the liability for the offence or the contravention of a civil penalty provision is discharged. Further proceedings cannot be taken in relation to the offence or the contravention, and there is no record of a conviction or contravention.

An infringement notice, which will set out the particulars of the offence, is intended to give the offender the option of either paying the penalty specified in the notice or electing to have the matter dealt with by a court. If paid on time no further liability arises. A person issued with an infringement notice is under no obligation to pay the penalty amount stated on the notice. If not so paid, the matter may be subject to subsequent court proceedings.

The decision to issue an infringement notice cannot be taken lightly, and there are appropriate checks and balances to ensure that this action is appropriate. The draft guidelines provide that the option for the regulator to issue infringement notices will only arise following a decision to take judicial action against a person for non compliance with a regulatory requirement. Before the TGA can make this decision, independent legal advice must indicate that there are reasonable grounds for bringing an action against a person for breach of a regulatory requirement.

It is important to note that TGA is required by law to act as a model litigant. Thus there will be no action brought for trivial matters; 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.

The availability of infringement notices under the Bill has been modelled on infringement notice provisions in other existing Commonwealth legislation, such as section 117 of the *Aviation Transport Security Act 2004*, and section 497 of the *Environmental Protection and Biodiversity Conservation Act 1999*.

Infringement notices are the only feature of the Bill that provide an alternative to court proceedings.

Attachment 5 provides a current list of the breaches where an infringement notice could be issued. It is proposed that infringement notices are issued only in relation to strict liability offences or contraventions of civil penalty provisions.

Enforceable undertakings

The Bill introduces provisions that enable the TGA to accept enforceable undertakings by a person to either remedy breaches of regulatory requirements or to not engage in future contraventions. 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. If an undertaking is breached, the TGA may seek enforcement of the undertaking by the Federal Court. A manufacturer will have a stipulated time period within which the undertaking is proposed to operate.

The use of enforceable undertakings may be more efficient and productive in particular circumstances, such as where a deficiency in a manufacturing process needs to be rectified by a manufacturer whose general manufacturing ability is not in question. Their use in appropriate situations will ensure that public health and safety is assured while access to therapeutic goods for which the public has a continuing need is maintained. The power to accept enforceable undertakings is already given under Commonwealth legislation to other regulators such as the Australian Competition and Consumer Commission and the Australian Securities and Investments Commission.

The TGA will not have the power to compel a sponsor or manufacturer to give an enforceable undertaking, and also will not be obliged to accept an enforceable undertaking from a sponsor or manufacturer.

Enforceable undertakings cannot be unilaterally enforced by the TGA and can only be used where those regulated agree to their use.

There are some circumstances where the TGA is unlikely to accept undertakings from manufacturers and sponsors. For example:

- where to do so would not adequately address any public heath or safety issues;
- where the breach has a clearly established fault element; or
- where the breaches have resulted or will likely result in harm or injury to the public.

The TGA intends to use the court enforceable undertakings as an option only when it believes that a resolution based on enforceable undertakings offers the best solution to ensure that no further breaches will occur or that the breach will be appropriately remedied.

A party to the undertaking may seek to have the terms of the undertaking varied with the TGA's consent. In seeking any variation, the party may provide information to the TGA and reasons why a variation is being sought. The TGA will take into consideration the information provided and the reasons why a variation is being sought in determining whether to consent to the variation in the undertaking.

The Bill requires the Secretary to publish details of enforceable undertakings. This is to ensure public accountability for the use of enforceable undertakings by the TGA. The TGA will undertake to not publish personal or commercially sensitive information wherever possible.

Introduction of a civil penalty regime

The Bill introduces a parallel civil penalty regime for breaches of the Act. The inclusion in the Act of civil penalties, alongside criminal penalties, will 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 non-compliance with regulatory requirements by body corporates, who represent the bulk of those regulated under the Act 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 is also a measure adopted under other Commonwealth legislation, including the *Environmental Protection and Biodiversity Convention Act 1999* (the EPBC Act), the *Occupational Health and Safety (Commonwealth Employment) Act 1991* (the Commonwealth OHS Act), and the *Corporations Act 2001*.

The introduction of civil penalties means that noncompliant persons can be fined rather than prosecuted in appropriate circumstances. In a number of cases this may be the TGA's preferred course of action unless the conduct has the characteristic of criminality and is likely to cause or has caused harm or injury to consumers. The level of fines applicable in a particular case will be determined by a court and will reflect its assessment of the seriousness of the conduct in question. The payment of fines rather than conviction is likely to be preferable to many persons in view of the adverse consequences on a person following a conviction.

Civil penalties would not be used where the breach causes, or has the potential to cause considerable harm or injury to the public, particularly where the action was taken deliberately by the manufacturer. In this circumstance, the TGA will pursue criminal prosecutions through the DPP.

Levels of Civil Penalties

Civil penalties generally allow for higher penalty levels than those imposed under criminal offences.

To quote from paragraph 26.14 of the Australian Law Reform Commission's Report No 95 (ALRC Report No. 95), *Principled Regulation Report- Federal Civil & Administrative Penalties in Australia*, "The emphasis in deterrence theory is both on pricing the illegal behaviour and having a penalty large enough to deter a well-resourced corporate offender."

The higher penalties imposed under the Bill make it clear, for example, that cost-cutting measures employed by companies may not necessarily pay off. The proposed higher civil penalties compared to those to be imposed under the equivalent criminal offence provisions are consistent with recommendation 26-3 of the ALRC Report No. 95. The recommendation states that:

> "When considering the relationship between criminal and civil penalties, the effect of a criminal conviction should be taken into account when considering the relative severity of penalties. This would mean that a penalty for a non-criminal contravention could be larger than the penalty for a parallel criminal offence."

We also note recommendation 26-1 of the ALRC Report No. 95, which states:

> "In setting civil penalties, legislators should have regard to whether the level set will achieve the aim of the deterrence, which is the principal purpose of civil penalties."

Many of the companies regulated by the TGA have a capital worth around the billion dollar mark or more. Maximum penalties therefore should be set at a meaningful level to achieve the objective of effective deterrence for non compliant activity. However, the maximum penalty is not automatically imposed by a court where the court finds there has been a breach of the Act. The maximum penalty represents the uppermost limit that a court is permitted to fine a person, taking into account all the circumstances of each case.

The maximum civil penalties proposed by the Bill are the same as those applying under other Commonwealth legislation, such as the *Environment Protection and Biodiversity Conservation Act 1999* and *Trade Practices Act 1974*.

Executive liability

The Bill emphasises the responsibilities of corporate executives for their company's compliance with regulatory requirements by extending the criminal liability of the company, or the contravention of a civil penalty provision by a company, to executive officers who take part or are involved in the high level management or decision making of the company. These new provisions make executive officers accountable for failing to prevent a company's non-compliance with regulatory requirements under the Act or the Regulations, where such executives are aware of the non-compliance and are in a position to prevent it. This is consistent with the principle that a company can act only through its officers.

Again, this is consistent with other Commonwealth legislation. For example in the *Commonwealth Authorities and Companies Act 1997*, civil penalties are applicable to directors and officers of the Commonwealth authorities who breach certain legislative requirements.

Civil search warrants

In view of the introduction of civil penalty provisions that impose higher levels of pecuniary penalties for breaches of regulatory requirements under the Act and the Regulations, separate search and seizure provisions are required to be included in relation to the gathering of evidence for contraventions of civil penalty provisions.

The gathering of evidential material for the purpose of civil penalty contraventions ranges from the monitoring of compliance with the Act and Regulations to the full-scale investigation of a serious contravention. Warrants are therefore required to enable evidence gathering for serious contraventions as well as monitoring compliance under the Act and Regulations.

Release of information about regulatory decisions

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.

It will be up to the regulator to exercise judgement in issuing media statements on regulatory breaches. The importance of alerting the broader community on possible harmful products will need to be balanced by considerations relating to the weight of evidence, the seriousness of the breach, and the impact on the manufacturer and the industry. This is not a simple matter, and fundamentally some level of judgment must reside with the regulator.

There is no intention that the regulator will "name and shame" manufacturers through the media. This inclusion is purely intended to ensure the community is informed of any harmful, or potentially harmful, products and lessen the likelihood of harm or injury.

Summary

The new provisions of the Bill are an adjunct to the TGA's existing administrative and criminal provisions and represent the Government's intention to address the problems associated with the limited options currently available to the TGA in exercising their enforcement role.

The Bill aims to introduce a tiered approach for a number of criminal offences under the Act, with sanctions that match the degree of seriousness of the consequences of non compliance with regulatory requirements that amount to unlawful conduct.

The TGA will continue to work collegiately with industry to ensure a safe and effective supply of therapeutic products to the Australian Public.

A more detailed response with specific references to the issues raised by the Senate Committee is at **Attachment 3**.

References (refer page 4)

(1) Australian Government Department of Industry, Tourism and Resources. Pharmaceutical Industry Fact Sheets dated May 2005 and July 2005. (http://www.isr.gov.au)
(2) Australian Institute of Health and Welfare (AIHW) 2004. Health Expenditure Australia 2002-03. AIHW Cat. No. HWE 27 (Health and Welfare Expenditure Series No. 20). Canberra: AIHW. Table A4, p.84
(3) http://www.ausbiotech.org/md_fast_facts.asp
(4) http://www.miaa.org.au/industry.htm

Attachment 1 – Draft Guidelines

THERAPEUTIC GOODS AMENDMENT BILL 2005 IMPLEMENTATION - GENERAL PRINCIPLES

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3. General Principles – Enforceable Undertakings

4. General Principles for the use of Media Releases to Inform the Public about Regulatory Actions Taken

1. GENERAL PRINCIPLES – *Therapeutic Goods Act 1989*

Civil Proceedings versus Criminal Prosecutions

1.1 Background

Enforcement provisions included in the proposed Therapeutic Goods Amendment Bill 2005 are designed to support regulatory requirements included in the *Therapeutic Goods Act 1989* (the Act), with the aim of giving effect to the objects of the Act. The Therapeutic Goods Administration places a high priority on the protection of public health and safety by ensuring as far as possible that the system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods, established by the Act, will work. For this reason, the Bill introduces further options, including new judicial sanctions, to:

- help achieve the objects of the *Therapeutic Goods Act 1989* and the Regulations;
- maximise compliance with the regulatory requirements under the Act and Regulations;
- promote the supply of safe and good quality therapeutic goods; and
- maintain public confidence in the supply, manufacture, import and export of therapeutic goods.

The Bill includes provisions that insert a number of parallel civil penalty and criminal offence provisions in relation to substantially the same conduct. The introduction of new civil penalties for dealing with breaches of existing regulatory requirements is based on a recognition that civil penalties are often more appropriate for sanctioning corporate wrongdoing. Also, where criminal culpability is absent but serious breaches of critical regulatory requirements has occurred civil action rather than criminal prosecution may be more appropriate. Higher pecuniary penalties, which is the main feature of civil sanctions, may also be a more effective deterrent for regulating commercial activities to cancel any financial gains obtained through corporate non compliance.

