

# **Assessment of Regulatory Options for Therapeutic Products**

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**Report to the trans-Tasman working group**

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We also thank the organisations and individuals in the pharmaceutical, complementary healthcare and medical device sectors in New Zealand with whom we consulted in developing this report.

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# EXECUTIVE SUMMARY

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## Purpose

This report assesses the impacts of:

- €# extending the regulation for complementary healthcare products and medical devices in New Zealand; and
- €# establishing a single regulatory regime across New Zealand and Australia for all therapeutic products, including pharmaceuticals<sup>1</sup>.

## Problem definition

In pursuing health and trade objectives, the Government is currently faced with three concerns:

- €# New Zealand's therapeutic products regulatory framework is inconsistent with that of other developed countries and deemed inadequate in managing public health and safety risks from the use of medical devices and complementary healthcare products;
- €# Due to the increasing difficulty and cost of attracting and retaining appropriately skilled staff, New Zealand will find it increasingly difficult to meet its regulatory objectives for pharmaceuticals to appropriate standards and within acceptable time frames; and
- €# Differences in therapeutic product regulation stand in the way of stated policy objectives to remove trans-Tasman trade barriers and integrate the New Zealand and Australian economies under the Trans Tasman Mutual Recognition Arrangement (TTMRA). In relation to the regulation of therapeutic products, the TTMRA has a special exemption that needs to be resolved by 2003.

The first two concerns point to selecting a regulatory arrangement for New Zealand that results in an efficient and sustainable level of risk management in the future, balancing public health and safety and trade benefits<sup>2</sup> with the costs of regulation.

The third concern is about the trade-off between, on the one hand, the benefits from an aligned regulatory scheme in the two countries (the additional contributions to trans-Tasman trade and economic integration and the more efficient use of scarce regulatory resources), and on the other hand the potential cost of a reduced ability to regulate according to the specific conditions and preferences of each nation.

Sales of therapeutic products in New Zealand in the late 1990s are estimated to have been between \$1.5 to \$1.7 billion per annum. The manufacturing base is relatively small in New Zealand, with most therapeutic products (approximately 80-85% by value) being imported, while exports account for about 12% of sales. Both imports from and exports to Australia account for about a quarter of external trade of therapeutic products.

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<sup>1</sup> Pharmaceuticals cover prescription and over-the-counter medicines, including biological products.

<sup>2</sup> Regulatory approval signals that the good or service has met some minimum standard. This reduces search costs for consumers, facilitating informed choice and domestic and external trade. Some regulatory options contribute more to such objectives than others.

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## Feasible options

In principle, harmonisation of prescription and over-the-counter medicine regulation could proceed independently of the decision to extend and/or harmonise regulation of other therapeutic products. However, officials deem this not to be a preferred option because in practice it is difficult to define clear boundaries between the different product groups, and there is some overlap in the technical skill sets required to regulate the different product groups. Therefore, this report considers four options for regulation of therapeutic products:

- €# The Status Quo (the Counterfactual) – Medsafe continues to evaluate pharmaceuticals as at present. There is no pre-market assessment of medical devices, and most complementary healthcare products continue to be regulated as dietary supplements under food legislation. Medsafe would continue to be funded through a mix of Crown funding and cost-recovery from industry. This option is the counterfactual against which others options are assessed.
- €# Enhanced Medsafe – Medsafe evaluates therapeutic products to international standards, funded through full cost recovery from industry. It covers two sub-options:
  - (a) expansion of Medsafe to regulate pharmaceuticals to stated performance targets, consistent with international standards of regulatory practice; and
  - (b) enhancement of the regulatory framework and regulatory capacity to incorporate complementary healthcare products and medical devices.
- €# Unilateral Recognition – a new regulatory framework as in (b) above, but regulatory decisions would be based on recognising product approvals granted by other specified regulatory authorities. Full cost-recovery is assumed.
- €# Joint Therapeutic products Agency (JTA) – a single regulatory regime for therapeutic products marketed in New Zealand and Australia, with regulation administered by a single trans-Tasman agency operating under full cost-recovery.

