Submission No 10

Australia's trade and investment relations under the Australia-New Zealand Closer Economic Relations Trade Agreement

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Australian Government

Department of Health and Ageing

SECRETARY

Dr Margot Kerley
Secretary
Trade Sub-Committee
Joint Standing Committee on Foreign Affairs, Defence and Trade
Department of the House of Representatives
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear Dr Kerley

I refer to the letter of 7 March 2006 from the Chairman of your Sub-Committee, the Hon Bruce Baird MP, calling for submissions to the Inquiry into the Australia-New Zealand Closer Economic Relations Trade Agreement. Please find attached a submission from the Australian Government Department of Health and Ageing.

Should you require any further information or want clarification on any matter, please contact Jenny Hefford on 6289 8019 or at jenny.hefford@health.gov.au.

Yours sincerely

Jane Halton
Secretary

May 2006

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Department of Health and Ageing Submission

Joint Standing Committee on Foreign Affairs, Defence and Trade Review of the Australia-New Zealand Closer Economic Relations (CER) Trade Agreement

1 Introduction

The Australian Government Department of Health and Ageing (the Department) welcomes the opportunity to contribute to the Review of the Australia-New Zealand Closer Economic Relations (CER) Trade Agreement.

The Health and Ageing portfolio has a diverse set of responsibilities, but throughout there is a common purpose, which is reflected in the Department's overall objective of seeking to provide better health and healthier ageing for all Australians through a world-class health system.

The services provided by the Health and Ageing Portfolio are delivered through eleven portfolio outcomes. The Department pursues these in association with other portfolio agencies including Food Standards Australia New Zealand (FSANZ) and the Therapeutic Goods Administration (TGA), to which will be added the soon-to-be established Australia New Zealand Therapeutic Products Authority (ANZTPA).

The terms of reference of the review focus mainly on "direct" trade issues. However this submission focuses on the fourth of the Inquiry's Terms of Reference: "Complementary policy approaches by the two governments", with particular reference to regulatory functions performed by national governments.

This has an indirect connection with trade, as the issues covered could be considered "Measures and provisions to minimise potential non – tariff barriers and access restrictions."

1.1 Relevant agreements

In addition to the CER Agreement, relations between Australia and New Zealand are governed by the Trans-Tasman Mutual Recognition Agreement (TTMRA). The purpose of the Arrangement is

> …to give effect to a scheme implementing mutual recognition principles between the Parties relating to the sale of Goods and the Registration of Occupations, consistent with the protection of public health and safety and the environment.

[in order to]

> remove regulatory barriers to the movement of goods and service providers between Australia and New Zealand, and to thereby facilitate trade between the two countries … to enhance the international competitiveness of Australian and New Zealand enterprises, increase the level of transparency in trading arrangements, encourage innovation and reduce compliance costs for business.

The TTMRA also identifies areas which are the subject of significant differences in regulation, including "Therapeutic Goods", and "Hazardous substances, industrial

chemicals and dangerous Goods", for trans-Tasman cooperation programmes. The aim of these is "to expedite the examination of differences in regulatory Requirements between the Parties, with a view to addressing them through mutual recognition, harmonisation or permanent exemption".

1.1.1 Exceptions

As with most trade agreements, there are some limits on the coverage of Australia's trade agreements with New Zealand, but in many areas the level of cooperation extends well beyond that required for free trade.

The CER Agreement allows standard exceptions from its provisions, for specified purposes, provided they are not used "as a means of arbitrary or unjustified discrimination or as a disguised restriction on trade". Some of the specified purposes include:

- protection of essential security interests
- protection of public morals and prevention of disorder or crime
- protection of human, animal or plant life or health
- protection of intellectual or industrial property rights or to prevent unfair, deceptive, or misleading practices
- the application of standards or of regulations for the classification, grading or marketing of goods.

The TTMRA also allows for temporary and permanent exemptions in a number of areas. Exemptions within the Department's area of responsibility include therapeutic products, industrial chemicals, medical practitioners, and genetically modified organisms (under the general exemption for quarantine). The Department is working toward the resolution of these exemptions.

1.1.2 Features of the Department's cooperative relationship with New Zealand

Australia and New Zealand have a long history of cooperation in the health and ageing portfolio, through a variety of arrangements adapted to the need of particular program areas and the nature of the regulatory regimes in both countries. These range from, at the most basic level, the pooling of information of common interest, through to models which go beyond the needs of free trade, such as shared administrative structures.