General guidelines are outlined below to provide guidance on how the TGA may choose to either prosecute a person for committing an offence under the Act, or take civil action by applying to the Federal Court for a civil penalty order for a breach of a civil penalty provision.

1.2 Criminal Prosecution

A criminal offence conviction is considered to be the ultimate sanction for breaching the law. According to the ALRC Report No 95 at paragraph 2.9:

> "The main purpose of criminal law is traditionally considered to be **deterrence** and **punishment.** Central to the concept of criminality is the notation of individual culpability and the criminal intention for one's actions."

Where the regulated conduct involves actual harm or injury to the public, or could pose considerable harm to the public, and the requisite mental elements relating to the conduct can be established, the TGA will generally pursue a criminal prosecution. This is particularly the case where the level of culpability of the person warrants criminal sanction.

A criminal prosecution will generally be pursued where:

- there is a significant degree of criminality or culpability on the part of the alleged offender
- previous administrative sanctions or other enforcement measures have not resulted in compliance
- where the Australian Government or the Australian public expects that a crime will be dealt with by way of a prosecution;
- the conduct in question will result, is very likely to result or has resulted in harm or injury to the public
- the alleged crime is of such a nature or magnitude that it is important to deter potential offenders and prosecution will act as a very effective deterrent.

Where culpability and criminality of the conduct are not apparent but there is a need to address breaches of the Act and effectively deter future non-compliance, particularly by a body corporate, it would be appropriate for the TGA to apply for a civil penalty order.

1.3 Civil Penalties

Civil Penalties have become a recognised means of enforcement under various regulatory frameworks in Australia as well as other countries including the United States and New Zealand.

The focus of a civil penalty is generally the regulation of commercial activity, and is directed against corporate or white-collar wrongdoing. Civil penalties are appropriate in regulating commercial activities involving the manufacture and supply of therapeutic products, particularly where the activities are undertaken in the main by incorporated bodies, including subsidiaries of multinational companies engaged in commercial operations. The financial disincentive that a civil penalty regime provides to address and deter breaches of the Act is considered most likely to be more effective in appropriate circumstances.

Civil penalties are proposed as an alternative sanction for activity or conduct that underpins requirements designed to ensure that therapeutic goods used by the community meet acceptable standards of safety, quality, and efficacy. These requirements include compliance with standards applicable to the goods themselves, and compliance with standards in relation to the way these goods are manufactured. Civil penalty provisions are also proposed to apply to breaches of requirements relating to the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the ARTG), or compliance with conditions applying to exemptions from the need to include goods in the Register.

A decision to pursue a civil action may take into account one or more of the following factors:

- a disregard for or a significant degree of indifference to the regulatory requirements under the Act or Regulations;
- the Australian Government or the community expects that the matter will be dealt with by way of a serious enforcement action;
- it is of such a nature or magnitude that it is important to deter future non compliance by the same wrongdoer;
- it is of such a nature or magnitude that it is important to deter non compliance by other potential wrongdoers;
- the conduct in question has resulted in commercial benefit for the person;
- the conduct was for the purpose of commercial gain or advantage.

2. GENERAL PRINCIPLES - *Therapeutic Goods Act 1989*

Issuing infringement notices

2.1 INTRODUCTION

The *Therapeutic Goods Act 1989* (the Act) is the legislative framework within which the Therapeutic Goods Administration (TGA) undertakes all its regulatory activities.

The purpose of the alternative enforcement measures contained in the proposed Therapeutic Goods Amendment Bill 2005 (the Bill) is to provide strong support to the primary objective of the *Therapeutic Goods Act 1989* (the Act), which is to establish a system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia.

This objective not only serves to protect consumers and patient groups to whom therapeutic goods are supplied. It also serves the interests of industry by maintaining international standards for therapeutic goods and the manner in which they are manufactured to ensure the supply of high quality and safe goods. Unless the regulatory requirements contained in the Act are complied with, the objectives of the Act may be undermined. Non compliant activities therefore should be discouraged, and as appropriate punished, where non compliance increases the risk of eroding public health and safety, and creates an uneven playing field for compliant members of the industry. Persistent non compliance or non compliance that may lead, or has led to, harm to the public could in cases even damage the reputation of the industry as a whole.

The Act is proposed to be amended to provide greater enforcement options for the TGA in dealing with non-compliant conduct. These options provide greater flexibility in managing non compliance and may provide a better alternative to regulatory action that may include suspending or cancelling manufacturing licences, or cancelling goods from the Australian Register of Therapeutic Goods. The new regime will include a tiered criminal offence regime and a parallel civil penalty scheme for dealing with specific non-compliant conduct under the Act. One of the new measures flowing from the introduction of strict liability offences and civil penalty provisions is the option of issuing infringement notices, in lieu of initiating a prosecution for a strict liability offence or bringing a civil action for a breach of a civil penalty provision.

The option for the regulator to issue infringement notices **only arises** following a decision to take judicial action against a person for non compliance with a regulatory requirement. This decision may be to either prosecute a person for the non compliance, or alternatively to apply to the Federal Court for a civil penalty order. This decision will be taken only after independent legal advice has been received that there are grounds either for laying charges against a person or for applying to the Federal Court for a civil penalty order. In deciding to bring a civil action against a person and in the conduct of any civil litigation the regulator is bound to observe the Model Litigant Rules applying under the Legal Services Directions, issued by the Attorney-General under section 55ZF of the *Judiciary Act 1903*. These Directions set out the framework and requirements for the performance of Commonwealth legal services and, in particular, the conduct of litigation by Commonwealth agencies.

Once a decision is made to take judicial action, the option of having the matter dealt with by way of an infringement notice then becomes open to the regulator. If the matter is dealt with by way of an infringement notice and payment is made in respect of that notice, no further

action in relation to that infringement may be taken by the regulator, and there is no record of either a conviction for an offence, nor a judgement of the Federal Court against the non compliant person.

Where the regulator believes that the particular non compliance should be the subject of judicial action, the regulator may choose this course instead of issuing an infringement notice. This would be the case where, for example, the regulator decides that the issue of an infringement notice would not adequately deter future non compliance with regulatory requirements by the same person, or the non compliance is so severe it should be more appropriately handled by a court.

It should be noted that a person issued with an infringement notice is under no obligation to pay the penalty stated under the order. The person receiving the notice may elect instead to have the matter dealt with by a court. This is provided for under the proposed Bill.

2.2 THE ISSUE OF INFRINGEMENT NOTICES

Infringement notices will only be issued where the readily assessable elements of the breach can be identified. Infringement notices are therefore intended to apply only to conduct regulated under offences of strict liability or no fault civil penalty provisions.

The following is a general guide to when an infringement notice may be issued:

- where the breach has not resulted in serious harm or injury to the public;
- where there is no record of any effort or attempt to comply with the regulatory requirement breached;
- where payment of an infringement notice is considered to be an adequate deterrent to prevent future breaches;
- where the breach or the contravention cannot be effectively addressed by informal enforcement action;
- where the breach has resulted in commercial benefit; or
- where the breach occurred for financial reasons or considerations.

The TGA will only issue an infringement notice in circumstances where, based on independent legal advice, it can be demonstrated that the TGA has reasonable grounds for pursuing a breach of the Act through the criminal court system or before the Federal Court.

In general, where a contravention has occurred in relation to a person for the first time and there is no threat to public health and safety and the person takes immediate steps to rectify the breach, a warning letter may be given to the person who has contravened the relevant regulatory requirement. This is particularly the case where a person may have acted inadvertently or has misunderstood what is required under the Act or Regulations, and the non compliance is one that can be readily addressed immediately by the person concerned.

Judicial action, including where appropriate, any issue of an infringement notice, may be pursued by the TGA, where the same person repeats the contravention or makes no effort to comply with regulatory requirements.

Whether or not an infringement notice will be issued in relation to a breach of a strict liability provision or a contravention of a civil penalty provision will depend on the initial decision to pursue the breach through a criminal process or a civil process.

Taking into account these considerations, an infringement notice may be issued:

(a) in lieu of prosecuting a person for a strict liability offence; or
(b) in lieu of applying to the Federal Court for a civil penalty order.

2.2.1 Strict liability v civil penalty contravention as the basis for issuing an infringement notice

For actions or conduct under the Act that are covered by a parallel strict liability offence and civil penalty provision, the TGA may seek to pursue a criminal conviction where there is an element of culpability, particular where an individual is involved, and pursue civil penalties in other circumstances. Conviction of a crime carries with it a range of consequences beyond the immediate penalty, whether the conviction results in imprisonment or a pecuniary penalty or both.

Where culpability and criminality of the conduct are not apparent but there is a need to address breaches of the Act and deter future non-compliance, or the non compliance is attributed to a company, the TGA may opt for a civil penalty fine.

Criminal conviction carries with it a stigma, particularly where the conviction is accompanied by imprisonment. As with other consequences discussed above, this will have more impact on a natural person rather than on a body corporate (as it cannot be imprisoned). For these reasons, it may often be appropriate to opt for a civil penalty where the wrongdoer is a corporation.

2.2.2 When Will An Infringement Notice Be Issued?

The infringement notice scheme will only be considered where the TGA contemplates judicial action ie. Where the regulator opts for either criminal or civil sanction.

An infringement notice will only be issued where a decision is made to:

(a) prosecute for an offence of strict liability; or
(b) commence civil proceedings for a contravention of a civil penalty provision.

The TGA intends to only issue an infringement notice where, based on preliminary independent legal advice, it can be demonstrated that the TGA has reasonable grounds for pursuing a breach of the Act through the criminal justice system or before the Federal Court for a civil penalty contravention.

An infringement notice is intended to penalise, and deter, future breaches. If payment is made within the time permitted the liability for the offence or the contravention of a civil penalty provision is discharged. Further proceedings cannot be taken in relation to the offence or the contravention, and there is no record of a conviction or a contravention. If the decision by the alleged offender is not to pay the infringement notice, the matter will be taken to the

appropriate court, and it is up to a court to determine whether the person is in breach or not, as well as the nature and level of the sanction to be applied.

However, the TGA will not necessarily issue an infringement notice in all circumstances. There may be circumstances that warrant direct prosecution or direct application for an order for a civil penalty contravention.

Matters that may be taken into consideration when determining whether to issue an infringement notice, based on the level of risk attached to a breach of a regulatory requirement, include the following:

(i) nature of the breach
(ii) degree of *likely* harm
(iii) number and frequency of breaches
(iv) nature of the product
(v) significance of breach in terms of safety, efficacy and quality
(vi) absence of any effort to ascertain and comply with regulatory requirements

An infringement notice can only be issued within 12 months of the commission of the alleged offence or civil penalty contravention.

