PART 6:

THE TRANS-TASMAN RELATIONSHIP

Chapter 17

Australia New Zealand Therapeutic Products Authority: Lessons from the Deep End of Trans-Tasman Integration

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17.1 Introduction

Regulation in its various forms in New Zealand occurs against a broad backdrop of economic and social policy. Part of that setting is the international dimension. The existence of the rest of the world provides opportunities and risks in the search for better regulation, as it does in many other areas of policy. More importantly, engaging with the rest of the world in one sphere almost always has implications in other spheres. So the international side of regulation is complicated and can be demanding.

As an example of a complicating factor we consider economic growth. Important amongst the factors that generate economic growth is the expansion of the market through trade.[1] So in our interconnected world, each jurisdiction seeks to improve its economic performance using all of its distinctive advantages to create competitive edges in world markets, given domestic constraints. And do international exchanges just happen and make countries better off? Of course not; all departures from the legal and other rules that characterise conventional arms-length relations between countries have to be structured and agreed. And that process is complex. It is especially so when the issues under debate are intertwined.

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[1] Charles C Jones and Paul M Romer "The New Kaldor Facts: Ideas, Institutions, Population and Human Capital" (2010) *American Economic Journal: Macroeconomics* 224.

17.1.1 *Case study*

This chapter examines a slice of recent international policy history to illustrate the way opportunities and risks play out in the quest to improve the New Zealand (and Australian) regulatory functions. The negotiations to set up the Australia New Zealand Therapeutics Product Authority (ANZTPA) form the case in point.

This discussion must be seen in the context of what has been a highly successful experiment in bilateral international cooperation, the modern history of which clicked into gear with CER[2] and has led to a large number of other cooperative arrangements, including the Trans-Tasman Mutual Recognition Arrangement (TTMRA), Food Standards Australia and New Zealand (FSANZ) and many other coordination activities.[3]

The motivation for the ANZTPA was to establish a world-class therapeutic product regulator for the trans-Tasman market.[4] By doing this, the aim was to improve public health and safety, reduce trade barriers, and encourage trade at the least cost. Furthermore, the role of good regulation is an important ingredient to promote trade since there is a virtuous circle for those industries which have good regulatory practices. Good regulation not only promotes trade but attracts more investment, which in turn generates further trade.

Part of the context to this development was that both countries have been keen to explore how they can develop more compatible regulatory frameworks. This would enable better connections with trading partners within wider political, economic, and institutional constraints. In the trans-Tasman context institutions are relatively strong,[5] since both countries have inherited and imported legislative and regulatory regimes from Britain where many of the processes have undergone hundreds of years of testing and development.[6] With increased global connectedness, however, new

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2 Australia New Zealand Closer Economic Relations Trade Agreement, Australia-New Zealand (opened for signature 14 December 1982, entered into force 1 January 1993). The Agreement is also known as ANZCERTA. It was, of course preceded by the unlamented New Zealand Australia Free Trade Agreement, Australia – New Zealand (opened for signature 31 August 1965, entered into force 1 January 1966), the main contribution of which was to stall and thereby trigger the (bolder) Closer Economic Relations discussions. For an example of trans-Tasman coordination see Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

3 For further detail see New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007).

4 See Australia New Zealand Therapeutic Products Authority www.anztpa.org (last accessed 15 August 2011).

5 Institutions are strong in the sense of being widely accepted.

6 The strength of the institutions is reflected in the wide variety of agreements that have been successfully developed. For further detail see New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration

challenges have presented themselves; more products being traded are more complex – in the sense of being harder to assess in terms of quality in use – particularly in the food and pharmaceuticals area.

For trans-Tasman regulators, this has created a situation where additional scarce expertise and equipment are required, increasing regulatory costs in order to properly manage and regulate the trade. To reduce these costs of the regulatory regime and at the same time ensure consistency and safety, trans-Tasman regulators proposed the ANZTPA as a way of coordinating an efficient regulatory regime and protecting consumers from potentially harmful products.

The analytical approach is to set up a stylised model of the "ideal" elements of the process, including the negotiating issues, to illustrate the underlying forces. By using this technique we can examine various aspects of the trans-Tasman integration process to build up a wider analytical discussion. This is built around:

- demand side factors (that is, the attitudes of stakeholders given what is politically possible, economically durable, and whether or not the institutional arrangements are able to sustain any particular integration proposal). Possibly these are issues that we cannot control; and
- supply side factors (i.e. the set of possible institutional approaches) which are issues that New Zealand could have more control over.

In this way, we will be able to demonstrate how the demand and supply side interact and examine some of the high-level lessons that can be learnt from the ANZTPA. Specifically, the rest of this chapter will:

- briefly examine the historical context of the trans-Tasman relationship;
- establish the framework for examining the negotiation process;
- explain the importance of each element of the framework and how it potentially shapes any particular standard, regulation or treaty proposal; and
- draw some conclusions.

While this chapter mainly focuses on relating to Australia, there may also be some lessons that are "portable" for a discussion about how New Zealand can approach wider international regulatory cooperation, especially in bilateral settings.

Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation (Australia and New Zealand School of Government, Victoria, 2007).

17.2 Background

17.2.1 *The importance of CER*

Modern trans-Tasman cooperation history begins in 1983 with CER. In world terms, CER was an important agreement since it showed how two countries could gain economically from closer integration. It went well beyond the usual limited and tentative coverage of regular trade agreements and included people movement and services.

However, the CER agreement did not come out of a vacuum; it was a product of a historical process where trade negotiators had taken on some harsh lessons from the previous trans-Tasman agreement, the New Zealand Australia Free Trade Agreement ("NAFTA"). Crucial design features based on these lessons were:

- ensuring that clear direction was given by the two Prime Ministers at the start. Everything was on the table to be negotiated according to opening communiqué;
- undertaking extensive domestic (New Zealand) consultation to help develop a general consensus that it was a good idea and it would benefit New Zealand. This assisted in:
    - allowing New Zealanders to give "voice" to their concerns and also express support for the agreement;[7]
    - incorporating a staged implementation process to allow businesses to adjust over time. This was the "accountability" mechanism used to allay "voiced" concerns;
    - designing the agreement to be outward looking so that its provisions could be easily applied to other countries, by each country acting independently if necessary; and
    - ensuring the agreement was completed within three years with the same political context and participants in the negotiation on each side of the Tasman.[8]

New Zealand took the lead in developing the key structural components of the agreement because the economic outcome was more important to New Zealand than to Australia. New Zealand wanted a free trade agreement rather than a customs union as suggested by Australia.

Australia engaged in the CER process not only for trade reasons but also for security reasons. They had become alarmed by the unorthodox economic policies practiced in New Zealand in the 1970s and the time-consuming and

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7 The overwhelming support given to the agreement was a crucial factor in persuading a sometimes reluctant Prime Minister, Mr Muldoon, to support Closer Economic Relations: Chris Nixon and John Yeabsley *New Zealand's Trade Policy Odyssey* (New Zealand Institute of Economic Research, Wellington, 2002).

8 Some of these factors were absent in the ANZPTA negotiation process and contributed to the shelving of the ANZPTA in 2007.

growingly ineffectual processes that were a feature of the NAFTA. At a higher level they did not want to deal with large numbers of New Zealand economic migrants coming to Australia as a result of New Zealand's unorthodox policies. In this respect, the key motivations of the Australian and New Zealand governments have not changed much in the intervening years. These are:

- Australia normally comes to the table with assumptions about what New Zealand might do. These assumptions are typically associated with security issues or joining a process that might advance wider Australian interests. For example, Australia has worked to persuade New Zealand to join them in the square kilometre array project, so that it could compete directly with the South African bid;[9] and
- New Zealand tends to arrive at the negotiating table with economic expectations, whether they are about trade, integration of regulatory functions, or how we might cooperate within third markets.

Understanding tends to break down when the Australian assumptions and the New Zealand expectations become blurred. A good example of this was the proposed open skies agreement that was scrapped in 1996, somewhat unexpectedly. While it was agreed to later, at the time, there nothing in it for Australia in terms of improving Australian security, or supporting an international agreement from which Australia or even Australian firms would benefit. New Zealand economic interests, however, were seen as gaining at the expense of Australian interests under the agreement (for example, Air New Zealand or its affiliates would have been able to compete head-to-head in Australia's lucrative (and protected) domestic market).

The main reason Australia finally signed the agreement was that the "airline game" had changed. Global interconnectivity eroded the ability of the players to maintain the lucrative market for domestic air travel. Australia saw that it was in its wider interest to allow increased competition in its air space.

