

Summary of key provisions in the exposure draft of the *Therapeutic Products Bill 2007* ("the Bill")

Offences and penalties

To secure compliance with the trans-Tasman Scheme, the Bill provides for offences and civil penalties. In general, these reflect the current enforcement mechanisms under the *Therapeutic Goods Act 1989* (Cth) ("TG Act").

Currently in Australia, therapeutic goods must be included on the Australian Register of Therapeutic Goods ("ARTG") before they can be lawfully supplied in Australia, unless they are exempt goods. Under ANZTPA, sponsors will be required to obtain a product licence for each product before they can lawfully supply therapeutic products, and there are penalties for supplying therapeutic products without a product licence. Each product will be required to include the product licence number on its labelling and packaging, much in the same way as AUST R and AUST L numbers are used currently. It is not clear, however, as to whether the product licence number will distinguish between registered and listed goods.

Similar offence provisions and civil penalty contraventions of the TG Act have been merged into one provision in the Bill. The Bill also provides for a tiered offence regime for a number of criminal offences. These include a high level fault-based offence with an aggravating element, which is conduct that results or will result in harm or injury; a strict liability offence with an aggravating element, which is conduct that is likely to result in harm; and an ordinary fault-based offence.

Some new penalties have been introduced, such as those relating to a failure to identify the sponsor of therapeutic goods when required. The offence and civil penalty contraventions in relation to advertising have also been expanded.

Offences relating to the provision of false or misleading information in a material particular in relation to an application for a product licence and conformity assessment certificate have been merged into one offence provision. The offence for this conduct has been upgraded to a very serious offence attracting a maximum penalty of 4,000 penalty units (currently, one penalty unit equals \$110) and/or five years imprisonment, instead of a tiered offence as is currently the case.

The Bill also provides for certain exceptions to the two serious offences of manufacturing without a manufacturing licence and a manufacturer failing to apply conformity assessment procedures to a therapeutic product supplied or exported. Both of these offences attract a maximum penalty of five years imprisonment and / or 4,000 penalty units unless the defendant can prove that the harm or injury did not, will not, or would not, result from the circumstances of the offence. The defendant, therefore, bears the legal burden of proving that the exception applies.

Similar to the current arrangements under the TG Act, the Bill provides for an option to issue non-compliance notices (infringement notices) as an alternative to initiating a criminal prosecution or a civil penalty action. This is, in effect, an optional enforcement tool which can be utilised when some formal enforcement action is justified to deter action, but when prosecution may not be warranted. The penalties are as follows:

- for a person who commits an Australian regulatory offence, the penalty must not exceed an amount equal to one-fifth of the maximum penalty that a court could impose on the individual for that offence.
- for a person alleged to have contravened an Australian regulatory civil penalty provision, the penalty must not exceed an amount equal to one-tenth of the maximum penalty prescribed for contravening that regulatory civil penalty provision.

ANZTPA has the power to accept a written undertaking from a sponsor, manufacturer or other person in connection with a matter in which ANZTPA has the power or function relating to the regulation of therapeutic goods. However, where ANZTPA believes that the person who gave the undertaking has breached any of the terms of the undertaking, ANZTPA may apply to the Federal Court to make orders of varying severity in relation to compliance with the undertaking. ANZTPA is prohibited from applying for an order of the Federal Court under the Bill if it has already applied to a court in NZ in relation to the same contravention by the

person, unless proceedings in NZ are discontinued or the court in NZ has stayed those proceedings on the ground that an application to the Federal Court of Australia should be made.

Taking into account the trans-Tasman nature of ANZTPA, the Bill permits criminal or civil proceedings to be commenced in either Australia or NZ. Similarly, ANZTPA can issue non-compliance notices or apply for court orders for the compliance of written undertakings in either Australia or NZ. On this basis, evidence obtained lawfully in NZ will be treated under the Bill as if it had been obtained lawfully in Australia (and vice versa).

A prosecution for an Australian regulatory offence may be started within six years of the commission of the offence. However, if the person prosecuted is an individual and the maximum penalty that may be imposed on the individual for the offence includes imprisonment for more than six months, or the person prosecuted is a body corporate and the maximum penalty that may be imposed for the offence includes a fine of more than 150 penalty units, the prosecution for the Australian regulatory offence may be started at any time.

Review of initial regulatory decisions

The Bill provides for a slightly different approach in relation to the review of decisions compared with the TG Act.

According to the Rules of the Ministerial Council, any person may apply to ANZTPA for an approval in relation to the manufacture, supply, import, export or promotion of the therapeutic product.ⁱ Such approvals are granted by the Managing Director of ANZTPA acting on behalf of ANZTPA.ⁱⁱ Notably, the Bill provides for an internal review of the decisions of ANZTPA in connection with the grant, amendment, suspension or revocation of approvals, or other classes of decisions specified in the Ministerial Council Rules.ⁱⁱⁱ However, it appears that internal review of an ANZTPA decision is not a mandatory process to be undertaken before a further review of the ANZTPA decision can proceed, provided that the decision was made by the Managing Director personally, acting on behalf of ANZTPA. Under ANZTPA, there is no proposed ministerial involvement in the review of an initial regulatory decision.