2.3 APPLICABILITY OF THE INFRINGEMENT NOTICE SCHEME

The infringement notice scheme will only apply to the offences of strict liability and civil penalty provisions in the Act. The tables below provide a current list of the breaches where an infringement notice can be issued in relation to the strict liability offence or the contravention of a civil penalty provision.

2.3.1 Provisions with strict liability and/or civil penalties

Existing provision under the Therapeutic Goods Act 1989		***Proposed provision in the Therapeutic Goods Amendment Bill 2005***		***Description of conduct***
Medicine or therapeutic device	**Medical Device**	**Strict liability offence**	**Civil penalty provision**	
Provisions related to compliance with standards (including manufacturing standards) and conditions applying to exemptions from complying with standards				
s14	s41MA	14(2,7,11) 41MA(2,6,10)	14A(1-3) 41MAA(1-3)	Breach of standard applying to goods
s15(2)	s41MC(2)	15(3) 41MC(3)	15AA 41MCA	Breach of condition attaching to standards
s35(1), s35(4)	s41ME	35(2,7) 41ME(2,6)	35A(1,2) 41MEA(1,2)	Manufacturing without a licence, not applying manufacturing standards
s35(2)	s41MN(2)	35B(2) 41MN(6)	35C 41MNA(2)	Beaching conditions of a licence or conformity assessment certificate
	s41EI	41EI(2)	41EIA	Providing a false/misleading statement in connection with conformity assessment certificate
Issues relating to inclusion/retention of goods in the Australian Register of Therapeutic Goods (ARTG)				
s20(1)	s41MI(1)	19B(2) 41MI(2)	19D(1)	Failure to include goods in ARTG as required
s22(2A) s22A	s41FE	21A(2) 41FE(2)	21B(1) 41FEA	Providing false statements when entering goods in the ARTG

s31(6)	s41JB(4)	31(5B) 41JB(5)	31AAA 41JBA	Providing false/misleading information in connection with entry or retention of goods in the ARTG
s22(3)	s41MN(1)	21A(6) 41MN(2)	21B(2) 41MNA(1)	Breaching condition of registration or listing
Failure to comply with recovery/notification requirements				
s30EC	s41KC	30EC(2) 41KC(2)	30ECA 41KCA	Goods required to be recovered as goods do not meet standards etc
s30F(5)		30F(4C)	30FA	Emergency goods where actual/potential threat to Australia, not fit for use
s42V(6)		42V(6A)	42VA	Tampered products

2.3.2 Provisions with strict liability offences and no civil penalty contraventions

Breach of condition applying to exempt goods		
Existing provision under the Therapeutic Goods Act 1989	***Proposed provision in the Therapeutic Goods Amendment Bill 2005*** ***- Strict liability only-***	***Description of conduct***
s22(7A) and (8)	21A(10) & (13)	Supply of goods not in accordance with authority or conditions
s41MO(1) and (2)	41MO(2) & (6)	Misuse of medical devices exempted for a special use
s20(2C)		Importation of goods in breach of conditions of exemption under s.18A

2.3.3 Provisions with civil penalty contraventions and no strict liability offences

Existing provision under the Therapeutic Goods Act 1989		***Proposed provision in the Therapeutic Goods Amendment Bill 2005*** ***- Civil penalty only***		***Description of conduct***
Medicine or therapeutic device	**Medical Device**	**Medicine or therapeutic device**	**Medical Device**	
s42E (applies to both)		42EA (applies to both)		Conduct dealing with counterfeit goods
s54AB(1) (applies to both)		54AC (applies to both)		Destruction & falsification of documents
s20(2)		19D(3,4)	-------	Failure to include ARTG no. on label of goods
s20(1B)		20A(1)	-------	Import, export, supply where Secretary not properly notified
s29A(1)	s41MP(1)	29AA(1)	41MPA(1)	Fail to notify of adverse events
s29B(3)	s41MQ(3)	29C(1)	41MR(1)	Fail to comply with notice to notify of adverse events
s29B(4)	s41MQ(4)	29C(2)	41MR(2)	False/misleading info when notifying of adverse events
	s41MH	----- -	41MHA	False statement in declaration
s22(4)	s41ML	21B(3)	41MLA(1)	Representing that medicines or devices are included in the ARTG, or are exempt etc, when they are not
s22(7AB)		22AA	-------	Act or omission breaches a condition of exemption under s.18A

2.4 WHAT LEVEL OF FINES WILL APPLY FOR INFRINGEMENT NOTICES?

The infringement notice scheme should not be viewed as allowing alleged offenders to get away with breaches of the Act lightly, in lieu of the TGA prosecuting or commencing civil proceedings. Payment of infringement notices has the effect of precluding the regulator from taking any further judicial action in relation to the breach of a regulatory requirement, and

furthermore there is no formal record of any infringement having occurred. The monetary penalties attached to infringement notices take this into account, and are also intended to reflect the degree of risk potentially posed by the non-compliant conduct.

2.4.1 Maximum level of monetary penalty for a strict liability offence

The maximum penalty for a strict liability offence range from 60-2,000 (but mostly in the range of 1,000-2,000) penalty units for an individual and 300-10,000 (but mostly in the range of 5,000-10,000) penalty units for a corporation. The maximum fine that an infringement notice may be issued for, in relation to a **strict liability** offence, cannot exceed:

1/5th of the offence penalty ie. 12-400 penalty units for an individual and 60-2,000 for a corporation.

If a decision is made to issue an infringement notice pursuant to a strict liability offence, the maximum level of fine allowable for an infringement notice will be issued.

2.4.2 Maximum level of monetary penalty for a contravention of a civil penalty provision

The maximum penalty for a civil contravention ranges from 200-5,000 (but mostly in the range of 3,000 to 5,000) penalty units for an individual and 2,000-50,000 (but mostly in the range of 30,000 to 50,000) penalty units for a corporation. The maximum fine that an infringement notice may be issued for, in relation to a contravention of a civil penalty provision, cannot exceed:

1/10th the pecuniary penalty attached to a civil penalty provision ie. 20-500 penalty units for an individual and 200-5,000 penalty units for a corporation.

The level of fine will be tiered on the basis of the risk multiplier discussed in paragraph 4.2 below.

2.4.3 Difference in the level of fines for a strict liability offence and a civil penalty contravention

The difference between the level of penalties under a strict liability offence and a civil penalty provision, and the corresponding fines under an infringement notice, reflects the more serious consequences and stigma associated with a criminal prosecution and subsequent conviction, compared to the declaration of a contravention of a civil penalty and the consequent pecuniary penalty imposed on a person.

2.4.4 Issuing an infringement notice for a contravention of civil penalty provision and the Risk Multiplier

An infringement notice issued when contemplating a contravention of a civil penalty provision will be based on a tiered fine system. The tiered system will be applied with a risk multiplier, where the maximum fine attached to an infringement notice for a civil penalty provision will be multiplied by 0.25 or 0.5, for the two lower level breaches.

The level of the tiered fine will be based of the following factors:

(i) nature and scale of breaches
(ii) recurrence of the same breach;
(iii) the degree of familiarity with or understanding of the regulatory requirements which the person ignores or continues to ignore;
(iv) failure to rectify breach after providing TGA assurances;
(v) financial gain incurred; and
(vi) cost-cutting measures apparent

2.4.5 Risk Multiplier

For infringement notices issued pursuant to a contravention of a civil penalty provision, a risk multiplier will be applied to the maximum fine allowed for an infringement notice. The risk multiplier will only apply to civil penalty provisions to allow for a reasonable level of fine for an infringement notice, in light of the higher pecuniary penalties that can be imposed for a contravention of a civil penalty provision. Under a civil penalty provision, the maximum penalty for a corporation is 10 times that of an individual.

Therefore, fines issued under this process will not automatically be at the maximum fine allowed, but rather have a range of fines for a less serious breach of the Act (Tier 1) to a more serious breach (Tier 3), where:

Tier 1 fine (individual) = $1/10^{th}$ civil penalty for individual x **0.25**;
(corporation) = $1/10^{th}$ civil penalty for corporation x **0.25**

Tier 2 fine (individual) = $1/10^{th}$ civil penalty for individual x **0.5**;
(corporation) = $1/10^{th}$ civil penalty for corporation x **0.5**

Tier 3 fine (individual) = $1/10^{th}$ civil penalty for individual
(corporation) = $1/10^{th}$ civil penalty for corporation

2.5. THE INFRINGEMENT NOTICE DOCUMENT

2.5.1 What information will be included in the infringement notice?

Pursuant to part 5A-2 of the Act, the Regulations will specify the information that should be included in an infringement notice.

An infringement notice will include:
a) the name of the person on whom the notice is being served;
b) that it is being served on behalf of the TGA and the authorised officer's name;
c) the nature of the alleged offence or contravention;
d) the time (if known), the date on and place at which the offence or contravention is alleged to have occurred;
e) the maximum penalty that a court could impose for the alleged offence or contravention;
f) the amount of fine payable under the infringement notice in respect of the alleged offence or contravention;

g) a statement that if the person receiving the infringement notice does not wish the matter to be dealt with by a court, that the person may pay to the TGA, within 28 days of service of the notice, the amount of penalty specified in the notice; and
h) a statement that the person may make written representations seeking withdrawal of the infringement notice.

Other relevant information that may be included in an infringement notice includes:
a) the manner in which payment of the penalty can be made;
b) the address or location where payment of the penalty can be made;
c) a telephone number or contact address to obtain further information about the allege offence or contravention or request extra time for payment of the fine;
d) a statement if the penalty is paid within 28 days of the service of the infringement notice that the person can not be prosecuted for the alleged offence or civil proceedings against them for the alleged contravention and will not be regarded as been convicted of the offence or that they contravened a civil penalty provision;
e) reasons for issuing the infringement notice.

2.6. WHAT HAPPENS IF A PERSON IS ISSUED WITH AN INFRINGEMENT NOTICE

2.6.1 Compliance with an Infringement Notice

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. Similarly, if complied with in relation to a contravention of a civil penalty, the person will not be the subject of a proceeding in the Federal Court seeking an order in relation to the contravention of a civil penalty provision, and the person will not be taken to have contravened the civil penalty provision. Payment of infringement notices is not mandatory. However, if the person elects to pay an infringement notice, the person is no longer liable for prosecution nor will the person be the subject of a contravention order for a breach of a civil penalty provision under the Act.

2.6.2 Contesting an Infringement Notice – Withdrawal of an infringement notice

The Regulations will allow for procedures for the withdrawal of an infringement notice. A person issued with a notice will have the opportunity to provide any facts or information that the person believes ought to be taken into account in relation to the alleged offence or civil penalty contravention, within a specified period after the service of the notice.

