Newsletter
Stephens Lawyers & Consultants

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THERAPEUTIC PRODUCTS: REGULATION UPDATE - ANZTPA & PBS

Australia New Zealand Therapeutic Products Authority (ANZTPA)

UPDATE: All consultations regarding the ANZTPA have been suspended indefinitely due to the official postponement of the joint regulatory scheme. This postponement was caused by insufficient support in the New Zealand Parliament to ensure passage of legislation implementing the ANZTPA.

The governments of Australia and New Zealand are currently in the process of implementing a new joint regulatory scheme, named the Australia New Zealand Therapeutic Products Authority (ANZTPA). It is envisaged that the ANZTPA will replace Australia's Therapeutic Goods Administration (TGA) and New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) possibly by late 2007 - early 2008.

The ANZTPA has been in development since 1996 when Australia and New Zealand signed the Trans Tasman Mutual Recognition Arrangement (TTMRA) to implement mutual recognition principles relating to the sale of goods and registration of occupations. Due to the significant differences in the manner in which therapeutic products are regulated in Australia and New Zealand, therapeutic goods were exempted from the TTMRA. To resolve this exemption an international agreement was signed by Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products in December 2003.

The ANZTPA will regulate the quality, safety and efficacy of therapeutic products including manufacture, supply, import, export and marketing. Therapeutic products comprise of complementary, over-the-counter and prescription medicines, medical devices and blood, blood products and tissues and cellular therapies.

The aim of the ANZTPA is to:

1. Safeguard the health and safety of Australians and New Zealanders and maximise the regulatory capacity for both countries
2. Harmonise the regulation of therapeutic products in Australia and New Zealand in line with international best practice models and establish an internationally recognised regulator of therapeutic products.
3. Create closer economic relations between the two countries
4. Avoid expensive replication of the regulatory approval process and unnecessary barriers to trade [1] .

Companies which are planning to apply for marketing approval of therapeutic products will need to ensure that they comply with the new regulatory requirements.

Regulatory Framework

The proposed ANZTPA will require:

- Pre-market assessment of therapeutic product safety, quality and effectiveness;
- Licensing of manufacturers to assure product quality;
- Standards setting to assure product quality and performance;
- Post-market monitoring of product safety and quality; and
- Surveillance to check for compliance [2] .

Implementation

The public consultation process regarding the Rules and Orders of the ANZTPA has already begun with the end of the second phase of consultation occurring in December 2006. The third and final phase was due to begin in March 2007 with the release of the draft Managing Director's Orders for public consultation. All consultation documents are published on the ANZTPA website (www.anztpa.org).

Implementing legislation will replace the *Medicines Act 1981* and *Medicines Regulations 1984* in New Zealand and the *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Device) Regulations 2002* in Australia. New Zealand and Australia hope to have enacted implementing legislation establishing the ANZTPA by late 2007 [3] .

The New Zealand *Therapeutic Products and Medicines Bill* which aims to establish the ANZTPA, narrowly passed its first reading in the New Zealand House of Representatives on 12 December 2006. The Bill has been referred to the New Zealand Government Administration Committee for submissions. The Committee will table its report to the New Zealand House of Representatives by April 2007.

Australia has yet to release an exposure draft of the Australian Therapeutic Products Bill.

Product Licence

Under the regulatory scheme there will be a three year transition period where companies which are currently supplying therapeutic goods in Australia and/or New Zealand will be automatically issued a three year interim Product Licence. The interim licence allows companies to continue to import, export and supply therapeutic products in the country or countries in which they already import, export and supply those products. However within this three year transition period companies must apply for a full Product Licence or else they will not be able to lawfully import, export or supply those products once the interim licence expires. A Product Licence does not authorise the manufacture of a medicine [4] .

The Product Licence will be issued by the ANZTPA and is an 'extract' of information contained in the ANZTPA register. The proposed ANZTPA Product Licence was released in September 2006 and must comply with the following requirements:

- A summary of the particulars of the medicine(s)/medical device(s) that is/are the subject of the licence, and set out or refer to the conditions, subject to which the licence has been granted. The Product Licence will include :

- the Product Licence identifier

-the date the Product Licence was granted

-the dates and details of variations to the Product Licence

-the country(ies) in which the Product Licence is valid

-particulars about:

i.the license holder

ii.the medicine(s) or medical device(s)

iii.the manufacture of the medicine(s) or medical device(s)m including manufacturers; and

iv.the intended use of the medicine(s) or intended purpose of the medical device(s) (the product indication)

-the conditions subject to which the Product Licence is granted and

-other information relevant to the issuing of the licence

- The particulars included on the Product Licence may vary depending on the classification of the medicine or medical device
- A full Product Licence (that is, one granted after the interim product licence expires) will remain valid provided annual fees are paid and the product licence is not suspended or revoked [5] .