Following the decision of ANZTPA, a person is able to apply to the Australian Review Tribunal for a review of the initial decision. Reviewable decisions of the Australian Review Tribunal are only those made personally by the Managing Director acting on behalf of ANZTPA, or those decisions that have been the subject of an internal review under the Ministerial Council Rules.^{iv}

Establishment of a Merits Review Panel and Australian Review Tribunal

The major difference between the current review process and the proposed review process under ANZTPA is the proposed establishment of a new Merits Review Panel and an Australian Review Tribunal ("ART"). It is proposed that:

- the Merits Review Panel will consist of persons appropriately qualified to serve as a member of the Review Tribunal, having regard to the person's knowledge of and experience in medicine, therapeutic products, public administration or law;
- the Merits Review Panel will be appointed by the Ministerial Council;
- the Ministerial Council will designate one member of the Merits Review Panel as the Principal Member in respect of merits review conducted in Australia. The Principal Australian member will determine the number of members who are to constitute the Australian Review Tribunal for the purposes of the proceedings; and
- the ART will consist of a minimum of three members constituted from the Merits Review Panel. Therefore, under ANZTPA, the members of the Administrative Appeals Tribunal, or the Australian Review Tribunal as it is known under the Bill, will be appointed by the Ministerial Council, that is, the Ministers of Health in Australia and NZ. The Bill also provides that a member of the AAT may be appointed as a member of the Merits Review Panel.

Thus, members of the ART will be drawn from the Merits Review Panel. Interestingly, the Bill provides that the Administrative Appeals Tribunal ("AAT") is the ART,^v and also provides that a member of the AAT may be appointed as either a member of the Merits Review Panel or a Member of the New Zealand Review

Tribunal.^{vi} However, there is a lack of clarity as to whether the Ministerial Council will have the power to appoint members other than AAT members to the Merits Review Panel. If so, presumably members of the ART will only have the power to review decisions of the Authority, unlike members of the AAT, who are authorised to review a range of administrative decisions.

The existing judicial review processes in Australia will be adapted to accommodate the joint regulatory scheme. Similar to the current arrangements in Australia, the Bill provides for judicial review, on a question of law, of decisions made by ANZTPA or the ART, including review of decisions made by ANZTPA under the Rules and Orders pursuant to the *Administrative Decisions(Judicial Review) Act 1977 (Cth)*.^{vii} Significantly, the Bill provides for the recognition, in Australian law, of orders made by the New Zealand courts under the judicial review scheme.^{viii} There is also a mechanism for the stay of proceedings in Australia in circumstances where it would be more appropriate for proceedings to be determined.^{ix}

Rules and Orders for the Joint Regulatory Scheme

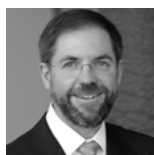
According to the Agreement, ANZTPA has the authority to make Orders for certain purposes, including declaring that particular products, or particular uses, promotions or presentations of a product, are or are not therapeutic products for the purposes of the Agreement. The Orders predominantly are intended to set out the technical standards to which therapeutic products must adhere, and are similar to the Therapeutic Goods Orders that currently apply. The Managing Director of ANZTPA is responsible for making such Orders.

Under the Bill, the Rules made by the Ministerial Council and the Orders made by ANZTPA will have the force of Australian law. Given that the Rules and Orders will be made under a trans-Tasman agreement rather than an Australian Act, they will therefore not be considered legislative instruments for the purposes of the *Legislative Instruments Act 2003*. The Bill thus provides for a special parliamentary scrutiny and disallowance regime. Under this regime, the Australian Health Minister must table each Rule or Order in each House within six sitting days after the day on which the Rule or Order is made. If it is not tabled within this time, the Rule or Order will no longer have, or will not take, effect. In addition, if the Rule or Order is not presented to the New Zealand House of Representatives or is disallowed by that House, that Rule or Order will not have force of law in Australia (and vice versa).

If you'd like further information about this topic, contact:



Amanda Turnill
Partner
T +61 2 9353 4134
F +61 2 9220 6700
aturnill@claytonutz.com



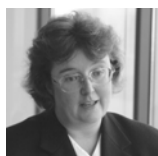
Colin Loveday
Partner
T +61 2 9353 4193
F +61 2 8220 6700
cloveday@claytonutz.com



Stuart Clark
Partner
T +61 2 9353 4158
F +61 2 8220 6700
sclark@claytonutz.com



Dr Teresa Baker
Consultant
T +61 2 9353 4826
F +61 2 8220 6700
tbaker@claytonutz.com



Dr Jocelyn Kellam
Partner
T +61 2 9353 4139
F +61 2 8220 6700
jkellam@claytonutz.com



Andrew Morrison
Partner
T +61 3 9286 6537
F +61 3 9629 8488
amorrisson@claytonutz.com



Ian Bloemendal
Partner
T +61 7 3292 7217
F +61 7 3221 9669
ibloemendal@claytonutz.com



Gary Berson
Partner
T +61 8 9426 8420
F +61 8 9481 3095
gberson@claytonutz.com

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- ⁱ Article 11 of the Agreement.
 - ⁱⁱ Article 7 (2) of the Agreement.
 - ⁱⁱⁱ Section 194 of the Therapeutic Products Bill.
 - ^{iv} Section 197(3) of the Therapeutic Products Bill.
 - ^v Section 195 of the Therapeutic Products Bill.
 - ^{vi} Section 196 of the Therapeutic Products Bill.
 - ^{vii} Subsection 206(1).
 - ^{viii} Section 207 of the Therapeutic Products Bill.
 - ^{ix} Section 208 of the Therapeutic Products Bill.