Possibly, this type of analysis is why the Single Economic Market (SEM) has become the focus of Australian and New Zealand interests. Both countries realise increased global interconnectedness has eroded market share for domestic players and see that improving competition in the trans-Tasman market is an important driving force that will assist in competing with third countries (in both domestic and foreign markets).

Despite these differences in approach and the hiccups along the way, the efforts towards integration have gone much further than in most other jurisdictions, possibly with the exception of the European Union, in terms of

[9] The Square Kilometer Array project is a radio telescope in development which will have a total collecting area of approximately one square kilometre. It will operate over a wide range of frequencies and its size will make it 50 times more sensitive than any other radio instrument. Currently, South Africa and Australia (with New Zealand involvement) are bidding for the project.

the treatment of goods and services. The next section gives a brief overview of these developments.

17.2.2 *The proliferation of contact*

While most regulation operates domestically, New Zealand and Australia's shared history, strong and similarly structured institutions and geographical proximity, offers an unusual chance to more tightly integrate, while at the same time maintaining independent stances on issues that are core to national interests (sovereignty).

Good regulation is a key ingredient to promoting trade and investment, and this further trade and investment is crucial for economic growth.[10] This is particularly so for small countries with small domestic markets who rely on exports for increases in their standard of living. According to Jacobs,[11] there is a virtuous circle for those industries which have good regulatory practices; good regulation not only promotes trade but attracts more investment, which in turn generates further trade.[12] This underpins the desire for Australia and New Zealand to seek a more integrated regulatory regime.

Despite there being few examples for New Zealand and Australia to follow, the relationship has made significant strides over the past 20 years to integrate the two economies in a way that economically benefits both.[13] Notably, this includes the Trans-Tasman Mutual Recognition Arrangements ("TTMRA"), Food Standards Australia and New Zealand ("FSANZ"), Joint Accreditation System of Australia and New Zealand ("JAS-ANZ") and many other treaties, memorandums of understanding and exchanges between the two countries. In sum, Australia and New Zealand have made concerted efforts to improve the efficiency of trade between the two nations.

The Australian and New Zealand School of Government ("ANZSOG"), sets out the scope of this cooperation:[14]

- Regular Ministerial meetings – there are five agencies that have formal arrangements, but there are many more informal arrangements;

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10 Charles I Jones and Paul M Romer "The New Kaldor Facts: Ideas, Institutions, Population, and Human Capital" (2010) 2 *American Economic Journal: Macroeconomics* 224.

11 Scott H Jacobs *Regulatory Reform in the United States: Enhancing Market Openness through Regulatory Reform* (Organisation for Economic Cooperation and Development, Paris, 1999).

12 See Daniel Kalderimis "Regulating Foreign Investment in New Zealand" in this volume (ch 16).

13 For example, trans-Tasman trade in both directions is at higher levels than prior to the agreement and both markets are the number one market for each other's small and medium-sized businesses (SMEs).

14 New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007) at 13–14.

- Meetings of officials – coordination, shared policy and operational lessons. Information sharing occurs across a wide range of areas particularly with customs, biosecurity and immigration;
- Shared representation on boards, councils, and other bodies;
- Staff exchanges between departments and other government agencies;
- Mutual recognition. A wide range of Memoranda of Understanding (MOUs) are in place, notably including the Trans-Tasman Mutual Recognition Arrangement (TTMRA) which allows:
    - all goods that may be legally sold in New Zealand to be legally sold in Australia and vice versa; and
    - all persons registered in New Zealand (with a few exceptions) to practise their occupation in Australia and vice versa;
    - joint ventures or other unincorporated activity (both multi-jurisdictional and trans-Tasman only);
    - joint bodies, companies or other incorporated institutions (both multi-jurisdictional and trans-Tasman only);
    - alignment through unilateral policy and law reform; and
    - the establishment of a single economic market (SEM) objective. The intent of the SEM is to allow businesses to conduct seamless operations across the Tasman without regulatory overlap.

As ANZTPA did not proceed, the current therapeutics regime is an exception to the TTMRA, since some therapeutic goods produced in New Zealand do not meet Australian or other international standards. While all Australian therapeutic products can be sold in New Zealand, not all New Zealand products can be sold in Australia, because they have not been through an internationally recognised testing regime.

17.2.3 *Food Standards Australia and New Zealand*

FSANZ is an example of a joint regulatory approach which provides clear regulatory direction, certainty and consistency at a lower cost than if both countries regulated food standards independently.[15] FSANZ is an independent agency that sets the standards for the food regulatory systems of Australia and New Zealand. It was established through the Food Standards Australia New Zealand Act 1991 and its amendments in 2007. Within New Zealand, FSANZ is responsible for retail and catering food standards, surveillance and policy evaluation. FSANZ in Australia also has control over the food safety enforcing regulations in all states. In New Zealand, this regulatory function is carried out by the New Zealand Food Safety Authority (NZFSA). Third country exports are not included in this process.

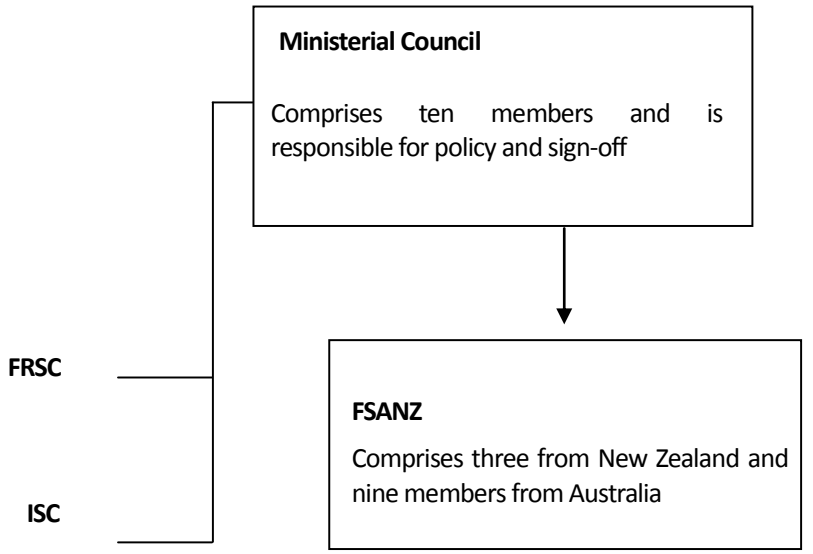
[15] See also Susy Frankel and Meredith Kolsky Lewis "Trade Agreements and Regulatory Autonomy: The Effect on National Interests" in this volume (ch 15).

(a) Structure of the Food Standards system

Figure 1 shows the structure of the food standards system in Australia and New Zealand. Policy and final approval for FSANZ is set by a Ministerial Council comprising one Minister from New Zealand, one Minister from the Australian Federal Government, and one Minister from each of the states and territories of Australia.

The Ministerial Council totals ten representatives in all and is dominated by Australian states. The states are responsible for implementation and enforcement of food regulation in Australia.

Figure 1: Food Standards regulatory structure



Source: Interview with FSANZ[16]

The board of FSANZ, which sits under the Ministerial Council, has three appointees from New Zealand and nine from Australia. Two other entities are also relevant in the food standards regulatory structure. They are:

- the Food Regulation Standing Committee ("FRSC)" which is responsible for food policy and report directly to the Ministerial Council; and
- the Implementation Sub-Committee ("ISC") which develops compliance plans to ensure implementation consistency.

16 Dean Stockwell, Manager Food Standards Australia New Zealand, November 2010.

(b) Ability to opt in or out

One of the important mechanisms in the food standards system is the ability of each nation to opt in or out of any particular proposal which leads to a food standard. A good example of this is the Country of Origin Labelling ("CoOL") proposal. Despite the costs of implementing the labelling scheme, Australia decided to adopt the proposal and New Zealand did not.

This has the dual advantage of having a consistent overall framework in which to examine each food standard, but also being flexible enough to allow each country to adopt or reject controversial food standards. In this way, the testing procedures and decision making processes are clear and transparent and the integrity of the overall regulatory regime is maintained. Relatively controversial standards, such as CoOL, can then be dealt with in different ways by each jurisdiction. In reality, very few standards are enforced in only one country.

(c) The 2007 amendments

The 2007 amendments to the 1991 FSANZ Act were adopted to streamline the processes associated with implementation and improve assessment procedures.[17] Two notable areas of reform have been:

- the Ministerial Council are now only be able to request one review of a decision made by FSANZ as opposed to the two allowed previously; and
- those making the appeals now have to provide their own evidence. Previously, when an appeal was made, FSANZ had to look into, and investigate all aspects of the proposal/standard in question.