Currently, sponsors of a therapeutic product must apply to the TGA to market in Australia and Medsafe to market in New Zealand. Under the ANZTPA sponsors need only apply to the ANZTPA to market in either or both Australia and New Zealand. The Product Licence holder must be a resident of, or carry on business in, Australia or New Zealand. Only one Product Licence will be supplied per product.

It has been indicated that where the same therapeutic product is registered in both countries by two different companies that do not have a commercial relationship, factors such as:

a. the marketing rights in each country;

b. who will hold the Product Licence;

c. brand name determination; and

d. the right to use any bioequivalence data,

will have to be decided between the companies and manufacturer. The ANZTPA will not be involved in commercial decisions or disputes between companies [6] .

Under requirements set down by the Australian-United States Free Trade Agreement, sponsors applying to market certain therapeutic products, more commonly known as 'generic' products, in Australia by relying on previously submitted evidence relating to the safety and efficacy of another therapeutic good must submit a certificate to the TGA stating that:

a. their product does not infringe a valid claim of a patent that has been granted in relation to the therapeutic good; or

b. a patent has been granted in relation to the therapeutic good, the sponsor proposes to market the 'generic' product before the end of the term of the patent and the sponsor has given the patentee notice of the application to market.

If a person intends to commence legal proceedings in relation to a 'generic' product that will be marketed under the above certificate, that person must submit to the TGA a certificate to the effect that the proceedings:

a. are to be commenced in good faith;

b. will have reasonable prospects of success; and

c. will be conducted without unreasonable delay.

The Draft Medicines Rule (released during the first consultation phase) states that the certification regime will continue under the ANZTPA as part of the Medicines Rule and the same obligations will be imposed on all applicants for a Product Licence for 'generic' products. However it is unclear whether this means that sponsors seeking to register 'generic' products also have to provide certification when relying on safety and efficacy information of a product the subject of a New Zealand patent and if the obligations in relation to commencing legal proceedings in Australia extend to proceedings commenced in New Zealand as well [7] .

As the Australian and New Zealand Governments aim to implement the new Authority within the next 12-18 months, companies will need to assess their current product range to determine which products they will take into the new scheme. This will avoid needless cost in transferring obsolete products. Companies will also have to take into consideration the impact of the ANZTPA Product Licence when entering into or renewing licensing agreements.

Review of the ANZTPA Decisions

Decisions made by the ANZTPA regarding approvals to manufacture, supply, import, export or market a therapeutic product would be subject to a two-stage merits review process. The ANZTPA can be requested to undertake an internal review of a decision and interested parties can further request to have the matter referred to an independent Trans-Tasman Merits Review Tribunal in either country. In Australia, the Administrative Appeals Tribunal (AAT) will act as the Tribunal. New Zealand will set up its own body to act as the New Zealand Tribunal. There will also be a right of appeal from a Tribunal decision on questions of law to the requisite court in the country where the review was conducted. Decisions of the Merits Review Tribunal or a Court in one country will have effect in the other country.

Existing Australian and New Zealand judicial review processes will be adapted to accommodate the proposed regulatory scheme and decisions made by the High Court of New Zealand or the Federal Court of Australia would be effective in both countries. As the separate judicial review systems will remain in place there is a possibility that parties may be able to choose the jurisdiction in which they hope will return the most favourable decision. Also if the therapeutic product is to be sold in both jurisdictions the determination of which jurisdiction should oversee the review process will need to be addressed in the implementing legislation [8] .

Pharmaceutical Benefits Scheme (PBS) Pricing Reform

From July 2007 the Government will be introducing pricing reforms to the PBS that aim to take advantage of market competition between the brands and eventually move to a system of price disclosure where the price that the Government pays will reflect the actual price at which the medicine is being sold.

The PBS is a government drug subsidy system that provides access to over 600 medicines, available in 1,800 forms and marketed as 2,600 differently branded items. The current cost of the PBS is approximately $6 billion.

