THERAPEUTIC GOODS AMENDMENTBILL 2005

OUTLINE

This Bill proposes to provide additional enforcement options to enhance the Therapeutic Goods Administration's (TGA) ability to secure compliance with the *Therapeutic Goods Act 1989* ("the Act"), so as to ensure that public health and safety are adequately protected. The Bill will introduce new alternative enforcement sanctions that may be more appropriate in particular circumstances and achieve better regulatory outcomes with minimum delay. The Bill builds on existing offences under the Act and therefore does not create sanctions for conduct that is not already regulated under the Act, except for the offence that will extend liability of a body corporate to executive officers in certain circumstances if the body corporate commits an offence.

The purpose of the Bill is to:

- supplement a number of existing criminal offences with a tiered offence regime, which will include offences of strict liability and higher penalties for more culpable conduct resulting in harm or injury. Penalties for some existing offences are proposed to be increased consistent with penalty levels for other offences contained in the Act. Proposed penalties for criminal offences with aggravating elements are comparable with those contained in other Commonwealth legislation;
- require a defendant to provide a pre-disclosure notice of evidence in support of an exception to an offence relating to the importation, exportation, manufacture or supply of goods that are not included in the Australian Register of Therapeutic Goods (the Register) prior to the defendant being committed for trial or prior to a hearing by a court of summary jurisdiction;
- provide for alternative verdicts for various tiered offences to the effect that if the jury acquits a person of an offence specifying an aggravating element, but is satisfied beyond reasonable doubt of facts that prove that the person is guilty of a lesser offence with no aggravating element, the jury may convict the person of the lesser offence;
- introduce a civil penalty regime for breaches of the Act;
- introduce infringement notices for minor offences under the Act and for conduct that is subject to the proposed civil penalty regime;
- introduce provisions for a person to provide enforceable undertakings to remedy breaches of regulatory requirements, or give undertakings not to engage in future conduct that would breach regulatory requirements;
- extend the territorial jurisdiction of the Commonwealth for certain offences under the Act to incorporate section 15.2 of the *Criminal Code Act 1995* – Extended Geographical Jurisdiction – Category B. This will provide for certain offences to extend to conduct by an Australian citizen or body corporate outside Australia and for an offence to extend to conduct by an Australian resident outside Australia, where there is an equivalent offence in the laws of the local jurisdiction;
- extend the liability of a body corporate to executive officers who are directly involved in the day-to-day management of the company, if the body corporate commits an offence or contravenes a civil penalty provision under the Act;
- extend powers under monitoring warrants to allow for the securing of evidence until a further warrant is obtained, if the authorised person believes on reasonable grounds that it is evidence in respect of a breach or suspected breach of a regulatory requirement attracting a civil penalty, and the authorised person believes on reasonable grounds that the evidence would be lost, destroyed or tampered with unless it is secured, and introduce a new warrant mechanism for the purposes of securing evidence relating to

contraventions of civil penalty provisions;

- enable the release, to the public, of information about actions taken or decisions made under the Act or Regulations and the release, to a person, body or agency of the Commonwealth, a State, a Territory, another country or an international organisation having responsibility or functions relating to therapeutic goods, health or law enforcement, of information relating to an offence or alleged offence or a contravention or an alleged contravention of a civil penalty provision involving therapeutic goods; and
- include minor amendments to certain advertising requirements, and an amendment to section 61(3A) of the Act to correct a technical omission by including a reference to section 31AA, and an amendment to section 56A to include an instrument of exemption issued under section 18A in the list of certificates that the Secretary may issue as evidence of certain matters.