FSANZ claims that these amendments have made the system faster and more efficient.[18]

(d) Perceived advantages and disadvantages

There are both demand and supply-side advantages of the FSANZ process for New Zealand. The demand side advantages are mainly to do with improved trade facilitation. Common food standards reduce trade transaction costs not only for trans-Tasman exporters but also for third country exporters. This reduces costs for businesses and makes them more competitive in third country markets.

The most important supply side advantage is that this arrangement improves efficiency and quality of the regulatory system. This has two impacts. First, in the domestic market, consumers are protected since New Zealand has access to Australian expertise and facilities (a skills and scale impact). The

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17 Food Standards Australia New Zealand Act 1991 (Cth); as amended by Food Standards Australia New Zealand Amendment Act 2007 (Cth).

18 Dean Stockwell, Manager Food Standards Australia New Zealand, November 2010.

improved capability has the impact of delivering a regulatory service at least cost and improves the science that can be applied to standards formulation. This increases assurance to New Zealand consumers regarding third country imports, since the risk analysis is consistent with Codex,[19] and it simplifies compliance costs for food companies. Secondly, for importing nations, high food standards mean that they can have confidence in the quality and integrity of food and the systems that govern its production. Increased quality assurance means that they can spend less time regulating the trade, thereby enhancing the chances of further imports for New Zealand and Australian companies.

It would be very difficult for New Zealand to replicate the consistency that FSANZ provides with a stand-alone agency, and it would not be able to do it at the same cost as currently incurred.

The perceived disadvantages of the FSANZ process are that:

- it impinges upon the organisation's accountability to New Zealanders[20] for the rules and regulations that it promulgates; and
- the involvement of the Australian states dilutes New Zealand's influence (that is, New Zealand's "voice" is lost in the crowd of Australian states).

All trade agreements will have some impact on sovereignty, and particularly national regulatory autonomy (in this case through voice and accountability).[21] In this case, however, the ability to opt out of proposed standards does give a degree of protection against New Zealand having its core sovereignty values compromised.

There is no question that having Australian states involved in the Ministerial Council has the potential to slow down the food standards process and dilute New Zealand's interests. However, Australian states do need to be involved at the Ministerial level because under the Australian constitution they are responsible for Australian implementation of food standards. If they do not have any influence at the highest level, it would increase the risk that they would find other ways of voicing resistance to any particular standard, which could potentially make implementation unworkable and undermine the joint food standards system.

It should also be noted that Australian states and New Zealand have become sufficiently confident in the food standards system to allow further streamlining through the 2007 amendments to the FSANZ Act. Therefore,

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19 The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.

20 For a discussion of accountability and participation of the public in regulatory processes see Mark Bennett and Joel Colón-Ríos "Public Participation and Regulation" in this volume (ch 2).

21 See Susy Frankel and Meredith Kolsky Lewis "Trade Agreements and Regulatory Autonomy: The Effect on National Interests" in this volume (ch 15).

efficiency has improved as New Zealand and the Australian states and Federal Government have become more "comfortable" with the process.

While New Zealand's voice is diluted, the way the food standards procedures have operated over time, and the ability to opt out of standards, have increased the overall confidence that all sides have in the process. Furthermore, the standards are likely to be more durable because they are agreed to by the Ministerial Council which reflects its members' support. This increases confidence further in the food standards system.

17.2.4 *The proposed ANZTPA*

New Zealand and Australia signed the ANZTPA arrangement in 2003. It set out the wish of both countries to jointly regulate therapeutic products. While New Zealand and Australia have had other joint arrangements none went as far as the ANZTPA in proposing a joint regulator in both jurisdictions. The move to the ANZTPA would have established a world-class regulator for the trans-Tasman market whose aim was to improve public health and safety, reduce trade barriers, and encourage trade; all at least cost.

The ANZTPA was an attempt to replace the Australian Therapeutics Goods Administration ("TGA") and the New Zealand Medical Devices Authority ("Medsafe"). It was designed as a single regulatory agency for the two jurisdictions. It was much more ambitious than other forms of trans-Tasman integration.

Currently, the therapeutics regime covers:

- pharmaceuticals that do not require a prescription (so called "over the counter" pharmaceuticals) and prescription-based pharmaceuticals;[22]
- medical devices in New Zealand that are not subject to pre-market regulation – Medsafe's role is one of post-market monitoring; and
- complementary health care products which are currently regulated as dietary supplements under the Food Act 1981[23] (and the Dietary Supplements Regulations 1985).[24]

(a) Structure

The structure of the ANZTPA was designed to be set up under the 2003 Treaty and once ratified would have been implemented through Acts of Parliament in each country.[25] Importantly, a single set of rules made by the Ministerial Council and technical orders by the Managing Director would direct the operations of the ANZTPA. This meant that there would be complete

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22 These are regulated by the Medicines Act 1981; and the Misuse of Drugs Act 1975.

23 Food Act 1981.

24 Dietary Supplements Regulations 1985.

25 In New Zealand this was introduced to Parliament as the New Zealand Therapeutic Products and Medicines Bill 2006.

harmonisation between Australia and New Zealand in therapeutics regulation. This was a step further than the FSANZ approach whose scope was confined to a standards writing body.

Also, unlike the FSANZ, the ANZTPA was to be overseen by a two member Ministerial Council comprising the Minister of Health in New Zealand and the Australian Minister of Health. According to ANZSOG,[26] the ANZTPA was also designed to have a five-member board. At the time, this was seen (in New Zealand) as an advance over FSANZ because New Zealand would have an equal voice when it came to developing policy.

As a legal entity, the ANZTPA would have been enshrined in legislation of both countries. It would have been directly accountable to the New Zealand and Australian ministers and to each Parliament. The aim was to have common regulatory outcomes and have authority to set regulations in both countries regarding reviews and appeals.

The importance of the ability to exercise a ministerial "voice" meant that there was a focus on "accountability" mechanisms within the ANZTPA regulatory regime. These included parliamentary scrutiny of the rules and orders developed within the ANZTPA, and the procedures for the review of regulatory decisions. Both Parliaments had access to planning, financial and corporate information with the aim of this relatively full disclosure to enable each Parliament to determine how the organisation was performing.

(b) Important issues

The unique features of ANZTPA, described above, have a bearing on the attitudes and stances taken by various stakeholders in the process.

From a New Zealand perspective, a New Zealand-only regulator would require significantly more investment than is currently undertaken to function effectively over the long term. There are a number of reasons for this. First, the nature of the job is highly specialised and skills are in short supply. The ability of Medsafe to attract these types of people is diminishing.[27] This is likely to have serious consequences for New Zealand's ability to provide consistent regulation in this area. Secondly, the risks to the general public from therapeutics products are also increasing. In the past such products have been seen as low risk. The risks are increasing, however, with more information available (of varying quality) on the internet, the ability for children to buy these products when they are typically not suitable for children, and the types of reactions that could potentially occur when mixed with alcohol.[28] And

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26 New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007) at 17.

27 Interview with an anonymous stakeholder (September 2010).

28 Interview with an anonymous stakeholder (September 2010).

thirdly, the increased possibility of the Crown being sued when products are approved that should not be.[29]

The increased risks associated with therapeutic products also meant that equal voice at a ministerial level was seen as important for New Zealand. At the time, this was seen as a major advance over FSANZ because New Zealand would not have been disadvantaged when it came to developing policy. This equal standing at the policy table would, the designers hoped, mitigate any loss in voice or accountability.

(c) Perceived advantages and disadvantages

The advantages and disadvantages of ANZTPA are broadly similar to FSANZ. The advantages of the ANZTPA would have been:

- the enhanced capability of the regulatory regime over the status quo;
- improved public safety, since the regulations would have been backed up by an enhanced analytical capability that would have an improved ability to anticipate problems/issues as they arose;
- enhanced trading opportunities which would attract more investment and improve trade further. Some New Zealand businesses, producing for the export market, would have reduced compliance costs because, instead of going through independent regulatory hurdles for each export market, the ANZTPA would have allowed for one set of regulatory compliance costs. Importing nations would have much more confidence in the ANZTPA process relative to the current regulatory regime and would not subject them to further regulatory scrutiny; and
- the enhanced capability would also have been the most efficient regulatory approach for New Zealand.[30]

The disadvantages of the ANZTPA would have been:

- the possible loss of voice and accountability, although this would have been mitigated by the joint regulatory approach; and
- some businesses would not have survived since they would have been unable to reach the standards required. It is very likely that some New Zealand businesses would have not been able to meet the regulatory requirements of the ANZTPA. These would have been the smaller firms producing for the New Zealand domestic market.

As already stated, all trade agreements involve giving up some sovereignty.[31] In this case it might be mitigated by New Zealand being one of only two at the

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29 Interview with an anonymous stakeholder (September 2010).