Where the person disputes the notice by notifying the issuer of any facts or matters that the person believes ought to be taken into account in relation to the alleged offence or alleged contravention of a civil penalty provision, the TGA must decide whether to withdraw the notice, taking into consideration the information provided by the person. The person will then be informed of the decision to withdraw or refuse to withdraw the notice.

It should be noted that at no time would a person be compelled to pay a fine in response to the issue of an infringement notice – the person issued with such a notice may elect to pay, or may decline to pay.

3. GENERAL PRINCIPLES - *Therapeutic Goods Act 1989*

Enforceable undertakings

3.1 Introduction

Court enforceable undertakings are alternative enforcement measures that are currently available to agencies such as the ACCC (section 87B of the *Trade Practices Act 1974*), Civil Aviation Safety Authority (section 30DK of the *Civil Aviation Act 1988*), ASIC (sections 93A and 93AA of the *Australian Securities and Investments Commission Act 2001*), COMCARE (Clause 16, Schedule 2 of the Commonwealth OHS Act) and the Australian Communications Authority (sections 37-40 of the *Spam Act 2003*). Section 42YL is drafted consistently with the above provisions, in particular, section 87B of the *Trade Practices Act 1974*.

Court enforceable undertakings could provide an alternative means for addressing and remedying breaches of the Act in lieu of taking legal action against a person, or taking administrative action, such as the cancellation of a manufacturing licence in relation to a person or the cancellation of a therapeutic good from the Australian Register of Therapeutic Goods.

Enforceable undertakings, like infringement notices, cannot be used to "coerce" sponsors or manufacturers to address or remedy breaches of the Act or the Regulations. Whether or not an undertaking is proposed by a person in relation to whom regulatory action may be taken is entirely up to that person, the TGA has no power to require any person to provide undertakings. However, once an undertaking is offered and accepted by the TGA, then undertaking should be honoured, and therefore the undertaking should be enforceable.

As a regulator, where a breach of the Act calls for regulatory action, the TGA has an obligation to protect public health and safety through the exercise of its powers under the Act and the Regulations. Enforceable undertakings represent an alternative option for addressing breaches of regulatory requirements by sponsors and manufacturers in a manner that can accommodate the operations of such parties while at the same time being acceptable to the TGA. Enforceable undertakings allow some flexibility in the way these breaches are to be addressed or remedied by sponsors and manufacturers. However, no one is not under any obligation to provide such undertakings and, if none is provided to the TGA, the TGA will still be required to take the necessary regulatory action available to it.

Enforceable undertakings will not be the appropriate option to resolve every matter involving a perceived breach. Enforceable undertakings are remedial in nature, not punitive.

As noted, the TGA is required to address breaches of the legislation it administers. In some cases, the regulatory action available to the TGA may not be the optimal solution in relation to a sponsor or manufacturer for addressing the identified breaches of the Act and the Regulations. Court enforceable undertakings are a mechanism to enable a person in breach to suggest an alternative solution to remedy breaches. Where an alternative suggestion that is offered by a sponsor or manufacturer is accepted by the TGA, then the proposed action or undertaking must be enforceable, in this case by a court of law, to justify the TGA not resorting to its usual powers. Otherwise the TGA may not be discharging its statutory obligation to protect public health and safety.

Once an enforceable undertaking is entered into, compliance will be obligatory. If an undertaking is not honoured, then the TGA will seek an order from the court requiring the relevant company or person to comply with the undertaking.

The TGA intends to use the court enforceable undertakings as an option only when it believes that a resolution based on enforceable undertakings offers the best solution to ensure that no further breaches will occur or that the breach will be appropriately remedied.

A party to the undertaking may seek to have the terms of the undertaking varied with the TGA's consent. In seeking any variation, the party may provide information to the TGA and reasons why a variation is being sought. The TGA will take into consideration the information provided and the reasons why a variation is being sought in determining whether to consent to the variation in the undertaking.

3.2 Decision to accept enforceable undertakings

The TGA will accept an enforceable undertaking if it offers the best and most appropriate solution for addressing a breach of regulatory requirements.

In deciding between litigation or other enforcement sanctions and an enforceable undertaking, the TGA may take into consideration the following:

(a) the nature of the breach or the alleged breach in terms of:

  (i) quality, safety, efficacy, or performance of the products; and
  (ii) the conduct of the person or the company in relation to the breach; and
  (iii) the type of therapeutic goods that are the subject of the breach; and
  (iv) the impact on public health and safety; and
  (v) the magnitude of the risk created; and

(b) the extent to which any meaningful undertakings can be given to remedy the breaches and mitigate the risk; and
(c) the likelihood that the enforceable undertaking will be fulfilled; and
(d) the apparent good faith of the company or person; and
(e) the ability of the TGA to properly monitor compliance with the enforceable undertaking; and
(f) the history of breaches of requirements under the Act and the Regulations, including any previous convictions or contraventions; and
(g) the prospect of an effective and timely resolution of the matter; and
(h) the apparent good faith of the person.

3.3 Acceptance of an enforceable undertaking

The TGA will not have the power to compel a sponsor or manufacturer to give an enforceable undertaking, and also will not be obliged to accept an enforceable undertaking from a sponsor or manufacturer. The TGA's primary responsibility is to protect public health and safety, and unless the acceptance of an enforceable undertaking will effectively address breaches of regulatory requirements and minimize any possible harm to the public, the TGA will not accept undertakings.

Undertakings must address the conduct or circumstance which has given rise to the alleged or perceived breach and its consequences. They must also include detailed future actions to prevent a recurrence of that breach of the Act and/or Regulations. The undertakings must be provided in writing.

3.4 Where an undertaking is not accepted

Where breaches of the regulatory requirements clearly establish the fault elements or where the breaches have resulted or will result in harm or injury to the public, the TGA generally will not agree to an enforceable undertaking as an alternative to, for example, prosecution or resorting to administrative sanctions.

The TGA will also not accept an undertaking if the terms of the undertaking purport to set up a defence for possible non-compliance or places an obligation upon the TGA.

3.5 Compliance with undertakings

Following acceptance of an undertaking, the TGA requires that its implementation and effectiveness be monitored by the other party to the undertaking. The terms of the undertaking may include the monitoring and reporting of the implementation and effectiveness of the undertakings.

Monitoring will generally be the responsibility of the person concerned. Where the TGA has reason to believe that the person has not complied with an undertaking, the TGA will try to resolve the matter initially by consultation.

If the approach fails, the TGA will not hesitate to apply to the Federal Court for appropriate orders.

Subsection 42YL(5) provides that if the court is satisfied that the person has breached a term of the undertaking, the court may make all or any of the following orders:

(a) an order directing the person to comply with that term of the undertaking;
(b) an order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach.
(c) any order that the court considers appropriate directing the person to compensate any other person who has suffered loss or damage as a result of the breach
(d) any other order that the court considers appropriate.

3.6 Variations to the terms of an undertaking

Subsection 42YL(2) allows the person to withdraw or vary undertakings at any time, with the consent of the Secretary.

This allows negotiations for changes if undertakings are subsequently found to be difficult to comply with, not practical, the terms do not appropriately address the perceived breach or alleged breach, or changes in circumstances occur.

The TGA will consider such requests as long as they do not alter the purpose of the original undertakings. The published undertakings will include the incorporated variations.

3.7 Monitoring an undertaking and information requirements

In order to ensure that the terms of the enforceable undertakings are complied with and to assist in monitoring that compliance, the TGA will seek the inclusion of provisions in the undertakings requiring reporting and the provision of relevant requirements to be made available to TGA.

3.8 Publication of enforceable undertakings

Proposed subsection 42YL(3) provides that the Secretary must publish details of the undertaking, as in force from time to time, on the Internet. This provision is consistent with subsection 30DK(4) of the *Civil Aviation Act 1988*. ACCC and ASIC (refer to subsection 93A(6) of the *Australian Securities and Investment Commission Act 2001*) also make enforceable undertakings publicly available.

Information relating to a suspension or revocation of a manufacturing licence, criminal convictions, findings by a Court relating to the contravention of a civil penalty provision, and recovery of some types of therapeutic goods that have been cancelled from the Australian Register of Therapeutic Goods would be information that is publicly available.

As court enforceable undertakings are an alternative enforcement measure for breaches of regulatory requirements under the Act (where it is considered appropriate), it is appropriate that information about undertakings and the terms of the undertakings are made publicly available.

It is possible that parts of the enforceable undertakings may contain commercially sensitive information or personal information. If that is the case and the party to the undertaking requests that the information not be released, then the TGA may agree that this class of information be deleted from the published form of the undertakings.

4. GENERAL PRINCIPLES - *Therapeutic Goods Act 1989*

Use of media releases to inform the public about regulatory actions taken

Provisions already exist in the Therapeutic Goods Act 1989 (the Act) that require a number of regulatory decisions to be made public through gazette notices. The use of media releases to inform the public about regulatory actions taken under the Act or Regulations will only be used if there is a public health safety risk.

Attachment 2 – Consultation Summary

Industry Meetings – re Therapeutic Goods Amendment Bill 2005

15 March 2005	-	Industry Briefing on Therapeutic Goods Amendment Bill - Complementary Healthcare Council of Australia (CHC)
15 March 2005		Industry Briefing on Therapeutic Goods Amendment Bill - Medicines Australia
16 March 2005	-	Industry Briefing on Therapeutic Goods Amendment Bill - Australian Self-Medication Industry (ASMI)
17 March 2005		Industry Briefing on Therapeutic Goods Amendment Bill – Medical Devices Industry of Australia (MIAA)
23 March 2005	-	Therapeutic/Industry Consultative Committee (TICC) Bi-lateral Meeting, Morning session with CHC &ASMI
1 April 2005	-	Industry Briefing on Therapeutic Goods Amendment Bill - Generic Medicines Industry Association (GMIA)
7 April 2005	-	ASMI meeting with TGA
22 April 2005	-	Direct Selling Association and CHC
4 May 2005	-	Industry Briefing on Therapeutic Goods Amendment Bill Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)
5 May 2005	-	Therapeutic Industry Consultative Committee meeting (TICC) Meeting of industry representatives at TGA MIAA, ASMI, CHC, Consumers Health Forum, Dental Industry Association, Australia Biotech, Medicines Australia, GMIA.
5 May 2005	-	ASMI meeting at TGA
12 May 2005	-	ASMI (topic of meeting ASMI issues in relation to data exclusivity and market protection)

Consultation on Draft Guidelines

2 September 2005	ASMI meeting at TGA to discuss draft guidelines for the Bill
9 September 2005	GMIA meeting at TGA to discuss draft guidelines for the Bill
16 September 2005	Medicines Australia meeting at TGA to discuss draft guidelines for the Bill
16 September 2005	CHC meeting at TGA to discuss draft Guidelines for the Bill
22 September 2005	MIAA, AusBiotech & ADIA meeting at TGA to discuss draft guidelines for the Bill
23 September 2005	ACCORD meeting at TGA to discuss draft guidelines for the Bill

Attachment 3 – Detailed Response to the Issues for Consideration by Senate Community Affairs Legislation Committee

PART A

(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)

(i) The scope of alleged breaches attracting infringement notices

Background

The Bill enables regulations to be made to support a scheme under which a person who is alleged either to have committed a criminal offence against the *Therapeutic Goods Act 1989* ("the Act"), or contravened a civil penalty provision of the Act, may be offered the option of paying a specified penalty top the commonwealth rather than undergoing criminal prosecution or civil penalty provisions.