## Assessment of regulatory impacts

### Framework

A cost-benefit assessment considers the full impacts of proposals on society as a whole, distinguishing in this case between consumers, producers, and the Government (the key funder of therapeutic products and healthcare). It compares the benefits of regulation – such as adverse health outcomes avoided, health benefits from informed choice, and trade benefits – with the costs of regulation. The latter include increased costs and reduced choice, and reduced international price competitiveness.

While some costs, such as regulatory fees and compliance costs, have been quantified, some costs and most benefits could not be quantified – such as the impact of each option on the level of public health and safety risk, or some of the benefits for trade and trans-Tasman relations. This does not mean that the latter are insignificant or do not exist. Instead, careful judgement is needed to balance costs and benefits.

### Pharmaceuticals

Extension of the regulatory regime would not have a significant impact on the pharmaceutical sector. However, the options to administer the regime will have different impacts. We consider the impacts relative to the Status Quo.

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Relative to the Status Quo, Enhanced Medsafe would offer quicker and more thorough pre-market assessment and approval and enhanced post-market surveillance, improving consumer health and safety. But it means a significant increase in regulatory fees. This is due to the greater number of technical staff required to conduct full local evaluation to international standards, and the move to full cost recovery. The cost increase would be passed on in higher prices and/or reduced volumes to consumers of healthcare, and to Government, as the main funder of pharmaceuticals and healthcare.

The option seems unrealistic given the reported international scarcity of therapeutic product regulatory expertise. It is highly unlikely that Medsafe would be able to recruit the required number of staff with appropriate expertise. The result would be that New Zealand would not achieve the desired reduction in delays in approving new or improved products, with subsequent foregone health benefits.

Given the extensive reliance on pharmaceutical imports, Unilateral Recognition may achieve the safety objectives at lower compliance costs than Enhanced Medsafe. It places greater reliance on overseas evaluations, meaning industry would submit fewer data (in New Zealand) for high-risk medicines, with more emphasis on post-market surveillance. But unilateral recognition would not achieve CER-related objectives, and could disadvantage local manufacturers. New Zealand may also find it difficult to get co-operation from other regulators if it has little to offer them in return.

The JTA would achieve safety objectives at lower cost than the other options. This would be due to economies of scale and enhanced potential for mutual recognition or cooperation agreements with other regulators. It would also contribute to trans-Tasman relations and trade (relevant for manufacturers of generics), which could offset some of the regulatory costs to the benefit of consumers and public pharmaceutical budgets. The JTA is likely to reinforce the existing trend for pharmaceutical firms to shift their activities to Australia as they take up the opportunity of having a single application, product approval and regulatory file for both countries.

## **Medical devices**

For medical devices the proposed regulatory arrangements and requirements on firms would be very similar for each of the new options. Given this, the key issue is whether or not to strengthen regulation. This choice depends on the extent to which regulation would reduce the risk – improving public health and safety – and how much society values that risk reduction, plus any trade benefits, compared to the costs of regulation.

Most medical devices used in New Zealand are imported, mainly from the US, Europe, Japan, and Australia, where they are required to meet safety standards for those markets. It is therefore likely that medical devices imported from those countries meet standards that are adequate for New Zealand. But without regulation in New Zealand there can be no guarantee. Likewise, there is nothing to prevent poor quality medical devices from other unregulated markets being sold here. This poses risks to public health and safety. Also, without pre-market registration of devices recalling products or following safety issues that arise locally or internationally is more difficult.

It has not been possible to quantify by how much domestic regulation of medical devices would reduce risks to consumers and the costs to society. In our view, assuming devices continue to be imported from the above countries, additional risk reduction would be relatively small. But there is no guarantee of that trade pattern continuing over time. Pre-market registration would give users and the Government assurance about the safety and quality of the devices sold in New Zealand. A register

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of medical devices would make post-market regulatory activities more cost-effective, and help hospitals and aged care facilities to avoid some of the costs they incur in evaluating the safety and quality of medical devices prior to purchase.