30 See *Assessment of Regulatory Options for Therapeutic Products: Report to the trans-Tasman working group* (New Zealand Institute of Economic Research, Wellington, 2002); *Therapeutic Product Regulation and Cost Recovery: Report to the trans-Tasman working group* (New Zealand Institute of Economic Research, Wellington, 2002).

Ministerial decision table. New Zealand would possibly have had a strong influence on policy.[32]

17.2.5 *Summary*

The development of the trans-Tasman regulatory processes has gathered speed over the past twenty years with a large number of integration processes being undertaken. Most of these have been very successful and have steadily improved the efficiency of the integration process through different approaches to the trans-Tasman regulatory system.

The shelving of the ANZTPA is an exception rather than the rule. Hence, it is important that we further understand the forces in play that led to this situation. In the next section, we examine some of the crucial issues and show how they impacted on the negotiation process.

17.3 Framework

A framework allows us to understand and illustrate the advantages and disadvantages from different approaches to further integration and to gain insights into integration opportunities and vulnerabilities.

The design of this analysis has been kept simple deliberately. It contains sufficient complexity and reality to allow us to consider the questions of interest, while illustrating the advantages and disadvantages of the strategies adopted for the ANZTPA trade policy episode.

Figure 2 shows the framework used. It concentrates on the interaction between the supply-led and demand-led processes, given the constraints/opportunities (third country compatibility).

In most markets the demand side factors are the dominant element.[33] This is because those close to the market have a better understanding of what will satisfy the market; and from the market, flows the revenue. Producers of regulatory design solutions do not always appreciate the subtlety of what is required, since they may be biased towards their particular regulatory design solution or may not fully understand the market and the way it works.

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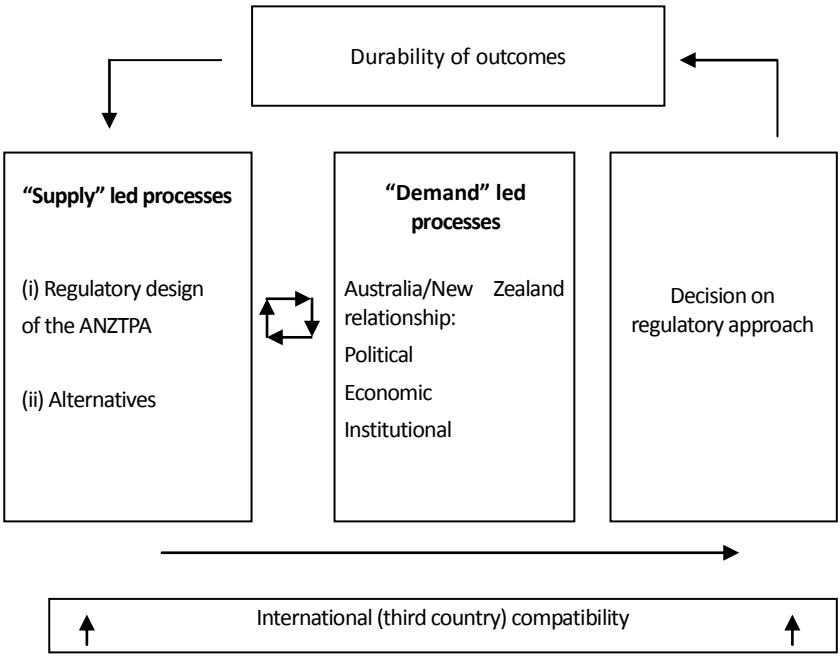
31 See Susy Frankel and Meredith Kolsky Lewis "Trade Agreements and Regulatory Autonomy: The Effect on National Interests" in this volume (ch 15).

32 Although, the unequal power relationship between Australia and New Zealand may mean that this is less of an advantage than the New Zealand designers of the ANZTPA might have thought. Sometimes it is more useful to have others in the room (such as Australian states) who can change the dynamics associated with the decision making process.

33 Robert D Buzzell and Bradley T Gale *The PIMS Principles: Linking Strategy to Performance* (The Free Press, New York, 1987).

Figure 2: Framework



Source: NZIER

In this case, the demand is coming from politicians and policy-makers on both sides of the Tasman who have various motivations for further integration. The challenge for parties negotiating any particular agreement is to align those motivations in a coherent way that leads to a durable agreement, given the details of the supply side issues (elements of the regulatory design).

17.4 Australia – New Zealand relationship (demand side)

Any successful attempt to further integrate two jurisdictions depends upon simultaneously addressing three vital questions:

- the political feasibility: the relationships developed and the degree of understanding of the other country's position and overriding concerns;
- the policy/economic feasibility: what we know about how integration can improve economic growth and other objectives of government and how it is applied practically; and

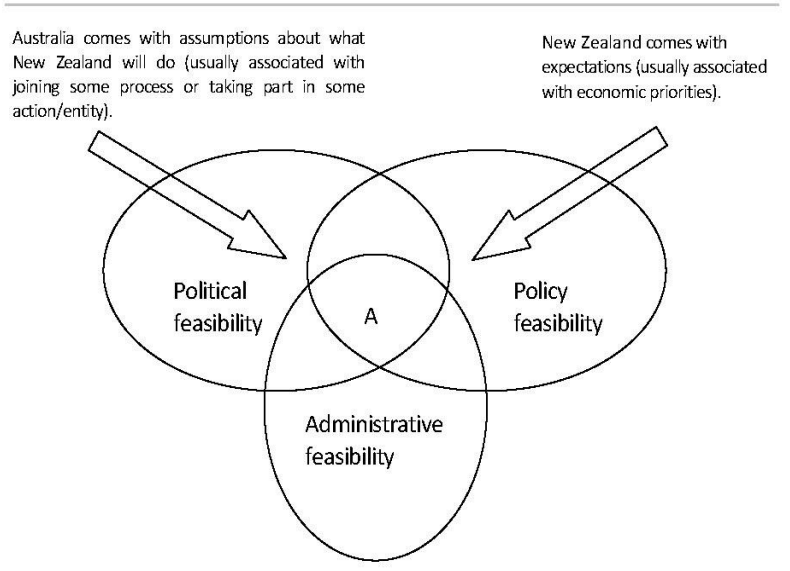
- administrative or institutional feasibility: how can it work practically over time.[34]

All three of these matter and are equally important for the achievement and durability of any particular agreement because any one can prevent success. Therefore, in seeking four realistic outcomes, all three need to be examined and aligned, since it is the details that will determine the fate of any particular potential agreement.

Figure 3 depicts this relationship. The aim of the negotiation is to produce an outcome that sits in the "sweet spot" represented in Figure 3 by point A, that is to say, where all three feasibilities intersect.

The most important aspect of this approach is its diagnostic capabilities. This concept of the successful strategy allows the participant to scrutinise the negotiating approach in terms of the necessary contributory elements.

Figure 3: The interplay between politics, economics and institutional feasibility



Source: Adapted from Lax and Sebenius[35]

If any of these elements are out of line then the negotiator knows that, for success, other elements need to adjust to bring back alignment. It is also a useful tool to assess what opportunities exist in the current situation.

34 See, for example, Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

35 Adapted from David A Lax and James K Sebenius *The Manager as Negotiator: Bargaining for Cooperation and Competitive Gain* (The Free Press, New York, 1986) at 266.

So, on both sides of the Tasman there were strong demand side motivations for developing the ANZTPA. Below we examine some of the political, economic/policy and institutional factors that need to be thought through before any further alignment can be achieved.

17.4.1 *Political feasibility*

Of all the demand side factors, it is the political imperative which is most important in the short run, such as the current focus by politicians on the SEM. The political actors have the most immediate impact on the process of any particular negotiation. As noted in Nixon and Yeabsley[36] the political climate:

- sets the tone (that is, the likelihood that both sides want to cooperate);
- affects the aspirations of the parties; and
- circumscribes what is able to be achieved in any particular negotiation.

Of special importance are issues of developing a domestic consensus, understanding the complexity of the issues, and the importance of flexibility, given that New Zealand is the junior partner in the relationship.

The development of the domestic consensus revolves around demonstrating to the general public that the deal is workable, will deliver real long-term benefits to New Zealand, and that it contains mechanisms that deal with voice and accountability issues (sovereignty). To understand why sovereignty is a sensitive subject particularly in New Zealand, the following quote by Horn, while possibly overdone, is useful:[37]

> If we [New Zealand] merged with Australia, someone said to me, what would we call it? The answer would be Australia.

Political feasibility relies on a number of factors, which are examined below.