Section 42YJ(2) of the Bill limits the maximum penalty an individual alleged to have committed an offence may be required to pay by way of an infringement notice to one-fifth of the maximum penalty that could have been imposed on an individual for that offence.

Section 42YJ(3) of the Bill limits the maximum penalty a body corporate alleged to have committed an offence may be required to pay by way of an infringement notice to 5 times the maximum penalty that could have been imposed on an individual for that offence.

Section 42YK of the Bill deals with infringement notices in respect of provisions of the Act imposing a civil penalty, noting at 42YK(1) that the Regulations may make provision enabling a person who is alleged to have contravened a civil penalty provision to pay to the Commonwealth, as an alternative to civil penalty proceedings against the person, a specified penalty.

Section 42YK(2) of the Bill limits the maximum penalty amount that may be required by way of an infringement notice to one-tenth of the maximum penalty prescribed for contravening that provision.

Implementation

The infringement notices will only be issued where the readily assessable elements of the breach can be identified. Infringement notices are therefore intended to apply only to conduct regulated under offences of strict liability or no fault civil penalty provisions. This is intended to be reflected in the Regulations that will be made to support the infringement notices scheme.

Guidelines have been drafted to provide an indication as to when infringement notices could be issued.

The option for the regulator to issue infringement notices **only arises** following a decision to take judicial action against a person for non compliance with a regulatory requirement. This decision may be to either prosecute a person for the non compliance, or alternatively to apply to the Federal Court for a civil penalty order. This decision will be taken only after independent legal advice has been received that there are grounds either for laying charges against a person or for applying to the Federal Court for a civil penalty order.

In deciding to bring a civil action against a person, and in the conduct of any civil litigation, the regulator is bound to observe the Model Litigant Rules applying under the Legal Services Directions, issued by the Attorney-General under section 55ZF of the *Judiciary Act 1903*. These Directions set out the framework and requirements for the performance of Commonwealth legal services and, in particular, the conduct of litigation by Commonwealth agencies.

Once a decision is made to take judicial action, the option of having the matter dealt with by way of an infringement notice then becomes open to the regulator. If the matter is dealt with by way of an infringement notice and payment is made in respect of that notice, no further action in relation to that infringement may be taken by the regulator, and there is no record of either a conviction for an offence, nor a judgement of the Federal Court against the non compliant person.

Where the regulator believes that the particular non compliance should be the subject of judicial action, the regulator may choose this course instead of issuing an infringement notice. This would be the case where, for example, the regulator decides that the issue of an infringement notice would not adequately deter future non compliance with regulatory requirements by the same person, or the non compliance is so severe it should be more appropriately handled by a court.

It should be noted that a person issued with an infringement notice is under no obligation to pay the penalty stated under the order. The person receiving the notice may elect instead to have the matter dealt with by a court. This is provided for under the proposed Bill.

The tables at Attachment 5 provide a current list of the breaches where an infringement notice could be issued in relation to the strict liability offence or the contravention of a civil penalty provision.

(ii) The use of alternatives to court proceedings

The only use of an alternative to court proceedings proposed by the Bill is the issue of an infringement notice in lieu of taking a matter to court.

<u>The use of infringement notices</u>

An infringement notice is a notice authorised by statute setting out particulars of an alleged offence or civil breach. It gives the person to whom the notice is issued the option of either paying the penalty set out in the notice to expiate the offence or civil breach, or electing to have the matter dealt with by a court. There is no compulsion for a person in receipt of an infringement notice to pay the fine. The Regulations will provide that the notice specifies the time and method for payment and the consequences if the person to whom the notice is issued fails to respond to the notice either by making payment or electing to contest the alleged offence or civil breach.

Infringement notices are an optional penalty mechanism that offers the alleged offender the opportunity to deal with their alleged offence or civil breach by paying the infringement notice penalty. The benefit for the offender in paying an infringement notice penalty is that it is generally quicker and easier to pay the infringement notice penalty without question than to undergo lengthy and potentially expensive court proceedings, and risking either conviction for a criminal offence or an order directed by a court to pay a civil penalty.

The Australian Law Reform Commission (ALRC) has described infringement notices as an offer of alternative penalty made by a regulator to an alleged offender to settle the matter without resort to conventional enforcement mechanisms, and that, considered in this way, an infringement notice is not a sentencing order made by a court subsequent to a binding determination of liability, but is simply a process for the expedient handling of certain offences[1].

Infringement notices have an obvious benefit for regulators such as the TGA, because they provide an expeditious and often less expensive means of dealing with and deterring breaches of the Act than court action[2]. They also provide relief from proceedings that would otherwise be required to enforce the law, and serve to encourage compliance with regulatory requirements by demonstrating that the risk of judicial sanction is real.

An infringement notice is intended to penalise, and deter, future breaches. If payment is made within the time permitted the liability for the offence or the contravention of a civil penalty provision is discharged. Further proceedings cannot be taken in relation to the offence or the contravention, and there is no record of a conviction or contravention.

Compliance with an infringement notice is not to be taken as an admission of any contravention of the Act. If the decision by the alleged offender is to not pay the infringement notice, the matter will be taken to the appropriate court, and it is up to a court to determine whether the person is in breach or not, as well as the appropriate level of sanction to be applied.

It is important to note that a person issued with an infringement notice is under no obligation to pay the penalty amount stated on the notice. They may elect instead to have the matter dealt with by a court. The capacity to pay a penalty pursuant to an infringement notice recognises that lengthy criminal prosecution or civil litigation proceedings may not be the optimal means of dealing with some breaches of regulatory requirements, both for the alleged offender and the TGA. The Regulations will provide that an infringement notice can only be issued within 12 months of the commission of the alleged offence or civil penalty contravention.

As referred to above, the TGA will only issue an infringement notice in circumstances where, based on independent legal advice, it can be demonstrated that there are reasonable grounds for taking judicial action to pursue a breach of the Act.

And as noted above, infringement notices are therefore intended to apply only to conduct regulated under offences of strict liability or under civil penalty provisions.

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[1] Australian Law Reform Commission (ALRC), *"Principled Regulation Report: Federal Civil and Administrative Penalties in Australia, Report 95"*, December 2002, p427.
[2] Australian Law Reform Commission (ALRC), *"Securing Compliance Discussion Paper: Civil and Administrative Penalties in Australian Federal Regulation, Discussion Paper 65"*, April 2002, pp 396-397.

Matters that may be taken into consideration when determining whether to issue an infringement notice, based on the level of risk attached to a breach of a regulatory requirement, include the following:

(i) nature of the breach;
(ii) degree of likely harm;
(iii) number and frequency of breaches;
(iv) nature of the product;
(v) significance of breach in terms of safety, efficacy and quality; and
(vi) absence of any effort to ascertain and comply with regulatory requirements.

In deciding to bring a civil action against a person and in the conduct of any civil litigation, the TGA is bound to observe the Model Litigant Rules applying under the Legal Services Directions, issued by the Attorney-General under section 55ZF of the *Judiciary Act 1903 (Cth)*. These Directions set out the framework and requirements for the performance of Commonwealth legal services and, in particular, the conduct of litigation by Commonwealth agencies.

The availability of infringement notices under the Bill has been modelled on infringement notice provisions in other existing Commonwealth legislation, such as section 117 of the *Aviation Transport Security Act 2004*, and section 497 of the *Environmental Protection and Biodiversity Conservation Act 1999*.

Enforceable undertakings are not an alternative to court proceedings

Court enforceable undertakings are a mechanism whereby a person in breach of a regulatory requirement of the Act or Regulations may suggest an alternative solution to remedy the breach. Enforceable undertakings are **not** a form of sanction, and they do not represent an alternative to court proceedings.

Section 42YL of the Bill enables the Secretary of the Department to accept *written* court enforceable undertakings as an alternative means of securing compliance with regulatory requirements. Under the proposed scheme, those in breach of regulatory requirements may have the option of providing undertakings to correct, address or remedy non-compliance, sometimes as an alternative to the TGA taking administrative action to address non-compliance, such as the cancellation of a manufacturing licence or the cancellation of a therapeutic good from the Australian Register of Therapeutic Goods (ARTG).

Enforceable undertakings represent an alternative option for addressing breaches of regulatory requirements by sponsors or manufacturers in a manner that can accommodate the operation of such parties without compromising public health and safety. Enforceable undertakings allow some flexibility in the way these breaches are to be addressed or remedied by sponsors and manufacturers.

Enforceable undertakings, like infringement notices, cannot be used to coerce sponsors or manufacturers to address or remedy breaches of the Act or the Regulations. Whether or not an undertaking is proposed by a person in relation to whom regulatory action may be taken is entirely up to that person, and the TGA has no power to require any person to provide undertakings. In addition, the TGA is not required to accept any undertaking that is offered. Section 42YL(1) of the Bill makes this clear where it notes-

"The Secretary may accept a written undertaking given by a person in connection with a matter in relation to which the Secretary has a power or function under this Act or the Regulations.".

Section 42YL(2) of the Bill permits a person who has given an enforceable undertaking in accordance with section 42YL(1) to withdraw or vary that undertaking at any time, but only with the consent of the Secretary. In seeking any variation, the person may provide information to the TGA and reasons why a variation is being sought. The TGA will take into consideration the information provided and the reasons why a variation is being sought in determining whether to consent to the variation of the undertaking.

Where an alternative suggestion offered by a sponsor or manufacture is accepted by the TGA, the proposed action or undertaking must be enforceable, in this case by a court, to justify the TGA not resorting to its usual powers to remedy or address breaches of regulatory requirements in discharging its statutory obligation to protect public health and safety.

Accordingly, once an enforceable undertaking is entered into, compliance is obligatory. If an undertaking is not honoured by the person who provided it, the TGA will seek an order from the court requiring the relevant company or person to comply with the undertaking.

This is made clear by sections 42YL(4) and 42YL(5) of the Bill, which provide that-

(4) If the Secretary considers that the person who gave the undertaking has breached any of its terms, the Secretary may apply to the Federal Court for an order under subsection (5).