This approach of working toward a uniform regulatory system (without imposing a single structure) has a number of benefits:

- adopting evidence-based best-practice standards rather than a "lowest common denominator" approach;
- sharing information between Australian agencies and their New Zealand counterparts to identify strategic issues and share best practice approaches.;

- avoiding duplication of effort by assessing similar products to similar standards, together with economies of scale, from operating a single administrative structure;
- preserving accountability to the Australian Minister and the Australian Parliament in unified administrative structures.

2 Specific programs with a particular relationship with New Zealand

2.1 Food Standards

The bilateral *'Agreement between the Government of New Zealand and the Government of Australia establishing a system for the development of joint food standards'* (the Treaty) is an example of the close relationship between Australia and New Zealand, and the commitment of both Governments to the closer integration of our two markets.

Food Standards Australia New Zealand (FSANZ), formerly known as the Australia New Zealand Food Authority (ANZFA), is a Commonwealth statutory authority established under the *Food Standards Australia New Zealand Act 1991* to develop joint food standards for Australia and New Zealand. Since December 2002, food businesses have used a common Australia New Zealand Food Standards Code developed and administered by FSANZ, and underpinned by the treaty.

The Code includes food standards pertaining to the microbiological safety of food; the composition of food, including contaminants, residues, additives and other substances; information about food, including labelling and advertising; and the interpretation and application of standards.

These food standards apply to all foods produced or imported for sale in Australia and New Zealand. The Code does not include joint standards for maximum residue limits for agricultural and veterinary chemicals in food, food hygiene, primary production or export requirements relating to third country trade. Where exceptional health and safety or environmental reasons apply, FSANZ may approve separate food standards for Australia and New Zealand. Where New Zealand considers that a joint food standard is inappropriate for New Zealand, on the basis of exceptional health, safety, third country trade, environmental or cultural factors, it may choose to vary from a joint food standard. Also, the Code does not replace separate quarantine systems in Australia and New Zealand. The single Code is intended to reduce compliance costs for business operating across the Tasman.

2.1.1 History

In March 1997, a Food Regulation Review Committee was formed to make recommendations to improve the efficiency of the current food regulatory arrangements and reduce their burden on the food sector, while protecting public health and safety. The Committee recommended a package of reform measures including a new food regulatory system. This package was agreed by the Council of Australian Governments (COAG) in November 2000. ANZFA was renamed as

FSANZ, and amendments to the 1995 Treaty came into force on 1 July 2002, providing that:

- future amendments to the Treaty, the FSANZ Act 1991 or the Food Regulation Agreement 2000 would maintain New Zealand's level of influence in the food standards system;
- each country would consult with and use its best endeavours to reach agreement with the other on the development of any amendments to relevant legislation;
- New Zealand would be entitled to three rather than two members of the Board of FSANZ, and representation on other food regulation bodies; and
- FSANZ would review a food standard if New Zealand had concerns about health, safety, trade, environmental or cultural factors.

As an essential part of the new food regulatory system, an Australia and New Zealand Food Regulation Ministerial Council (the Council) has been established. The Council comprises Ministers with responsibilities for health, agriculture and other relevant portfolios from Australia and New Zealand as well as State and Territory governments. Each of the 10 jurisdictions brings a "whole of government" view to the Council.

A review of the effectiveness of the Treaty has recently commenced. It is aimed at identifying possible improvements to the operation of the joint food standards system, and identifying the extent to which the objective of reducing unnecessary barriers to trade has been met.

This review is overseen by an Australian Inter-Agency Committee led by officers from the Australian Government Department of Health and Ageing, and including officers from the Department of Agriculture, Fisheries and Forestry, the Department of Prime Minister and Cabinet, the Australian Quarantine Inspection Service, the Therapeutic Goods Administration, Office of Small Business and the Department of Foreign Affairs and Trade.

It is anticipated that a preliminary report on the second review of the Treaty will be submitted to relevant Ministers in July 2006.

The overall intention of the Treaty is to facilitate the implementation of a single Food Standards Code that ensures consistency between New Zealand and Australia. However, under the TTMRA, products (including food) that comply with New Zealand legislation can be exported from New Zealand and sold in Australia, and vice versa. This applies even in circumstances where New Zealand regulations are inconsistent with the Australia New Zealand Food Standards Code, which occurs in a small number of situations.

For example, New Zealand retains separate regulations for food-type dietary supplements. Therefore, food-type dietary supplements (eg highly fortified soft drinks) can be manufactured in New Zealand in compliance with New Zealand legislation, and exported to Australia under the TTMRA. These same products are not permitted to be manufactured in Australia for the Australian market.