(a) Developing a domestic consensus

What put the ANZTPA on hold, when there was a clear willingness for both governments to engage on therapeutics regulation? Primarily it was the inability of the New Zealand Government to deliver the numbers to ratify the ANZTPA. On the surface, at least, this suggests a lack of domestic consensus within New Zealand led to the indefinite postponement of the ANZTPA.[38] In

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36 Chris Nixon and John Yeabsley *New Zealand's Trade Policy Odyssey* (New Zealand Institute of Economic Research, Wellington, 2002) at 22.

37 Murray Horn "Economic questions: choices for New Zealand" in Bruce Brown (ed) *New Zealand and Australia – Where are we Going?* (New Zealand Institute of International Affairs, Wellington, 2001) at 59.

38 See Australian New Zealand Therapeutic Authority www.anztpa.org (last accessed 15 August 2011).

the MMP environment not only do resources have to be put into informing the public but also ensuring that two major political parties agree that it is a worthwhile exercise. Without major party agreement, the governing party is more susceptible to pressure from minor parties in its coalition. This was certainly the case in the ANZTPA negotiation.

In the past, New Zealand, compared to bigger countries, had been able relatively easily to form a consensus on trade policy issues. Between 1880 and 1994, there was largely an unquestioned acceptance by New Zealanders of the overall worth of achieving trade and regulatory agreements with other jurisdictions.[39]

When agreements moved away from agricultural products, where New Zealand has a clear economic advantage in some products (and clearly the benefits outweigh the costs), the New Zealand public seem to have been unprepared to accept, without receiving additional information, the real worth of further integration. In these situations, the government prepared the ground with extensive consultation to highlight why the proposals were worth doing for New Zealand.[40]

CER was perhaps the most clear cut example of where New Zealand moved towards a trade agreement not based around agricultural liberalisation. Despite strong opposition from certain groups, including most (domestically protected) manufacturers, the New Zealand public seem to have favoured signing CER.[41] The situation is changing, however, and the ANZTPA is an example of the way that change works. Perceptions of what it is worth "paying" to achieve some form of trade liberalisation/foreign cooperation has shifted over the past 20 years. During the 1980s, unilateral liberalisation was part of the reform process. More recently, however, sharper questions about the costs of New Zealand integration with the world have been asked by pressure groups, who perceive that they may suffer, at least from the initial impacts of such a process; for example, the opposition to the free trade agreement with China, particularly by domestic manufactures.

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39 This made forming a consensus on trade policy a relatively straightforward affair, since accessing foreign markets with (mainly) agricultural products was a priority. In specific instances, New Zealanders were prepared to wear the very real costs of this achievement. So the country seems to have been solidly behind confirming New Zealand trade policy endeavours whether they were securing priority access to the British market: United Kingdom *Imperial Economic Conference at Ottawa 1932: Summary of the Proceedings and Copies of Trade Agreements* (HMSO, London, 1932); access into Europe (through the United Kingdom's accession to the European Economic Community in 1973), or further agricultural liberalisation through the World Trade Organization (opened for signature 15 April 1994, entered into force 1 January 1995).

40 Chris Nixon and John Yeabsley *New Zealand's Trade Policy Odyssey* (New Zealand Institute of Economic Research, Wellington, 2002) at 41–47. See also Joel Colón-Ríos and Mark Bennett "Public Participation and Regulation" in this volume (ch 2).

41 Chris Nixon and John Yeabsley *New Zealand's Trade Policy Odyssey* (New Zealand Institute of Economic Research, Wellington, 2002) at 127–152.

While there was a long and sustained commitment by ANZTPA negotiating teams, working with their opposite numbers, domestic political parties had not had their views sufficiently well incorporated into the negotiation process to support the process and therefore its ratification was not pursued in the New Zealand Parliament. This suggests that one of the most important reasons for its initial rejection was that not enough work was done on developing a domestic consensus, over a long enough period, to explain why the costs of an integrated regulatory regime were outweighed by the benefits.

(b) Complexity, changing stances, and importance of timing

Once a negotiation starts, the clock is ticking – the sooner a ratification agreement can be reached the more likely the political numbers will line up in support of an agreement. This is particularly so in a New Zealand context with an MMP environment, where changes in Ministers or even slight changes in the numbers (such as occurred at the 2005 general election) can change the complicated negotiations.

For this reason, having a clear joint statement from political leaders about the intent of the negotiations would have been useful in overcoming inevitable sticking points. In the ANZTPA negotiation, there was no such statement, which contributed to a lack of direction once sticking points arose and drew out the negotiations further. Also, inevitably, Ministers and officials changed during the negotiation period and as time dragged on views changed, adding more delays.

One of the main issues is that there are very real differences between the Australian and New Zealand regulatory systems – differences that were not fully appreciated when negotiations started. Addressing these complexities dragged out the negotiations. By the time compromises were reached, the political landscape had changed enough for the deal to be shelved.

As for the ANZTPA, the negotiations lasted nearly five years before they were abandoned, and as political actors/negotiators changed there was no clear mandate, in the form of an opening joint communiqué, to keep the parties focused on the goals.

(c) Ensuring those in the room have authority

When the ratification negotiations started, they were delegated to relevant parts of each country's Ministry of Health. However, the political and economic forces they were left to grapple with were non-trivial and had implications for other (more powerful) parts of government. In fact, some issues were wide and significant; thus, they would necessarily have to be passed on to others for the final call. A great deal of time was lost bringing these wider officials up to speed on various aspects of the negotiations. A mechanism to smoothly engage with all other potentially involved departments was required right from the beginning of the process.

This points to a wider problem for New Zealand. In the trans-Tasman relationship it is New Zealand that needs to make the trade policy "play". As noted, agreements between New Zealand and Australia are more relatively important in an economic sense to New Zealand than they are for Australia. Also, in a trade policy sense the trans-Tasman relationship is the cornerstone of New Zealand's trade policy – what happens in the Australian market not only impacts on other regulatory possibilities in the trans-Tasman area but also further afield. A good case could be made that the shelving of the ANZTPA has impacted on other regulatory initiatives, for example progress towards a single economic market with Australia.

One of the key issues is that Australia is seen as a domestic market issue for New Zealand policy-makers. It is not, and issues that need attention are far more complex than domestic market issues. Therefore, for ANZTPA-type agreements to be successful, more direction and strategic input is required from New Zealand trade policy specialists so that New Zealand can maximise the chances of success.

(d) Maintain flexibility

New Zealand is a policy taker in most negotiations.[42] New Zealand has little ability to take the substantive high ground and somehow persuade, browbeat or otherwise obtain concessions from larger, more powerful nations. This particularly applies to Australia, which holds quite strong views about New Zealand's place in the world.

In this situation, one of New Zealand's key negotiating weapons is flexibility and the ability to remain nimble throughout the negotiation process. In the therapeutics negotiations, there do not appear to have been preparations made around a Plan B. Was there another way to achieve most of the benefits – perhaps a less formal process – that could have achieved most of what New Zealand wanted?

In these processes, New Zealand needs to take the initiative, since the simple reality is that New Zealand needs to find ways to reduce its regulatory burden – much more than the larger Australia. The insight here is that we had not heeded the lessons of CER across government. CER was a major victory for New Zealand because New Zealand trade negotiators were able to structure the agreement in the way that suited New Zealand; in particular, in having a free trade agreement rather than a customs union as Australia favoured. In the therapeutics negotiation it does seem New Zealand went into the process without a coordinated strategy to build a domestic political consensus that supported the aims and objectives of the ANZPTA.

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42 Chris Nixon and John Yeabsley *New Zealand's Trade Policy Odyssey* (New Zealand Institute of Economic Research, Wellington, 2002) at 10.

17.4.2 *Policy/economic feasibility*

(a) Unknown territory

The ANZTPA took New Zealand and Australia into a negotiation process which required a much deeper form of integration. This suggests that there might be more risk associated with ANZTPA relative to other integration processes. Given that the economic and policy consequences were greater for the smaller country, we would have expected New Zealand to put significant resources into a whole of government approach so that as many of the potential risks could have been uncovered. As it was, the potential risks/pitfalls were only uncovered as negotiations over ratification went on.

The advantages of this approach would have been to:

- develop a systematic approach or check list that set out the questions that any particular agency would need to contemplate prior to the negotiations;
- attempt to uncover some of the unknown difficulties that potentially could have occurred or have mechanisms that automatically reviewed progress of negotiations at a senior level to give early warning of risks;
- be in a position to forewarn ministers about potential risk issues; and
- reduce the timeframes of negotiations.