(5) If the Court is satisfied that the person has breached a term of the undertaking, the Court may make all or any of the following orders:

- *(a) an order directing the person to comply with that term of the undertaking;*
- *(b) an order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach;*
- *(c) any order that the Court considers appropriate directing the person to compensate any other person who has suffered loss or damage as a result of the breach;*
- *(d) any other order that the Court considers appropriate."*.

Enforceable undertakings are currently available to agencies such as the Australian Competition and Consumer Commission (at section 87B of the *Trade Practices Act 1974*), the Civil Aviation Safety Authority (at section 30DK of the *Civil Aviation Act 1988*), the Australian Securities Investment Commission (at sections 93AA and 93A of the *Australian Securities and Investments Commission Act 2001*), Comcare (at clause 16 of schedule 2 of the *Occupational Health and Safety (Commonwealth Employment) Act 1991*) and the Australian Communications Authority (at sections 37-40 of the *Spam Act 2003*).

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 will occur or that the breach will be appropriately remedied. The TGA's primary responsibility is to protect public health and safety, and unless the acceptance of an enforceable undertaking will effectively address breaches of regulatory requirements and minimise any possible harm to the public, the TGA will not accept such undertakings.

Undertakings must address the conduct or circumstances which have given rise to the alleged or perceived breach and its consequences. They should also include detailed future actions to prevent a recurrence of that breach of the Act or the Regulations.

It should also be noted that section 42YL(3) of the Bill provides that the Secretary of the Department must publish details of the undertaking, as in force from time to time, on the Internet. This provision is consistent with the approach taken in enforceable undertaking schemes in comparable Commonwealth legislation, such as section 30DK(4) of the *Civil Aviation Act 1988*, and section 93A(6) of the *Australian Securities and Investment Commission Act 2001*).

As court enforceable undertakings are an alternative enforcement measure for addressing breaches of regulatory requirements under the Act (where it is considered appropriate), it is appropriate that information about undertakings and the terms of the undertakings are made publicly available.

It is possible that parts of the enforceable undertakings may contain commercially sensitive or personal information. If that is the case and the person providing the undertaking requests that the information not be released, the TGA may agree that this class of information be deleted from the published form of the undertakings.

(iii) 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)

The Bill builds on existing offences under the Act and does not add any new offences to the Act apart from the offence that will extend the liability of a body corporate to executive officers in certain circumstances if the body corporate commits an offence, and the introduction of an offence for a failure to provide certain assistance to the Secretary in relation to an application for a civil penalty order where the Secretary has requested that assistance in writing.

The enforcement provisions included in the Bill are designed to support the regulatory requirements that are already in the Act (many of which have been part of the Act since its commencement in 1989), in order to better give effect to the objects of the Act. The Bill introduces new alternative sanctions that may be more appropriate and effective in particular circumstances, and are intended to achieve better and more effective regulatory outcomes with minimum delay. The Bill also includes provisions that insert a number of parallel civil penalty and criminal offence provisions in relation to substantially the same conduct.

The provisions in the Act that set out the powers of authorised officers in relation to investigating breaches of the Act have been in place for some time (see Part 6-2 of the Act), and will not be changed by the Bill.

An authorised officer seeking to exercise the power to investigate a possible breach of the Act by entering premises to search and/or seize evidential material can only do so with the permission of the occupier of the premises, or under a warrant issued by a magistrate.

There are provisions in the Act dealing with requirements for obtaining warrants before a magistrate, including the requirement for authorised officers to provide assurances, on oath, to

a magistrate when applying for a warrant to search premises and/or seize material in relation to an investigation.

The existing provisions of the Act already operate to ensure the fairness and integrity of the investigation process for breaches of the Act.

Similarly, provisions already exist in the Act in relation to the publication of information to inform the public about regulatory actions taken – such as section 30EA (public notification and recovery of therapeutic goods), section 41EV (publication of revocation etc of conformity assessment certificates in relation to medical devices), section 41GP (publication of cancellation of entry from the ARTG in relation to medical devices), and section 412KA (Public notification and recovery of medical devices).

Media releases to inform the public about regulatory actions taken under the Act or Regulations will only be used if there is a public health safety risk, and not per se to provide information in relation to investigations or prosecutions that are occurring in relation to breaches of the Act. The public release of information in relation to the investigation of breaches of the Act could compromise those investigations.

PART B

(b) Ascertain if the Bill adequately accommodates differences between registrable and listable goods

Because products may be classed as inherently lower risk (eg. listable goods), this does not necessarily mean that the goods will not cause harm or injury or potentially expose the public to the risk of harm or injury. Practices adopted in the manufacture or supply of any therapeutic goods, including listable or "lower risk" therapeutic goods, can lead to issues of public health and safety, as the examples below indicate.

The failure to observe appropriate manufacturing practice requirements as set out in the Code of Good Manufacturing Practice (GMP) may have serious risk implications for public health and safety, even in relation to products that are claimed to be lower risk consumer products that are self selected by users for non serious conditions and disorders. The risks are particularly great in the following areas:

- Failure to adequately control starting materials, which could result in impure, contaminated or wrong active substances being in the product. Any failure to adequately mix materials could result in variable amounts of active substances in different dosage units. Examples of this include: Cimifuga racemosa (Black Cohosh), where toxicity from a substituted herb such as Blue Cohosh can constrict coronary blood vessels; Aristolochia, where toxicity from Aristolochia substituted for other herbs has been linked to severe kidney damage and urinary tract cancer; Selenium, where toxicity from exposure to high doses can have neurological effects, and; Vitamin A, which at high doses can cause birth defects.

- Failure to follow proper cleaning procedures could result in cross-contamination between medicines, increasing the potential for severe allergic reactions and in rare cases fatalities. This may be particularly so for asthma and allergy sufferers.

- Failure to follow GMP procedures may result in products that are contaminated with micro-organisms or that have very little preservative efficacy. Such contamination can lead to serious infection or illness if taken orally. Of particular concern are products that come into contact with eyes or products indicated for use on open wounds.

These potential instances of breaching behaviour demonstrate the importance of the TGA as the Australian regulator for therapeutic products having an adequate range of sanctions available in order to respond meaningfully and adequately to deter behaviour that breaches the Act and places public health and safety in jeopardy.

Therefore, rather than having different sanctions applying in relation to registrable goods and listable goods, the Bill proposes a tiered offences regime for a number of criminal offences under the Act, with sanctions that match the degree of seriousness of the consequences of non compliance with regulatory requirements that amount to unlawful conduct. The new tiered offences structure will be comprised of the following alternative offences:

- A new fault-based offence introduced by building an aggravating consequence onto the previously existing offence. The aggravating element here is that the prohibited conduct results in or will result in harm or injury to a person. This is the most severe level of consequence of conduct, and it attracts a maximum penalty of 4,000 penalty units and/or 5 years imprisonment;

- A new strict liability offence also introduced by building an aggravating consequence onto the previously existing offence. In this case the aggravating element is that the prohibited conduct would be likely to result in harm. The maximum penalty attaching to a strict liability offence is 2,000 penalty units, with no term of imprisonment; and

- The existing fault-based offence with no aggravating element, which will be retained as is or with the level of associated penalty increased where appropriate, consistent with the level of penalties currently in the Act applying to similar offences or to conduct that results or could result in similar circumstances.

The introduction of the tiered regime of criminal offences is intended to better tailor penalties to criminal conduct so that more serious conduct resulting in or that is likely to result in harm or injury will attract more appropriate sanctions. The penalties for the offences with aggravating elements are significantly higher than the existing offences without the aggravating element, to reflect the fact that breaches of these provisions have resulted in, or may be likely to result in, a serious and direct threat to public health and safety.

The tiered regime is proposed for existing offences in the Act where the conduct is considered to be of significant importance in the regulatory scheme and thus is intended to apply where:

- the conduct is in relation to the supply of unassessed or unapproved therapeutic goods in the market, which is not otherwise permitted. Such conduct has the potential to increase the risk that consumers may suffer injury or even death by consuming goods the safety, efficacy and quality of which have not been established, where the goods are used for therapeutic purposes;

- there are breaches of conditions attaching to the inclusion of therapeutic goods in the ARTG. The conditions imposed by the Secretary are designed to maximise the safety of therapeutic goods or their safe use and relate to, amongst other things, ensuring as far as

possible that goods granted marketing approval for supply to the general public will remain safe, that appropriate use of the goods will be assured as far as possible, that any requirement to monitor the supply of goods to enable detection of problems will be observed, and that any particular risk associated with the use or misuse of the product is adequately addressed. Breaches of such conditions could compromise public health and safety, and can lead to serious health risks resulting in injury or even death;

- the conduct relates to compliance with standards applicable to therapeutic goods, including essential principles for medical devices. Standards represent the appropriate level of requirements applying to therapeutic goods that assure their safety, efficacy and quality. Breaches of certain standards may compromise the integrity of products to the extent that their safety, efficacy or quality can no longer be assured. In such circumstances, the potential harm to patients or consumers represent unacceptable consequences that a regulator should seek to prevent as far as possible;

- the conduct is related to manufacturing standards (including conformity assessment procedures or standards for medical devices). Again manufacturing standards represent benchmarks for ensuring that products will be produced to the specification under which they were approved for general marketing, and that the conditions under which the goods have been manufactured and the various checks required to be placed at various stages of manufacture have been complied with to provide assurance that the purity and quality of the goods remain within acceptable parameters of safety for use in humans;

- the conduct relates to a failure to comply with any condition applying to particular exemptions in relation to the inclusion of goods in the Register. Exemptions to the requirement to include goods in the Register recognizes that in some circumstances, access to unevaluated or unassessed therapeutic goods, or to experimental goods, by an individual or a larger group, may be warranted. However, where it is necessary to reduce the risk of harm to an individual as a result of using such goods, conditions for particular exemptions may be imposed. Breaches of some of these conditions therefore can result in harm or injury to patients that could otherwise be avoided or minimized had the conditions been complied with; and

- where there is a requirement that therapeutic goods be removed from the marketplace and there is a failure to comply with recovery and notification requirements to remove unsafe or defective goods from the market.

The Bill will also introduce an alternative sanction, in the form of a civil penalty provision, to certain existing offences. A civil penalty is a punitive sanction of a financial nature, with no aggravating element and no fault element, imposed through civil court proceedings rather than through the criminal prosecution process. It takes the form of a monetary penalty only, and does not result in any criminal conviction. A criminal prosecution is considered to be a more appropriate sanction where a contravention is deliberate, where fraud may be involved, where the conduct demonstrates recklessness, where there is a serious pattern of continuous intentional contraventions, or where conduct has endangered lives or has caused death or serious injury.

The focus of a civil penalty scheme is generally on the regulation of commercial activity. The inclusion of a civil penalty regime is proposed to strengthen the TGA's enforcement options to more quickly and effectively address and deter non-compliance with regulatory requirements, particularly by incorporated bodies. A civil penalty is appropriate to enable sponsors and

manufacturers to be fined for breaches of the Act where other sanctions, such as criminal prosecution, may not be as effective or appropriate in the circumstances.