A further example of this discrepancy between the two countries can be seen in relation to Country of Origin Labelling (CoOL) where New Zealand has opted out of the CoOL standard. In this case a situation may arise where a food can either be produced in or imported to New Zealand without country of origin labelling, and then exported to Australia under the TTMRA.

In practical terms these disparities can create a situation of market disadvantage for Australian food manufacturers. The reverse may also be true however there are no current examples of foods which would be able to be produced in Australia and not in New Zealand.

2.2 Drugs of dependence

Illicit drug manufacture, trafficking, links to organised crime and drug use are significant global problems that transcend national boundaries. Nations are increasingly sharing information, intelligence and other resources to improve our response to emerging patterns of drug use, associated chronic disease and other social and economic harms.

Australia's cooperation with New Zealand in a number of important drug policy fora is designed to facilitate a complementary approach based on evidence, and avoid duplication of effort.

2.2.1 Intergovernmental Committee on Drugs

The Intergovernmental Committee on Drugs (IGCD) is made up of senior health, law enforcement and education officials from each jurisdiction in Australia, as well as from New Zealand. This body is the primary source of advice to Ministers on drug policy, programs and research.

Through the IGCD, Australia and New Zealand benefit from discussions about law enforcement efforts to combat local production of illicit drugs, drug supply and international trafficking, domestic drug use trends and patterns of harm. Whilst there are some contextual differences between Australia and New Zealand, there are efficiencies made through this open dialogue. It is also a measure of the relationship that government business at the state, territory and federal level is shared in this forum with New Zealand.

As a marker of the high-level cooperation between Australia and New Zealand on drug policy matters, IGCD members have been asked to provide feedback to the New Zealand Ministry of Health on the development of the next five-year New Zealand Drug Policy. A shared approach to broad objectives is considered important given the propensity for the displacement of drug problems if Australian and New Zealand drug policies were to be substantially different.

New Zealand health officials have made supportive statements about the overarching benefits of being engaged in health-policy matters through the IGCD.

2.2.2 Precursor Chemicals

A good example of cooperative Trans-Tasman relationships exists through the National Working Group on the Prevention of the Diversion of Precursor Chemicals into Illicit Drug Manufacture (Precursor Working Group). This Group is co-chaired by the Minister for Justice and Customs, Senator the Hon Chris Ellison and the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Christopher Pyne MP. The Group also includes government and industry representatives from around Australia and includes law enforcement representatives from New Zealand.

The work of the Precursor Working Group also extends to a number of sub-committees which are developing intelligence sharing tools such as law enforcement data bases on illicit drug laboratories, recommending changes to packaging and sale of pharmacy products containing pseudoephedrine, and developing guidelines for remediation of clandestine laboratory sites. These issues are common to Australia and New Zealand in the context of rising psychostimulant drug use and trafficking. Sharing of this intelligence is of critical importance to law enforcement and regulatory authorities, in terms of the trafficking of both precursor chemicals and illicit drugs.

New Zealand law enforcement officials who participate on the Working Group have described the benefits of being able to share experiences and intelligence with Australian law enforcement officials, leading to better approaches to dealing with illegal drug laboratories and associated policy issues.

2.2.3 International meetings

Australian and New Zealand officials engage in close communication to develop shared approaches and strategies where appropriate at international meetings such as WHO meetings on alcohol problems in the Western Pacific, the United Nations Commission on Narcotic Drugs, and meetings about the Framework Convention on Tobacco Control, under the auspices of the WHO.

2.2.4 National Research Centres of Excellence

Australia has demonstrated considerable international leadership on information, evidence and data collections to support its drug policies and practices. The Australian Government Department of Health and Ageing funds national research centres of excellence, which contribute to cooperation with New Zealand:

- the National Drug and Alcohol Research Centre (NDARC) has been able to help New Zealand evaluate its Illicit Drug Monitoring System. (Internationally, Australia has advocated standards for drug related data collection and reporting to assist global efforts to counter drug problems. Sharing these resources and technical skills supports this position);
- the National Centre for Education and Training on Addiction (NCETA) makes workforce development research and resources for the drug and alcohol sector available to New Zealand.

2.3 Therapeutic Products

2.3.1 The Australia New Zealand Therapeutic Products Authority

Therapeutic goods were initially exempted from the TTMRA until 1 May 2006; this exemption has now been extended until 30 April 2007.

On 10 December 2003 the Governments of Australia and New Zealand signed a treaty establishing a joint scheme for the regulation of the quality, safety and efficacy of therapeutic products to resolve the special exemption for therapeutic goods.