(b) The importance of economic coherence

While political feasibility is necessary, it is not sufficient. History is littered with agreements that have been made that are economically unsustainable and fail. Therefore, the lasting outcomes are strongly affected by the underlying economic forces, which in New Zealand's case depend heavily on its economic performance (dominated by its export performance). While these impacts are complex and short-term, inevitably self interest is paramount so any agreement must deliver economic benefits to all participants over the long run for it to be durable. In this negotiation there was a clear indication that work had been done on the detailed impact of having a joint regulator. The cost-benefit analyses undertaken by NZIER[43] show a clear benefit from having a common trans-Tasman regulator relative to the next best alternative.

Other issues are also important but are quite difficult to quantify. The current regulatory approach is only a temporary option and, at some stage, changes will need to be made to protect the integrity of the therapeutics regulation in New Zealand. This will involve further costs.

High-quality regulation attracts further investment, particularly in companies that have high-quality standards. These high-quality standards will

[43] NZIER (2002) *Assessment of Regulatory Options for Therapeutic Products: Report to the trans-Tasman working group* (New Zealand Institute of Economic Research, Wellington, 2002).

also assist exporters in reducing compliance costs in third markets. Some companies, however, will inevitably go out of business because they cannot meet these standards.

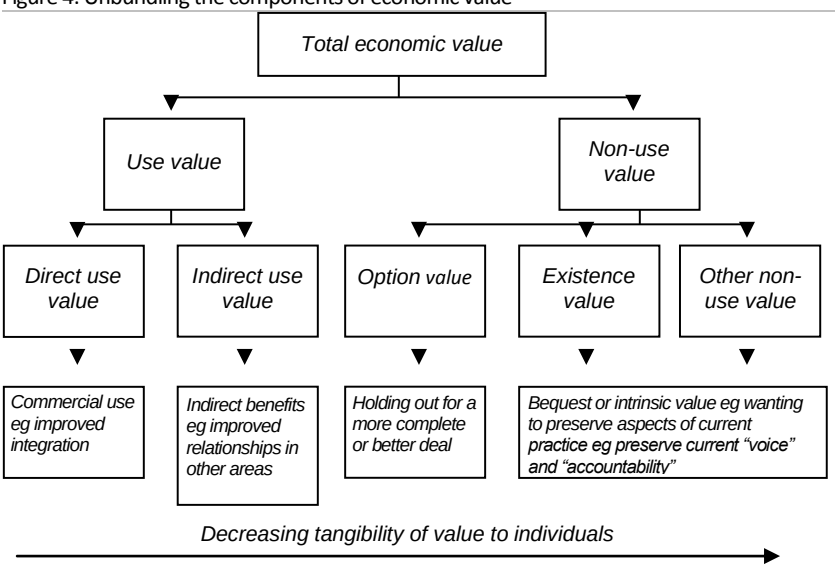
(c) Unbundling the economic impacts

When dealing with market and non-market processes it is important to ensure that all economic factors are taken into account. Figure 4 sets out the approach to total economic value associated with integration.

Use values or the values that can be measured in the market are more easily gauged relative to other forms of economic value. This is because the impact of further integration can be shown in terms of increased/decreased business and other economic activity.

Non-use values are more challenging to analyse since evaluating how successful economic integration can impact upon other areas of the relationship, such as defence, is not easy. Nevertheless, successful approaches to economic integration can spill-over and impact upon other areas.

Figure 4: Unbundling the components of economic value[44]



Source: Adapted from Serageldin[45]

[44] Note that this diagram is analysed in Chris Nixon and John Yeabsley "The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road" in this volume (ch 14), in the context of multilateral agreements moving towards closer economic integration.

[45] Ismail Serageldin *Very Special Places: The Architecture and Economics of Intervening in Historic Cities* (The World Bank, Washington DC, 1999) at 27.

Non-use values can also be option values. The potential they relate to can include holding out for a better structured trade deal or set of regulations. Inherent in such an approach is understanding the cost of such an option, in terms of economic opportunities forgone and spill-over impacts on other parties of the relationship.

More intangible are the existence and bequest values associated with trade agreements. How much of these values are eroded in the process of more tightly integrating the trans-Tasman economies, and how does the perception of this erosion change over time? For example, non-agricultural businesses were relatively hostile to the signing of CER in 1983, however now they see CER as incredibly important to their future.[46]

It would also be a mistake just to take into account market related transactions in estimating the costs and benefits of "tighter" integration, since the full economic impacts stem more from the spill-over impacts of regulations. These can include, for example, the dynamic efficiency gains as firms realise the potential of new regulations; or the lack of domestic accountability for the actions of firms under the new regulations.

17.4.2 *Administrative feasibility*

While New Zealand and Australia have very high-quality institutions,[47] our institutions and regulatory frameworks are not identical – this situation has the potential to cause problems under joint regulation, for example, in New Zealand much more information can be released under the Official Information Act 1987 (OIA) than happens in Australia. How can this be worked through in the case of a joint regulator? Or is it more helpful to use existing governance regimes to apply mutual recognition principles?

Therefore, if a joint regulator is the best option:

- the resources (including expertise) needed to complete the deal must be made available for as long as it takes to close the deal;
- preparations for the negotiations need to be extensive. As part of this process alternatives must be looked at carefully and costs and benefits of options assessed; and
- politicians need to be made aware of what is required (that is, potentially "in play") and how long it might take to achieve the deal.

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46 Chris Nixon *Closer Economic Relations (CER) as a Competitive Weapon? Report to the Australian Trade Commission and New Zealand Trade and Enterprise* (New Zealand Institute of Economic Research forthcoming 2011).

47 An institution, in its broadest sense, sets the rules, conventions and norms that establish a standard of behaviour for members of society: see Douglass C North "Institutions" (1991) 5 *Journal of Economic Perspectives* 97. High quality institutions require consistency and transparency of regulation. This means that businesses can anticipate any reaction of regulatory authorities to their actions.

During the negotiation process, progress must be continually reassessed and compared with the next best alternative. Since the details of the various differences between regulatory systems matter and while these details may not be insurmountable in an administrative context, the time taken or the on-going costs may mean that integration is not politically or economically feasible.

17.5 Regulatory design alternatives (supply side)

To further understand the different ways of thinking about a therapeutics agreement, we have set out a number of approaches and elements of approaches that could be considered. Some of these are quite close to the approach taken to the ANZTPA, while others are radically different.

The approach is based on Petrie,[48] Goddard[49] and ANZSOG[50] which set out a taxonomy of mechanisms that could be used to assist trans-Tasman integration.

Being able to mix and match different approaches is important because it is not always known how differently specified approaches will work out in practice. In the trans-Tasman integration process a variety of approaches and combinations of approaches have been used successfully to achieve closer integration depending on the issue and other factors such as world trends, compatibility of institutions and political aims, and a detailed understanding of the regulations on both sides of the Tasman.

The approaches discussed represent a spectrum of possible options against the base case which is a form of horizontal integration, that is, the joint regulator model as proposed in the ANZTPA. We have examined four different approaches and compared them with a base case. All five are set out in Table 1 and include:

- The *base case*:
    - horizontal integration represents a deeper form of integration backed up by a legally binding regulatory approach. In this case the

48 Murray Petrie "Jurisdictional Integration: How Economic Globalisation is Changing State Sovereignty" (PhD, Victoria University of Wellington, 2009).

49 David Goddard "Business Laws and Regulatory Institutions: Mechanisms for CER Coordination" in Arthur Grimes, Lydia Wevers and Ginny Sullivan (eds) *States of Mind: Australia and New Zealand 1901-2001* (Victoria University of Wellington Institute of Policy Studies, Wellington, 2002) at 179.

50 New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007).

development of a joint regulator with decision making authority remaining at the national level of both countries;

- The possible alternatives to the base case are:[51]
  - *unilateralism (and mutual recognition)* where:
    - regulatory approaches are adopted from other jurisdictions. This approach is most likely to occur when the international regulation in any particular area is converging; and
    - regulatory recognition where Australia/New Zealand unilaterally recognise Australia's/New Zealand's laws in a specific area. This would mean that if Australia recognises New Zealand's regulation, then New Zealand firms who operate in that sector and in Australia can do so under New Zealand's regulatory framework.
  - *simple cooperation* which involves a diverse range of activities depending on the interests of the countries involved. They include information exchanges and company introductions, through to consultations over various matters of interest and the establishment of information networks;
  - *coordination* which relates to mainly non-binding pathways to integration. These include: technical cooperation, agreed policy guidelines for enforcement, cross-border appointments and a large number of other mechanisms that set out ways to develop parallel or equivalent approaches to further integrate economies. Non-binding initiatives assist in developing transparent pathways to integration, while maintaining a very high degree of flexibility,[52] through the development of systematic integration approaches; and
  - *vertical integration* which involves the imposition of rules by a third party (although New Zealand may be a member of that third party organisation). This could include third party rule making, third party enforcement, and third party adjudication (such as before the WTO).