The civil penalty regime is also intended to act as a deterrent to behaviour that breaches regulatory requirements, and as an incentive for sponsors and manufacturers to establish systems designed to avoid breaches of regulatory requirements. In these ways the civil penalty scheme is intended to prevent instances where public health and safety is or could be placed in jeopardy.

The new civil penalty provisions impose, in most cases, either a maximum of 3,000 or 5,000 penalty units for an individual and 30,000 or 50,000 penalty units for a corporation.

It is anticipated that the level of civil penalties will act as an effective financial disincentive against non-compliance with regulatory requirements, especially for corporations for whom imprisonment is not available.

It is also important to note that very serious consequences can result from breaches of regulatory requirements in relation to listable goods. For example, the products involved in the breaches of regulatory requirements, including manufacturing standards, manufactured by Pan Pharmaceuticals Ltd were listed therapeutic goods rather than registered goods.

Since 2003 the level of non compliance regularly uncovered through unannounced GMP audits and through post market monitoring and surveillance, continues to be unacceptable and indicates that existing sanctions and regulatory options are not adequate in deterring inappropriate and dangerous practices that place the health and safety of the Australian public at considerable risk.

The introduction of the new penalty and offence measures in the Bill are not intended to unduly alarm therapeutic goods industry participants or to place unreasonable burdens upon sponsors and manufacturers of listable products, but to ensure the safety, efficacy and quality of both registrable and listable therapeutic goods imported into, exported from, supplied in or manufactured in Australia by focussing on the repercussions of behaviour that breaches the Act and could imperil public health and safety.

Sponsors and manufacturers that adhere to the regulatory requirements in the Act would not be affected by any of the measures contained in the Bill.

PART C

(c) Examine inequity implications for Australian-based manufacturers due to the non-applicability of the civil penalty regime for foreign entities

Australia cannot impose its legislation within the territorial boundaries of other sovereign states, and for that reason it would only be possible to issue and enforce the civil penalties proposed by the Bill within Australia.

However, the basis for the imposition of sanctions, such as civil penalty provisions, is ultimately to ensure public confidence in the safety and quality of therapeutic products supplied for use.

Although Australia's sanctions regime cannot extend beyond its borders, provisions nevertheless exist under the Act to enable the TGA to prevent substandard products from being imported into Australia, or if already imported, to remove these products from the marketplace.

For example, section 20(1) makes it clear that a person is guilty of an offence if the person *imports into*, exports from, manufactures in *or supplies in*, Australia, therapeutic goods for use in humans, and the goods are not registered or listed goods in relation to the person, or are not exempt goods including under section 18A of the Act (which relates to exemptions because of emergency), or are not the subject of an approval under section 19A of the Act (which relates to exemptions where there is an unavailability etc. of therapeutic goods).

Section 20(1AA) of the Act provides that an offence against section 20(1) is punishable on conviction by imprisonment for 12 months or a fine not more than 1,000 penalty units. Section 14 of the Bill proposes to apply the tiered regime of sanctions to the existing section 20 in line with the different penalty levels discussed under (b) above, which would mean that for the fault-based offence in relation to conduct in breach of section 20 the maximum penalty would be 5 years imprisonment or 4,000 penalty units.

The effect of section 20 of the Act is that persons wishing to import into, export from, or manufacture or supply in Australia therapeutic goods, must ensure that the goods meet with acceptable standards, including eg. manufacturing standards, before they are permitted to be registered or listed (on the ARTG), unless either one of the quite specific exemptions from registration or listing covered under Part 3-2 of the Act (Registration and listing of therapeutic goods) applies.

This requirement for registration or listing, as the case may be depending upon the product in question, means that goods manufactured outside of Australia, for import into and supply in Australia, must meet a range of important requirements in order to become registered or listed on the ARTG.

Section 25 of the Act deals with the evaluation and registration of therapeutic goods, and it outlines a range of requirements relating to the quality, safety and efficacy of therapeutic goods in relation to which an application is made for registration. Section 25 of the Act covers both therapeutic goods manufactured in Australia and those manufactured outside of Australia.

Section 25(1)(d) of the Act requires goods to be evaluated for registration having regard to whether the quality, safety, efficacy of the goods for the purposes for which they are to be used have been satisfactorily established. Section 25(1)(f) of the Act requires goods to be evaluated for registration having regard to whether the goods conform to a standard applicable to the goods.

Section 25(1)(g) of the Act requires goods to be evaluated for registration having regard to, if a step in the manufacture of the goods has been carried out outside Australia – whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable.

Section 25(2) of the Act provides that, in making a decision for the purposes of section 25(1)(g), the matters that may be taken into account include-

"(a) whether the applicant has provided:

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA – an EC/EFTA attestation of conformity in relation to the goods; or

(ia) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA – a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

(iii) in any other case – an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard; and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.".

Section 26 of the Act deals with the listing of therapeutic devices and export only medicines. Section 26(1) of the Act sets out a range of bases upon which the Secretary may refuse to list the goods in relation the person in relation to whom the application for listing is made.

Section 26(1)(d) of the Act makes it clear that one of these bases is that the goods are not safe for the purposes for which they are to be used, and section 26(1)(f) of the Act notes another grounds for refusal to list the goods is where the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable under Part 5-1 of the Act or under the Regulations.

Section 26(1)(g) of the Act provides that the Secretary may refuse listing in relation to goods if a step in the manufacture of the goods (not being therapeutic devices other than devices prescribed for the purposes of this paragraph) has been carried out outside Australia, the manufacturing and quality control procedures used in the manufacture of the goods are not acceptable. Section 26(1)(g) mirrors in relation to the listing of therapeutic goods the requirements of section 25(1)(g) of the Act discussed above.

Section 26(2) of the Act then sets out the matters that may be taken into account in relation to the making a decision for the purposes of section 26(1)(g) of the Act include-

"(a) whether the applicant has provided:

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA – an EC/EFTA attestation of conformity in relation to the goods; or

(ia) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA – a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

(iii) in any other case – an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard; and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:

(i) funds for the carrying out of that inspection by the Department; and
(ii) evidence that the manufacturer has agreed to such an inspection.".

The Manufacturer Assessment Section of the TGA currently undertakes both announced and unannounced inspections of overseas manufacturers' procedures, and in the case of announced inspections requires manufacturers to provide full funding for the TGA's inspections prior to their departure from Australia.

Section 26A(3) of the Act provides that, in relation to listable medicines, if a step in the manufacture of the medicine has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

Under section 26A(7), section 26A(3) of the Act would not apply to therapeutic goods which would be exempt from the operation of Part 3-3 of the Act (Manufacturing of therapeutic goods) under the Act and the Regulations.

While it may not be possible to apply civil penalties directly to overseas manufacturers of therapeutic goods imported into and/or supplied in Australia, the existing sections of the Act described above make it clear that unacceptable manufacturing procedures are grounds upon which the TGA may refuse to register or list goods manufactured outside Australia.

In addition, section 28(2) of the Act enables the Secretary to impose conditions in relation to the manufacture of therapeutic goods upon the inclusion of the goods on the ARTG.

Section 30(2) of the Act provides a further measure at the TGA's disposal to deal with substandard manufacturing of therapeutic goods overseas.

Section 30(2) of the Act allows the Secretary to cancel the registration or listing of therapeutic goods on a number of grounds, including if it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable (section 30(2)(a)), if the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject (other than the condition under paragraph 28(5)(d) of the Act regarding the provision of records for inspection), or the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable to the goods under Part 5-1 of the Act or under the Regulations.

Section 30(1)(a) of the Act also permits the Secretary to cancel the registration or listing of therapeutic goods if it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury.

In addition to refusal to register or list, and cancellation of registration or listing, section 31(1) of the Act permits the Secretary to require information in relation to the method and place of manufacture of therapeutic goods or the preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods.

Section 31(4) of the Act makes it clear that it is a strict liability offence to fail to comply with a notice given under section 31 to provide requested information to the TGA, with a resulting maximum penalty of 60 penalty units. Under section 37 of the Bill, this is proposed to be increased to a maximum of 500 penalty units.

The TGA, then, under the current provisions of the Act as outlined above, has the power to 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.

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.

PART D

(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

As noted above under (a), infringement notices are a means of allowing a breach of regulatory requirements to be expeditiously dealt with, in lieu of having the matter considered judicially and a court then imposing its own sanction.

In its Report No. 95 titled *Principled Regulation: Civil and Administrative Penalties in Australian Federal Regulation* (the Report) the ALRC considered that an infringement notice was better characterised as an offer of settlement made by the regulator in respect of prospective proceedings (at paragraphs 12.7 and 22.24 of that report)[3]. The ALRC stated that the alleged offender is under no compulsion to accept the offer and for this reason it is difficult to contemplate how a court or tribunal could effectively review this decision.

Thus, a person served with an infringement notice may elect to pay the penalty, provide relevant information and seek the withdrawal of the notice, or may refuse to pay the penalty and defend the matter in court. The ALRC recommended (at recommendation 22-2) that external merits review of a decision to issue an infringement notice should not be available[4].

The TGA agrees with this recommendation.

Decisions to take a matter to court, such as applying to the Federal Court for a civil penalty order, should also not be subject to judicial review, as generally the issue of whether or not the Commonwealth has grounds to pursue a matter is one that will be dealt with in the course of proceedings brought before that court. A decision to commence proceedings (either in the

[3] Australian Law Reform Commission (ALRC), *"Principled Regulation Report: Federal Civil and Administrative Penalties in Australia, Report 95"*, December 2002, pp 427 and 735.
[4] Australian Law Reform Commission (ALRC), *"Principled Regulation Report: Federal Civil and Administrative Penalties in Australia, Report 95"*, December 2002, p 734.

form of a criminal prosecution or an application for a civil penalty order) is only preliminary in nature and is not "ultimate or operative".

The person adversely affected by a regulator's decision to take judicial action can contest the matter during the court proceedings, and time limits will apply in relation to the commencement of prosecutions and applications for civil penalty orders. The addition of a review process prior to the commencement of these proceedings could cause significant delays, frustrate the commencement of proceedings and may adversely affect the public interest.

In its Report the ALRC recommended (at recommendation 23-1 and 23-2) that decisions to institute proceedings for the imposition of a civil penalty and the imposition of a quasi-penalty for contraventions of a law of the Commonwealth should be immune from review under the *Administrative Decisions (Judicial Review) Act 1977*[5]. It considered the law should be harmonised with the law that a decision to institute criminal proceedings is immune from review under the *Administrative Decisions (Judicial Review) Act 1977* (provided for under Schedule 1 of that Act).