The Bill follows on from a number of changes to the Act and the *Therapeutic Goods Regulations 1990* ("the Regulations") made in 2003, as a result of the TGA's action in suspending Pan Pharmaceutical Ltd's manufacturing licence. These changes were made to tighten up the regulatory requirements relating to compliance with standards and to enable manufacturers of therapeutic goods to be more readily identifiable. Further regulatory actions by TGA taken against other manufacturers since the suspension of Pan's licence have identified a need to introduce additional legislative measures considered to be necessary to enable the TGA to adequately protect public health and safety. These include incorporating alternative sanctions, including measures for addressing minor breaches of regulatory requirements and options that will allow some flexibility to the Therapeutic Goods Administration and a person in breach of a regulatory requirement to agree on remedial action where appropriate, and to provide adequate incentives that counter regulatory breaches that may be commercially driven.

Tiered offence regime

The Bill proposes a tiered offence regime for a number of criminal offences under the Act, with sanctions that match the degree of seriousness of the consequences of conduct that currently constitutes an offence. The new tiered offences structure will be made up of the following alternative offences:

- a new fault-based offence with an aggravating element (conduct that results or *will* result in harm) attracting a maximum penalty of 4,000 penalty units and/or 5 years imprisonment; or
- a new strict liability offence with an aggravating element (conduct *likely* to result in harm), attracting a maximum penalty of 2,000 penalty units with no term of imprisonment; or
- the existing fault-based offence (with no aggravating element), which will be retained as is or with the level of penalty increased, where appropriate, consistent with the level of penalties already in the Act applying to similar offences or to conduct that results or could result in similar consequences.

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

The Bill will introduce aggravating elements to the offences that currently exist under the Act. These offences directly link the conduct with the adverse consequences resulting from the regulated conduct (*resulting in or likely* to result in harm or injury to a person). The aggravated offences are not intended to apply where the harm or injury to a person was caused by reasons other than a breach of the Act. The new fault-based offences that include an appropriate aggravating element will have maximum penalties that exceed the penalties for the existing offence relating to the same conduct but without the specified aggravating element.

The test for the strict liability offences is an objective test, where the conduct/use of the goods "is *likely* to result in harm or injury to any person". The word *likely* used in this context is an objective test where it is reasonably *likely* that harm or injury would occur. The strict liability offence will attract a lower penalty, with no imprisonment, compared to the fault-based offence resulting in harm that attracts the highest moral culpability reflected in the size of the maximum penalty.

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:

i) the conduct is in relation to the supply of unassessed or unapproved therapeutic goods in the market, not otherwise permitted. Such conduct increases 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;

ii) there are breaches of conditions attaching to the inclusion of therapeutic goods in the Register. The conditions imposed by the Secretary 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 requirements to monitor supply of goods to enable detection of problems will be observed, and that any particular risks associated with the use or misuse of the product is adequately addressed. Breaches of such conditions designed to maximise the safety of therapeutic goods could severely compromise public health and safety, and can lead to serious health risks resulting in injury or even death;

iii) the conduct relates to compliance with standards applicable to therapeutic goods. 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;

iv) the conduct is related to manufacturing standards (including essential principles for medical devices). Again manufacturing standards represent benchmarks for ensuring that products will be produced to the specification that goods have been 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 provide assurance that the purity and quality of the goods remain within acceptable parameters of safety for use in humans with medical

conditions;

v) the conduct relates to 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 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

vi) 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.

Civil penalty provisions

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 a civil court procedure 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, or where fraud may be involved, or where the conduct demonstrates recklessness, where there is a serious pattern of continuous intentional contraventions, or where conduct has endangered lives, 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 deter non-compliance with regulatory requirements designed to protect public health and safety. 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 intended to act as a deterrent in attempting to prevent breaches and thus prevent instances where public health and safety is or could be placed in jeopardy.

The new civil penalty provisions impose a maximum of 5,000 penalty units for an individual and 50,000 penalty units for a corporation. It is anticipated that the level of civil penalties will act as an effective financial disincentive against con-compliance with regulatory requirements, especially for corporations for whom imprisonment is not available.