The joint scheme will be administered by the new Australia New Zealand Therapeutic Products Authority (ANZTPA), which will replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). ANZTPA will be accountable to both the Australian and New Zealand Governments and will be recognised in law in both Australia and New Zealand. ANZTPA will be headquartered in Australia.

The joint scheme will provide for the regulation of prescription, over-the-counter and complementary medicines, medical devices (eg prosthetics) and other products such as some sunscreens, blood and blood components.

The Australian position in the development of ANZTPA has been that:

- the harmonised system will be largely based on Australia's regulatory framework;
- there will be no lessening of Australia's standards;
- there will be clear opt-out provisions to preserve Australia-only action; and
- there will be no lessening of accountability to the Australian Minister and the Australian Parliament.

The establishment of ANZTPA is an important priority for both Governments and sets a precedent for greater trans-Tasman harmonisation of regulatory frameworks.

The Therapeutic Products Interim Ministerial Council (TPIMC), comprising the Australian Parliamentary Secretary to the Minister for Health and Ageing, Christopher Pyne, and the New Zealand Minister for State Services, Annette King, was established to facilitate the establishment of the ANZTPA.

In April 2004 the TPIMC created the Joint Agency Establishment Group (JAEG) with Mr Philip Davies appointed as Transitional Director in December 2005, to oversee the development of the implementing legislation and other regulatory arrangements for ANZTPA.

The TPIMC also established a Joint Agency Management Committee (JAMC) which is responsible to the TPIMC and oversees the work of the JAEG. The JAMC is chaired by the Transitional Director and consists of senior representation from the

TGA, Medsafe, the Australian Government Department of Health and Ageing, and the New Zealand Ministry of Health.

The joint regulatory scheme was originally due to commence on 1 July 2005. Australia and New Zealand have agreed to defer the start date to allow for an extensive consultation program to enable industry, in particular, to review and comment on the legislation and rules for the new Authority. Negotiations with New Zealand are continuing on the timetable of activities leading to the commencement of the new scheme.

Further information on the ANZTPA is available on the TGA website at www.tga.gov.au/tta/index.htm.

2.3.2 Gene Technology

The Office of the Gene Technology Regulator (OGTR) is part of the Australian Therapeutic Goods Administration (TGA) in the Australian Department of Health and Ageing.

The OGTR supports the work of the Gene Technology Regulator, a statutory office holder established by the *Gene Technology Act 2000* (the GT Act). The GT Act prohibits the use of most genetically modified organisms (GMOs) in Australia unless they have been assessed and are approved under a GMO licence or instrument.

The GT Act and decisions by the Gene Technology Regulator only apply to Australia. The equivalent agency with responsibility for regulating GMOs in New Zealand is the Environmental Risk Management Authority (ERMA) under the *Hazardous Substances and New Organisms Act 1996*. Regulation of GMOs is covered by the general exemption for quarantine under the TTMRA.

ANZTPA will have responsibility for the joint regulation of Australian and New Zealand medicines and medical products. However, gene technology regulation in Australia and New Zealand will not be combined, and will not be the responsibility of ANZTPA.

ANZTPA will thus not have any substantive impact on the current legislation regulating gene technology either in Australia or New Zealand. The regulatory processes and legislative decisions of the Gene Technology Regulator will remain enforceable under Australian domestic legislation and will not be enforceable in New Zealand. ERMA, the equivalent agency in New Zealand, will retain responsibility for regulating GMOs under the *Hazardous Substances and New Organisms Act 1996*.

The OGTR has established and maintains contact with ERMA to exchange information on regulatory processes and technical issues. For example ERMA has contributed to the revision of the OGTR's *Risk Analysis Framework* and there has been liaison between the ethics bodies of both agencies in the development of their respective ethical statements.

2.3.3 Chemical Safety

Industrial chemicals are currently exempted from the TTMRA.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), within the Office of Chemical Safety (OCS), is the Australian Government regulator for industrial chemicals including cosmetics. The Environmental Risk Management Authority (ERMA) regulates hazardous substances and new organisms in New Zealand.

Because of the different regulatory regime in New Zealand, OCS will be exercising their regulatory roles in relation to Australia only, under Australian law, although they will be sharing information with ERMA, and comparing experiences.

The Office of the Australian Safety and Compensation Council (formerly the National Occupational Health and Safety Commission Office) within the Department of Employment and Workplace Relations is the lead agency for the Chemicals Cooperation Program (CCP). ERMA is the corresponding agency in New Zealand.