The TGA agrees with this recommendation. The decision by the TGA to seek an order from the Federal Court for the payment of a civil penalty is not an ultimate or operative determination, and therefore should not be a reviewable decision by the AAT or under the *Administrative Decisions (Judicial Review) Act 1977*.

[5] Australian Law Reform Commission (ALRC), "*Principled Regulation Report: Federal Civil and Administrative Penalties in Australia, Report 95"*, December 2002, pp 745-746.

Attachment 4 - Frequently Asked Questions

Can TGA issue an infringement notice whenever it feels like it?

Infringement notices will only be used where a decision has been made to pursue judicial action.

Before any civil action may be brought against anyone, the Legal Services Directions require that the TGA must obtain independent legal advice that there are reasonable grounds for commencing an action.

Where there is any concern that claims may be brought against anyone on spurious grounds, complaints may be lodged with the Office of Legal Services Coordination, which has responsibility for enforcing the Legal Services Directions.

Was industry consulted in development of the Bill?

A draft of the proposed amendments to the *Therapeutic Goods Act 1989* ("the Act") was released to industry for comments in March 2005. Organisations that were given a copy of the Bill, together with a brief verbal briefing on its contents included: Medicines Australia; Complementary Healthcare Council of Australia (CHC); Australian Self Medication Association (ASMI): Generic Manufacturers Industry Association of Australia; Medical Industry Association of Australia and Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD). These meetings enabled Departmental officials to fully understand industry concerns, and to further explain the intent of the draft Bill.

Isn't the current combination of administrative and criminal sufficient to deal with most/all foreseeable problems?

The TGA's risk-management approach is designed to strike a balance between ensuring public health and safety, while avoiding unnecessary administrative and financial costs to industry through excessive regulation.

In explaining the need for the new, more flexible range of enforcement options contained in this Bill, the Government has sought to emphasise that this measure is in line with the need to maintain this balance. Currently, in the instance of a company that fails to comply with regulatory requirements, the TGA is restricted in its options to either criminal prosecution or administrative sanctions such as withdrawal of a manufacturing licence. In contrast, the new enforcement options proposed in this Bill are seen as affording the TGA with the flexibility necessary to achieve a more optimal regulatory outcome—that is one capable of striking a balance between the health and safety needs of consumers (including their need to have access to therapeutic products) and the viability of industry.

Isn't the use of enforceable undertakings like coercion?

Enforceable undertakings, like infringement notices, cannot be used to "coerce" sponsors or manufacturers to address or remedy breaches of the Act or the Regulations. As a regulator, where a breach of the Act calls for regulatory action, the TGA has an obligation to protect public health and safety through the exercise of its powers under the Act and the Regulations. Enforceable undertakings represent an alternative option for addressing breaches of regulatory

requirements by sponsors and manufacturers in a manner acceptable to the TGA. The enforceable undertakings also allow some flexibility in the way these breaches are to be addressed or remedied by sponsors and manufacturers. However, sponsors are not under any obligation to provide such undertakings and, if none is provided to the TGA, the TGA will still be required to take the necessary regulatory action available to it.

Why wasn't the legislation updated to deal with these matters in 2003?

Penalties under the Act were last increased in May 2003. Because of the very tight timeframe for effecting the amendments at that time, only selected offences provisions or regulatory requirements that directly addressed some of the concerns were able to be amended. As a consequence of the increases to penalty levels for only some of the offences contained in the 2003 amendments, a greater disparity in penalty levels under the Act resulted for offences of a similar kind in other parts of the Act. In addition, identical or comparable offences relating to the same or similar conduct in other parts of the Act not updated in May 2003 are no longer consistent with the 2003 amendments.

In addition, since that time evidence from further monitoring and auditing by Australia's therapeutic goods regulator, the TGA, has shown that further amendments to the Act are required to more effectively address continuing failure by other manufacturers to adequately comply with regulatory requirements.

Isn't there an argument that complementary medicines are lower risk than regulated products and therefore should be regulated differently?

Although products may be classed as inherently lower risk (eg. listable goods), this does not necessarily mean that the goods will not cause harm or injury or potentially expose the public to the risk of harm or injury. Practices adopted in the manufacture or supply of any therapeutic goods, including listable or "lower risk" therapeutic goods, can lead to issues of public health and safety, as the examples below indicate.

The failure to observe appropriate manufacturing practice requirements as set out in the code of GMP may have serious risk implications for public health and safety, even in relation to products that are claimed to be lower risk consumer products that are self selected by users for non serious conditions and disorders. The risks are particularly great in the following areas:

- Failure to adequately control starting materials, which could result in impure, contaminated or wrong active substances being in the product. Any failure to adequately mix materials could result in variable amounts of active substances in different dosage units. Examples of this include: Cimifuga racemosa (Black Cohosh), where toxicity from a substituted herb such as Blue Cohosh can constrict coronary blood vessels; Aristolochia, where toxicity from Aristolochia substituted for other herbs has been linked to severe kidney damage and urinary tract cancer; Selenium, where toxicity from exposure to high doses can have neurological effects, and; Vitamin A, which at high doses can cause birth defects.

- Failure to follow proper cleaning procedures could result in cross-contamination between medicines, increasing the potential for severe allergic reactions and in rare cases fatalities. This may be particularly so for asthma and allergy sufferers.

- Failure to follow GMP procedures may result in products that are contaminated with micro-organisms or that have very little preservative efficacy. Such contamination can lead to

serious infection or illness if taken orally. Of particular concern are products that come into contact with eyes or products indicated for use on open wounds.

In 2003 the Government established the Expert Committee on Complementary Medicines in the Health System (ECCMHS), consisting of 18 members from industry, academia, and clinical practice.

ECCMHS took into account the fundamental principles of the need to protect public health and safety; the right of consumers to make informed choices on matters of health care; and the ethical responsibilities of all health care providers, and found that "*the current model of a single regulatory framework for medicines is appropriate for the regulation of complementary medicines in Australia*" and that "*the current two-tiered, risk-based regulatory system for complementary medicines should be maintained…"*

How will the Bill benefit industry?

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.

The purported benefits of this greater flexibility are encapsulated in the Parliamentary Secretary's comments 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 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.
- As such, the Government sees the measures in this Bill as promoting optimal outcomes for all players in the therapeutic goods sector.

Industry will benefit from greater consumer confidence in therapeutic products that they use. The public can be assured that there are real deterrents to poor and unsafe manufacturing behaviour and that where breaches of law occur, we can act accordingly. Companies that are working within the law have nothing to worry about.

There is no increase in red tape or administration for manufacturers. The Bill does not introduce new regulatory requirements for the industry. The Bill introduces alternative measures to more flexibly deal with non-compliance with existing regulatory requirements and introduces more effective judicial sanctions to deter or punish serious breaches of regulatory requirements. Companies already complying, and who continue to comply, with the *Therapeutic Goods Act 1989* will not be issued with infringement notices or any of the other revised penalties and sanctions under the Bill.

Attachment 5 - List of the breaches where an infringement notice could be issued

Provisions with strict liability and/or civil penalties

Existing provision under the Therapeutic Goods Act 1989		***Proposed provision in the Therapeutic Goods Amendment Bill 2005***		***Description of conduct***
Medicine or therapeutic device	**Medical Device**	**Strict liability offence**	**Civil penalty provision**	
Provisions related to compliance with standards (including manufacturing standards) and conditions applying to exemptions from complying with standards				
s14	s41MA	14(2,7,11) 41MA(2,6,10)	14A(1-3) 41MAA(1-3)	Breach of standard applying to goods
s15(2)	s41MC(2)	15(3) 41MC(3)	15AA 41MCA	Breach of condition attaching to standards
s35(1), s35(4)	s41ME	35(2,7) 41ME(2,6)	35A(1,2) 41MEA(1,2)	Manufacturing without a licence, not applying manufacturing standards
s35(2)	s41MN(2)	35B(2) 41MN(6)	35C 41MNA(2)	Beaching conditions of a licence or conformity assessment certificate
	s41EI	41EI(2)	41EIA	Providing a false/misleading statement in connection with conformity assessment certificate
Issues relating to inclusion/retention of goods in the Australian Register of Therapeutic Goods (ARTG)				
s20(1)	s41MI(1)	19B(2) 41MI(2)	19D(1)	Failure to include goods in ARTG as required
s22(2A) s22A	s41FE	21A(2) 41FE(2)	21B(1) 41FEA	Providing false statements when entering goods in the ARTG
s31(6)	s41JB(4)	31(5B) 41JB(5)	31AAA 41JBA	Providing false/misleading information in connection with entry or retention of goods in the ARTG
s22(3)	s41MN(1)	21A(6) 41MN(2)	21B(2) 41MNA(1)	Breaching condition of registration or listing
Failure to comply with recovery/notification requirements				
s30EC	s41KC	30EC(2) 41KC(2)	30ECA 41KCA	Goods required to be recovered as goods do not meet standards etc
s30F(5)		30F(4C)	30FA	Emergency goods where actual/potential threat to Australia, not fit for use
s42V(6)		42V(6A)	42VA	Tampered products

Provisions with strict liability offences and no civil penalty contraventions

Breach of condition applying to exempt goods		
Existing provision under the Therapeutic Goods Act 1989	***Proposed provision in the Therapeutic Goods Amendment Bill 2005 - Strict liability only***	***Description of conduct***
s22(7A) and (8)	21A(10) & (13)	Supply of goods not in accordance with authority or conditions
s41MO(1)&(2)	41MO(2) & (6)	Misuse of medical devices exempted for a special use
s20(2C)		Importation of goods in breach of conditions of exemption under s.18A

Provisions with civil penalty contraventions and no strict liability offences

Existing provision under the Therapeutic Goods Act 1989		***Proposed provision in the Therapeutic Goods Amendment Bill 2005 - Civil penalty only***		***Description of conduct***
Medicine or therapeutic device	**Medical Device**	**Medicine or therapeutic device**	**Medical Device**	
s42E (applies to both)		42EA (applies to both)		Conduct dealing with counterfeit goods
s54AB(1) (applies to both)		54AC (applies to both)		Destruction & falsification of documents
s20(2)		19D(3,4)	-------	Failure to include ARTG no. on label of goods
s20(1B)		20A(1)	-------	Import, export, supply where Secretary not properly notified
s29A(1)	s41MP(1)	29AA(1)	41MPA(1)	Fail to notify of adverse events
s29B(3)	s41MQ(3)	29C(1)	41MR(1)	Fail to comply with notice to notify of adverse events
s29B(4)	s41MQ(4)	29C(2)	41MR(2)	False/misleading info when notifying of adverse events
	s41MH	----- -	41MHA	False statement in declaration
s22(4)	s41ML	21B(3)	41MLA(1)	Representing that medicines or devices are included in the ARTG, or are exempt etc, when they are not
s22(7AB)		22AA	-------	Act or omission breaches a condition of exemption under s.18A