Infringement notices

The Bill will introduce infringement notices, as an alternative to prosecution for a criminal offence or the commencement of civil penalty proceedings. This enforcement option recognises that a lengthy prosecution process or a civil litigation may not be the optimal way of dealing with some breaches of regulatory requirements. Infringement notices provides a person with the option of paying a fine rather than being dealt with before the courts in relation to breaches of regulatory requirements. An infringement notice will set out the particulars of the a breach and is intended to give a person the option of either paying the

penalty set out in the notice to expiate the offence/breach or electing to have the matter dealt with by a court.

Infringement notices are proposed to be issued where, for example, the readily assessable elements of a breach of the Act are identified. The relevant offences or civil breaches of the Act in relation to which an infringement notice may apply include conduct amounting to minor breaches of standards applying to therapeutic goods and medical devices, a failure to comply with manufacturing standards as required and a failure to meet advertising requirements. Infringement notices are also proposed to be available for conduct relating to a failure to enter goods in the Register as required and a failure to comply with requirements attaching to exemptions in relation to the entry of the goods in the Register.

Details of the infringement notice provisions are to be prescribed in the Regulations consistent with 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

The Bill will also introduce a mechanism to enable the Secretary to accept enforceable undertakings as an alternative means of securing compliance with regulatory requirements. Under this scheme, those in breach of regulatory requirements have the option of providing undertakings to correct, address or remedy non-compliance, as an alternative to having sanctions imposed. The undertakings are intended to be another measure to ensure compliance with the Act, and are enforceable by a court.

Court enforceable undertakings agreed to by the Secretary and the relevant person would allow the Secretary to tailor enforcement responses to specific circumstances, taking into account regulatory requirements, public health and safety, and the sponsor's or the manufacturer's needs. Undertakings are intended to provide a speedy remedy and, in appropriate circumstances, an alternative to, for example, revoking or suspending a manufacturing licence or cancelling goods from the Register, which would represent the ultimate penalty for some businesses.

Full suite of sanctions

The provisions that will attract the full suite of alternative sanctions applying are those considered to be critically important to the supply of safe and efficacious goods of acceptable quality. This would include, for example, those provisions dealing with conduct associated with the entry of therapeutic goods onto the Register. The full suite of sanctions will be aimed at regulating other conduct that significantly impacts on the quality, efficacy and safety of therapeutic goods, and that could have a direct impact on public health and safety. The full suite of alternative sanctions refers to the following:

1. Existing fault-based offence;
2. Fault-based offence with aggravating circumstances (*will* result in harm);
3. Strict liability with aggravating circumstances (*likely* to result in harm); and
4. Civil penalty (with no aggravating circumstance).

The following table lists and describes the existing provisions in the Act that will have the full suite of alternative applying to them.

Current Offence Provision		**Description**
Medicine or Therapeutic Device	**Medical Device**	
s14	s41MA	Non-compliance with standards for goods imported, exported or supplied for use in Australia.
s15(2)	s41MC(2)	Breaching a condition of consent provided by the Secretary under s14 or s41MA.
s20(1)	s41MI(1)	Offences relating to importation, exportation, manufacture and supply of goods not included in ARTG.
s22(2A)	s41FE	Making a false or misleading certification in connection with the listing of medicines and inclusion of medical devices in the ARTG.
s22(3)	s41MN(1)	Breaching condition of registration or listing, or inclusion in the ARTG
s22A	s41EI	False statements in applications for registration or to enable inclusion in the ARTG.
s30EC	s41KC	Failure to comply with public notification and recovery requirements where therapeutic goods are cancelled from the ARTG or recalled.
s30F(5)		Failure to comply with requirement to withdraw batches of exempt goods under section 18A not conforming to standards.
s31(6)	s41JB(4)	Providing false or misleading information that the Secretary requested in relation to registration or registered therapeutic goods.
s35(1) and (4)	s41ME and 41MF	Offences relating to manufacturing and licences; Failure to apply conformity assessment procedures (in relation to medical devices)
s35(2)	s41MN(2)	Breaching a condition of a licence or conformity assessment certificate.
42V(6)		Failure to comply with recall and notification requirements imposed by the Secretary where product tampering suspected.