The past two years have seen a decline in the growth rate of the PBS. In 2005-06 the PBS grew at a rate of 2.7% which is significant but less than the rate of inflation [9] . This is due to the fact that many of the most commonly prescribed medicines are coming off patent, and more will do so during the next 5-10 years, leading to more generic products being included on the PBS [10] . The addition of generic products triggers an automatic price drop on the originator product due to the price reduction policy and price referencing system.

Grouping of Medicines

From 1 August 2007 medicines on the PBS will be separated into two groups, each subject to different pricing arrangements:

F1 Group

This group contains both on patent and off patent medicines where there is only a single brand listed and are not substitutable with other brands or medicines. There will be no mandatory price reductions for these medicines and existing reference pricing linkages will be retained within this group.

F2 Group

This group contains medicines where there are many brands listed and groups of medicines that are interchangeable. There is already the requirement for a 12.5% price reduction when the first new brand of a medicine is listed on the PBS. A further reduction in the price of these medicines will occur from 1 August 2008, as follows:

-a price reduction of 2% a year for three years for medicines where price competition is low; and

-a one-off price reduction of 25% for medicines where price competition between brands is high

Through information provided to the Department of Health and Ageing by stakeholder groups, Group F2 has already been separated into the low and high competition groups. For example, simvastatin, omeprazole, ranitidine, amoxicillin and felodipine have all been classified as multiple brand medicines with high competition. Approximately 100 drugs currently costing $2 billion a year will fall into the high competition group.

Price Disclosure System

Also from 1 August 2007, a price disclosure system will be phased in for medicines that operate in a competitive market:

-From 1 August 2007 suppliers of any new brand listing, where competition is low, must agree to disclose its price as a condition of listing. Price changes based on disclosure will commence for these medicines from 1 August 2009.

-From 1 January 2011 suppliers of any new brand of listing, where competition is high, must agree to disclose its price as a condition of listing. Price changes based on disclosure will commence for these medicines from 1 August 2012.

The Government will introduce implementing legislation for the new pricing and price disclosure arrangements based on the systems operating in comparable countries such as the US and the UK. Information on cash and in-kind arrangements negotiated with pharmacies will be collected as part of disclosure.

Over the next 10 years the Government projects savings of over $3 billion with $580 million in the next four years [11] . These savings should give the government more scope to include on the PBS drugs that are not currently listed or innovative drugs, thus giving the public access to new treatments at affordable prices.

Stephens Lawyers & Consultants' intellectual property lawyers have extensive experience and represent leading pharmaceutical and biotech companies in both commercial and litigious matters.

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To register for newsletter updates and to send your comments and feedback, please email stephens@stephens.com.au

[1] *Overview of the Proposal to Establish a Trans-Tasman Regulatory Scheme for Therapeutic Products - Fact Sheet*, January 2007 http://www.anztpa.org/about/fs-overview.htm

[2] Ibid.

[3] *Stakeholder Consultation Programme 2006/07 - Fact Sheet*http://www.anztpa.org/consult/programme0607.htm

[4] *Guidelines for Transition to the Joint Regulatory Scheme for Class 1 Medicines, Class 2 Medicines and Medical Devices - Consultation Draft,* May 2006 http://www.anztpa.org/consult/dr-translicensing.pdf

[5] *Proposed Australia New Zealand Therapeutic Products Authority (ANZTPA Product Licence*, Therapeutic Goods Administration, Australian Government & Medsafe, New Zealand, September 2006 http://www.anztpa.org/consult/dr-prodlicence.pdf

[6] Consultation Draft, *'Guidelines forTransition to the Joint Regulatory Scheme for Class 1 Medicines, Class 2 Medicines and Medical Devices'*, May 2006 p. 21

[7] Consultation Draft , *'Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines Rule) 2006'*, 15 August 2006, http://www.anztpa.org/consult/dr-devrule.pdf

[8] *Structure, Governance and Accountability Arrangements for the New Authority - Fact Sheet* January 2007, http://www.anztpa.org/about/fs-structure.htm

[9] *Strengthening your PBS - Preparing for the Future*, Department of Health and Ageing, Australian Government http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Strengthening-your-PBS.htm

[10] *New PBS Investment as PBS* Slows, Medicines Australia Media Release, 21 June 2006 http://www.medicinesaustralia.com.au/pages/images/MR%20Jun%202106%20New%20PBS%20Investment%20as%20PBS%20Slows.pdf

[11] Op Cit. No. 8