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51 See Chris Nixon and John Yeabsley "The Challenges and Opportunities of Conformity in the Wider Asia-Pacific Context: Tiny Steps on a Long Road" in this volume (ch 14), for a further discussion of these alternatives in the context of economic integration in the Asia-Pacific region.

52 See Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

Table 1: Spectrum of jurisdictional integration

Base case	**Other possible approaches**			
Horizontal Integration	**Unilateralism**	**Simple Cooperation**	**Coordination**	**Vertical Integration**
Joint institutions	Unilateral adoption	Information exchange	Technical cooperation	Third party rule making
Harmonisation	Unilateral (or mutual recognition)	Consultations	Jurisdictional interface rules	Third party enforcement
Contracting arrangements		Information networks	Institutionalised mechanisms for policy development	Third party adjudication
			Agreed policy or enforcement guidelines	
			Sanctioned self-enforcement	
			Third party monitoring and/or review	
			Cross agency appointments	

Source: Adapted from Petrie and ANZSOG[53]

To illustrate the types of issues that stakeholders need to be aware of and differences between the approaches, we have used the key judgements adapted from ANZSOG:[54]

- how simple is the arrangement?
- how much certainty is required? If certainty is required then more formal arrangements are required.
- how much influence in the decision-making is required? If influence is sought then some formal engagement (a seat at the table?) is required.
- how much flexibility is required to accommodate one-offs and unique situations?
- how feasible is the option?

53 Adapted from Murray C Petrie "Jurisdictional Integration: How Economic Globalisation is Changing State Sovereignty" (PhD, Victoria University of Wellington, 2009) at 75; New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government 2007).

54 New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007) at 24.

17.5.1 *Base case*

(a) Horizontal integration

Binding agreements between two or more countries create deeper integration and improve efficiency. This is certainly what was envisaged under the ANZPTA. Under the ANZTPA deeper horizontal integration was proposed with the development of a joint institution.

The ANZPTA approach has the advantage of certainty; once the single regulator has decided upon an approach it is written into the regulations that govern therapeutics in both countries. It also allows for influence by having a seat at the decision-making table since the Australian and New Zealand Governments are key decision-makers. It does, however, require that there is consensus about minimum standards and what they consist of. And it does mean New Zealand policymakers need to focus on:

- the amount of influence they are able have with the Australian government, given the unequal (political) power relationship. Having others in the room, such as Australian states, may dilute the power of the Australian Federal Government and restrict its ability to take advantage of its political power to impose its will;
- the accountability mechanisms in place in which New Zealanders could seek some redress for perceived transgressions or even opt-out clauses;
- the administrative practicalities and how regulators would cooperate. The negotiations for the ANZPTA were not simple; it was assumed that the differences in regulatory regimes would be minimal, however the subtle differences caused long time delays as regulatory differences were ironed out; and
- the reduced flexibility associated with cementing in place a joint regulatory system (and creating certainty).

Table 2 sets out the factors of influence associated with the ANZPTA. While the process of negotiating the agreement was complex the agreement would have provided certainty and influence. However certainty and influence are traded off against flexibility since increased commitment reduces the options for regulatory approaches.

Currently, the ANZPTA has been unable to pass the political test in New Zealand because of the perceived costs to the industry and possibly more intangible issues such as a lack of voice and accountability of a joint regulator. This is despite cost benefit analysis demonstrating that there are real economic benefits for joining with Australia and developing a therapeutics regulatory structure.

Table 2: Factors of influence for horizontal integration

	Simplicity	Certainty	Influence	Flexibility	Feasible
Horizontal integration	**X**	✔	✔	✔ **x**	**?**

Source: Nixon and Yeabsley

17.5.2 *Alternatives*

(a) Unilateral recognition

Another approach would be to unilaterally recognise (as domestic) laws say in the United States or Europe that guide their therapeutics regimes. Typically, this is seen as a viable option where worldwide regulatory approaches and policy stances are converging. It has the advantage of being relatively straight-forward since New Zealand could either chose a model that is been used internationally or adopt some of the regulations internationally in an "à la carte" fashion.

ANZSOG also suggests adopting laws unilaterally from another country. New Zealand has, for example, adopted safety standards for electrical appliances and fittings issued in Australia.[55]

The unilateral approach is a highly flexible approach that includes benefits of:

- reducing compliance costs for firms and other entities who have to comply with one regime. It also reduces learning costs since firms only have to learn one regime; and
- being simple and easy to apply.

In the therapeutics regulatory world, however, convergence is yet to occur. There are discrepancies between, for example, the European Union and the United States regimes. This potentially could lead to over-reliance on other regulators without any influence on decision-making.

Table 3 sets out the factors of influence. Unilateral recognition is relatively simple to enact, however there is very little certainty that a regulatory regime will not be prone to change and New Zealand will have very little influence on how the regime develops. There is however, flexibility in the approach that could be taken. In terms of feasibility, the lack of convergence of international regimes around therapeutics makes unilateral recognition less attractive.

[55] New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007) at 20.

Table 3: Factors of influence for unilateral recognition

	Simplicity	Certainty	Influence	Flexibility	Feasible
Unilateral recognition	✔	**X**	**X**	✔	**?x**

Source: Nixon and Yeabsley

(b) Simple cooperation

Many examples of simple cooperation occur between Australia and New Zealand. Simple cooperation involves a diverse range of agreements that at a practical level amount to information exchanges, consultations and information networks.

Simple cooperation has the advantage of flexibility.[56] However, whether this approach is feasible given the significant investment in people and infrastructure (that is, testing regimes and consistency and confidence in results) is a major drawback of this approach.

Feasibility, therefore, is unknown since the level of commitment and motivations for signing or participating in these engagements is relatively small or unknown. The type of commitment required to improve efficiency is probably much more than contemplated in the simple cooperation case.

Table 4: Factors of influence for simple cooperation

	Simplicity	Certainty	Influence	Flexibility	Feasible
Simple cooperation	✔	✔ **x**	✔ **x**	✔	**?x**

Source: Nixon and Yeabsley

(c) Coordination

According to ANZSOG,[57] bilateral coordination allows for reciprocity between countries; that is, allowing each country to have regard to each others' laws while undertaking reforms that seek to reduce compliance costs. Bilateral undertakings essentially allow for a commitment of further integration (through cooperation) while still maintaining a high level of flexibility. Examples of this in trans-Tasman cooperation include standards development,

56 See Susy Frankel and Megan Richardson "Trans-Tasman Intellectual Property Coordination" in this volume (ch 18).

57 New Zealand Ministry of Economic Development and Australian Government Department of Finance and Administration *Views from the Inside no 1: Arrangements for facilitating trans-Tasman government institutional co-operation* (Australia and New Zealand School of Government, Victoria, 2007).

security enforcement cooperation between agencies such as Customs, and cross-agency appointments.

Table 5 sets out the factors of influence. This approach has the advantage of being relatively simple and flexible, however:

- New Zealand would have almost no influence on Australian therapeutics regulations which possibly means we would be playing catch up with Australian regulations and often out of step;
- it would be much more costly than the status quo since Medsafe would have to gear up to match Australian regulations and enforcement regimes, which means there is a question mark over its feasibility;
- there would be less certainty relative to a joint regulatory regime because it is debatable whether New Zealand has the capacity or willingness to spend the resources to follow through on the requirements; and
- the price of New Zealand developing its own capability in this area (essentially the status quo) is relatively high. Further, the ability to maintain this capacity in a rapidly changing world is likely to become harder.

Table 5: Factors of influence for cooperation between regulators

	Simplicity	Certainty	Influence	Flexibility	Feasible
Coordination	✔	✔ x	✔ x	✔	?

Source: Nixon and Yeabsley

(d) Vertical integration

Vertical integration is more closely aligned with the unilateral approach than other approaches. Essentially, rules, adjudication or enforcement are imposed upon a jurisdiction through a multilateral institution (for example, through agreements such as the WTO). The impact of such agreements depends on how aligned a country is with international norms.[58]

These agreements are relatively simple to adopt (although difficult to negotiate) and they provide some certainty. However, the amount of flexibility small countries have on these third party agreements depends on whether mechanisms can be built into the agreement to allow for opting out of certain parts of the agreement, since once signed it is almost impossible for a small country to renege on the agreement (unless of course everybody else is as well, such as with the Kyoto Agreement on climate change).