The achievement of mutual recognition for chemicals under the CCP requires both Australia and New Zealand to work together to identify and progress elements for harmonisation of regulation. There are two aspects to progressing the TTMRA for chemicals. The first is the assessment and notification of chemicals prior to entry into either country. The second aspect is the consistent implementation of the Globally Harmonised System for Classification and Labelling of Chemicals, which outlines requirements for classification and labelling of chemicals in either country.

In 2004 Australia and New Zealand agreed a 5-year work plan to progress work to resolve the special exemption for industrial chemicals under the TTMRA, and address and domestic poisons scheduling. The work plan includes deliverables and milestones, to determine which elements of the Australian and New Zealand schemes could be mutually recognised or harmonised. A Joint Annual Report on Trans-Tasman Mutual Recognition Arrangement; Hazardous Substances, Industrial Chemicals and Dangerous Goods (Chemicals) Cooperation Program was presented to the Council of Australian Governments in December 2005.

A Memorandum of Understanding (MoU) for cooperation between NICNAS and ERMA (including the exchange of information and promotion of harmonisation) is available from the NICNAS website at
http://www.nicnas.gov.au/International/Bilateral_MOU_ERMA_NICNAS_PDF.pdf

2.4 Health Workforce

The TTMRA covers all occupations for which some form of legislation-based registration, certification, licensing, approval, admission or any other form of authorisation is required by individuals in order to legally practise the occupation, with the sole exception of medical practitioners.

2.4.1 Doctors

In developing the TTMRA, the participating parties agreed that medical practitioners be exempted from the arrangement as mutual recognition-type arrangements were already in place in Australia at that time.

Under Australian Government and complementary State and Territory laws, a doctor who is registered without conditions in one State or Territory can practise in another participating state (but must register with the relevant Medical Board and pay a registration fee).

The Australian Medical Council (AMC) is a national body which advises State and Territory Medical Boards on uniform approaches to the registration of medical practitioners, and accredits medical courses in Australia and New Zealand. The AMC also conduct examinations of overseas-trained doctors to assess their medical knowledge and clinical skills against Australian and New Zealand standards, defined as the level of attainment required of newly qualified graduates of Australian medical schools who are about to commence intern training.

In general, in order to be registered in an Australian State or Territory, overseas-trained doctors (OTDs) must pass AMC examinations

However, there is an exception for graduates of AMC-accredited New Zealand medical schools who have completed an approved period of intern training, who automatically receive registration from State and Territory Boards.

Doctors who are registered but were not qualified in New Zealand are not covered by this exemption, and must complete the examination.

The Department has taken the view that simply extending the Australian mutual recognition arrangements to include New Zealand would not provide adequate quality assurance in respect of doctors in this latter category, since unlike New Zealand-trained doctors, there is no assurance that their training meets AMC standards.

Accordingly, the Department supports the continued exemption of medical practitioners from the TTMRA.

All OTDs, including doctors trained in New Zealand, who first started working as doctors in Australia after 1996 are subject to Medicare provider number restrictions. These affect where an OTD can work in Australia. The restrictions for a permanent resident OTD differ from those for a temporary resident.

If an OTD wishes to provide medical services that will attract Medicare rebates, the Australian Government will generally only issue a Medicare provider number for the doctor to work in a district of workforce shortage. A permanent resident OTD who is not vocationally recognised as a specialist or fully qualified general practitioner will also need to obtain a placement on an approved training or workforce program.

Further details are available on the Australian Government's website for overseas trained doctors, www.doctorconnect.gov.au.

2.4.2 Nurses

The Australian Government has a leadership role in health policy and an overall interest in the supply, distribution, demand and quality of the health workforce. The Department's objective is to health professionals in health policy development, planning and implementation.

The Department supports State and Territory nursing legislation that is underpinned by nationally agreed principles, and which includes the requirement for assessment against the Australian Nursing and Midwifery Council (ANMC) competencies for the initial registration of registered and enrolled nurses.

The ANMC Collaborative Advisory Panel provides advice to the ANMC and Australian and New Zealand nurse regulatory authorities, and informs processes for their recognition of overseas qualified nurses. This process of collaboration, and the provision of advice, improves the standards for the purpose of mutual recognition, supporting the TTMRA.

2.5 Communicable Diseases

New Zealand is represented on the Communicable Diseases Network Australia (CDNA) by an official from the NZ Ministry of Health, and it is through CDNA that Australia and New Zealand regularly share information on surveillance and disease outbreaks.