Similarly, how much influence a small country has on an international agreement will depend on how useful that country has been in constructing

[58] See Susy Frankel and Meredith Kolsky Lewis "Trade Agreements and Regulatory Autonomy: The Effect on National Interests" in this volume (ch 15).

any particular agreement. Normally, a small country does not set the international agenda; it can, however, play a role in bringing parties together and finding solutions where bigger countries are a long way apart.

In therapeutics, the chances of convergence of regulatory frameworks are relatively slim. It is, therefore, unlikely that an international agreement of any description will be signed in the near future. Vertical integration is unlikely to be feasible.

Table 6: Factors of influence for vertical integration

	Simplicity	Certainty	Influence	Flexibility	Feasible
Vertical integration	✔	✔ **x**	✔ **x**	✔ **x**	**?x**

Source: Nixon and Yeabsley

17.6 Implication of the supply side approaches

In Table 7, we have set out the summary of the supply side tools that could potentially be used. We would emphasise that there is no single best solution option between the base case and the alternatives. It will depend on a series of judgements made by politicians, negotiators and policymakers as to the way forward. Furthermore, because an approach has been shelved in the past does not mean that circumstances could not arise again in the "shifting sands" of the trans-Tasman relationship so that it could again become a "live" prospect (in the same way the open skies policy did).[59]

In Table 7 we have compared the base case (a form of horizontal integration proposed under the ANZTPA) with the other alternatives. Horizontal integration increased certainty and it gave New Zealand some influence over the regulatory regime. It was a complex process, however, with limited flexibility. Currently, it is uncertainty whether this approach will be pursued further given that it has not been ratified by the New Zealand parliament.

[59] See Nixon and Yeabsley (ch 16).

Table 7: Summary of approaches

	Simplicity	Certainty	Influence	Flexibility	Feasible
Base case					
Horizontal integration	**X**	✔	✔	✔ **x**	**?**
Alternatives					
Unilateral recognition	✔	**X**	**X**	✔	**?x**
Simple cooperation	✔	✔ **x**	✔ **x**	✔	**?x**
Coordination	✔	✔ **x**	✔ **x**	✔	**?**
Vertical integration	✔	✔ **x**	✔ **x**	✔ **x**	**?x**

Source: Petrie, Goddard and Nixon and Yeabsley[60]

Unilateral recognition is relatively simple to administer and is highly flexible since New Zealand could "pick and mix" its regulatory regime. However, it would not provide any certainty, given the inconsistencies in therapeutics regulation around the world, nor would New Zealand have influence on the regulations it puts in place. Furthermore:

- it would not be an efficient mechanism since New Zealand would still need to verify the safety and quality of the products imported into New Zealand (similar to the status quo); and
- other countries would still require New Zealand exports to go through the importing country's own safety and quality testing regimes (similar to the status quo) since New Zealand regulatory approvals would not be as "trusted" as the single regulator model under the ANZTPA.

The uncertainty associated with feasibility arises from its lack of impact on trade and possible increase in regulatory costs as regulatory capability is enhanced to keep up with other jurisdictions. New Zealand will still need to provide testing facilities and specialist capabilities to maintain confidence in the regulatory regime, while at the same time not delivering the same internationalised product that a joint regulator would provide.

Because of the complexity of the testing regimes and the skills required, a simple cooperation agreement is not useful for either side since it does not really help improve the efficiency of the regulatory process.

Signing a more in-depth but non-binding cooperation agreement has the advantage of being simple while providing a measure of certainty. Although the degree of certainty would not be as great as developing a joint regulatory

[60] Adapted from Murray C Petrie "Jurisdictional Integration: How Economic Globalisation is Changing State Sovereignty" (PhD, Victoria University of Wellington, 2009); David Goddard "Business Laws and Regulatory Institutions: Mechanisms for CER Coordination" in Arthur Grimes, Lydia Wevers and Ginny Sullivan (eds) *States of Mind: Australia and New Zealand 1901–2001* (Victoria University of Wellington Institute of Policy Studies, Wellington, 2002); and Chris Nixon and John Yeabsley *New Zealand's Trade Policy Odyssey* (New Zealand Institute of Economic Research, Wellington, 2002).

regime or simply buying services off the Australians, since New Zealand would not have the capability of the Australian regulatory regime. Because of its lack of capacity and skills, New Zealand would be a follower in this situation and would have no influence on the Australian regime. Flexibility would be limited although it is of little importance in therapeutics regulation.

An international agreement as represented by vertical integration would not be feasible in this situation, since therapeutics regimes are quite different particularly between the United States and Europe.

While there is no one right solution for public and business confidence the most important issue is certainty. Also important are influence and simplicity since both attributes can assist when demand side influences come in to play. This is because the simplicity of the arrangement means that a deal can be done relatively quickly when trans-Tasman political will is aligned and influence can be useful in mitigating against perceived loss of sovereignty.

17.7 Conclusions

We have considered the example of the ANZTPA as it represents one end of a spectrum of ease of using international cooperation to enhance local regulation. The trans-Tasman relationship is extremely strong. CER – its core – has been in place for many years and steady progress has been made in seeking to add other linkages. These have encompassed different approaches, unilateral recognition, policy coordination, mutual recognition, and joint institutions. Most of these endeavours have been successful.

In the case of the ANZTPA, however, success has been elusive and therefore it is likely to show in sharper relief points that can be learnt from. Thus we have investigated the issues that have caused problems in trying to develop the international therapeutic regulation scheme. It contrasts with the success of other joint trans-Tasman bodies such as FSANZ.

In developing the model displayed here, the most important elements are on the demand side, since it is the demand side that shapes the parameters of possible outcomes in any particular negotiation. Key factors on the demand side are political, economic and administrative feasibility. Also important are the attitudes each negotiating side brings to the table. Australian and New Zealand negotiators usually come to the table with different views and objectives.

On the supply side are the set of options from which negotiators can select. These broad categories of design processes include:

- the development of a horizontal regulatory regime (similar to the proposed ANZTPA model);
- unilateral recognition of some international standards or regulatory regime;
- a simple cooperation model;

- a more in-depth cooperation model but not legally binding approach, for example, such as mutual recognition of the Australian regulatory regime; and
- a vertical integration model where both countries adhere to an international agreement.

While the strength of demand for integration sets the limits of what is possible, it is the interaction between demand and supply side issues that create the integration opportunity. One of the most important issues in the ANZTPA negotiations was that it was not well understood that while New Zealand and Australia had similar regulatory systems they differed enough to add significant complexity to the negotiations and dragged them out over time.

Drawing out the negotiations meant faces changed on each side of the negotiating table, but more importantly, the political attitudes changed on both sides of the Tasman. This meant that the initial aims and objectives became blurred as other issues imposed themselves on the negotiation.

17.7.1 *Specifics*

Key lessons from this process include:

- a joint vision for the negotiations has to be articulated by both governments in an opening communiqué so it is clear to the negotiators what the principles of the proposed agreement will be. This will assist negotiators when the inevitable sticking points arise;
- negotiations need to be seen within the context of previous negotiations. Where negotiations cover deeper integration on new areas the risks of complications increase;
- the risks are likely to have a disproportionate economic and policy impact on the smaller player; Australia has an interest but New Zealand is committed;
- significant resources need to be devoted to the preparation of a full negotiating position prior to any negotiation. This includes not only setting out a preferred negotiating position but also developing alternatives (with their relative values assessed) and seeking specialist help across government. In particular, the role of trade policy specialists is crucial in providing strategic advice;
- there is no right way to go about the integration process and, as the analysis here shows, thinking outside normal government-to-government relations can produce potentially workable solutions;
- the importance of understanding what the other side wants from the negotiation and when. Australia had less to gain from the negotiations than New Zealand, therefore once New Zealand had attracted Australia's attention it needed to endeavour to complete the process while it lasted;

- while we do not believe that taking into account the interplay between supply and demand factors and how they shift over time is an easy process, this role falls necessarily to the small player in international negotiations;
- New Zealand therefore has to make the play on trans-Tasman issues, and has to come up with the innovative ideas that make the integration process work;
- New Zealand is the more sensitive about the impact on its industry and voice and accountability concerns, therefore the political and public consensus process is a vital and integral part of the negotiation process; and
- each case of integration is different and therefore different tools are required to satisfy the various important factors that can make integration durable, for example, simplicity, certainty, flexibility, influence and feasibility.

17.7.2 *Wider notions*

In the context of seeking a better regulatory process and outcomes, the international setting is an obvious asset. But this analysis has shown that, even in the best-developed international partnership New Zealand has, working jointly on enhanced regulation is a demanding task that does not always reach its desired solution.

More positively, looking closely at the case study has suggested that the process of considering an international approach to any particular regulatory issue is likely to be specific to the issue and the times.