Given the potential economies of scale and the contribution to wider CER objectives, the JTA option is the superior regulatory option for medical devices if a decision is made to extend the regulation. That is because it imposes the lowest compliance costs.

A single regime can also assist New Zealand medical device manufacturers and distributors to export to the Australian market (and beyond). But, given the reliance on imports and the relatively small manufacturing base in New Zealand, the direct trade benefit to New Zealand is likely to be small. Imports from Australia would become more competitive relative to imports from other countries.

### **Complementary healthcare products**

As for medical devices, there are specific examples of harm or potential harm (e.g. from contamination or adulteration with potentially toxic ingredients), poor quality in manufacture (e.g. product is contaminated or does not work because it is poorly formulated) or misleading information (e.g. incorrect or incomplete labelling). But, as for medical devices, a lack of data makes it difficult to assess the level of risk complementary healthcare products pose to consumers, and the extent to which this risk can be mitigated at reasonable cost.

The trade-offs for complementary healthcare products differ from those for medical devices. Local manufacturing and trade with Australia is relatively more important (although other imports are substantial), and often consumers use these products without health professional advice. Given a relatively weak US regime, increased use of novel ingredients with little or no history of use in traditional medicine, and increasing signs of adulteration of complementary healthcare products, public health and safety risks are slowly increasing.

Again, the decision to regulate these products depends on a judgement about whether the uncertain risk reduction and potential benefits for trans-Tasman trade and relations are worth the costs. Our conclusions here are similar to those for medical devices. The immediate benefits from reduced health risks may be relatively small. However, regulation may forestall any future increases in risk from complementary healthcare products, and would increase the cost-effectiveness of post-market surveillance.

If a decision were to be made to extend regulation, the JTA would be more attractive to manufacturers, distributors and consumers than the other options. This is because the compliance requirements for industry would be smaller and there would be some added trans-Tasman trade benefits.

Relative to the Status Quo, the net impact of a JTA on trade for New Zealand may not be substantial, however. Under the JTA, imports from Australia become more competitive relative to other imports, which would now face licence fees. Production costs for some local manufacturers would also rise, which would affect profitability if costs cannot be passed on to domestic consumers.

### **Distribution of impacts**

The distribution of impacts among consumers, industry and Government is summarised in Table 1.

**Table 1: Distribution of the impacts compared to status quo**

Option	Consumers	Industry	Government	Additional compliance cost
<b>Enhanced Medsafe</b>				
<b>Benefits</b>	Meets health objectives through higher standards and better consumer information for complementary healthcare products and devices.	\$3.5m reduction in trans-Tasman import duties if Tariff amended to exclude complementary healthcare products (is an equivalent cost to Government)	Reduced cost of product alerts / recalls for complementary healthcare products and devices. Cost-recovery transfers regulator costs to industry	
<b>Costs</b>	Price increases for all therapeutic products, and reduced choice for medical devices complementary healthcare products.	Higher fees will reduce profitability, with consequences for viability of some firms. Costs passed on to consumers.	Some impact on ACC and Health budgets. Does not contribute to CER-type objectives. Does not resolve sustainability concerns.	\$40.9 million (+/- 20%) 2.5% of industry sales
<b>Unilateral Recognition</b>				
<b>Benefits</b>	As above.	As above.	As above. Reliance on other regulators addresses sustainability concerns.	
<b>Costs</b>	As above, but less so for pharmaceuticals. Precautionary stance may further reduce choice, and overseas regulatory decisions may not always "fit" NZ circumstances.	As above. While pharmaceutical firms will face increased fees, compliance cost would be lower.	As above. Loss of sovereignty due to reliance on other regulators without any influence on their decision-making	\$24.5 million (+/- 20%) 1.5% of industry sales
<b>Joint Agency</b>				
<b>Benefits</b>	As above. Potentially lower pharmaceutical prices.	For importing pharmaceutical companies compliance costs will be lower. Single regime facilitates trans-Tasman trade. Import duties fall if Tariff is amended to exclude complementary healthcare products.	As above. Contributes to CER objectives. Lower pharmaceutical costs may increase Health and ACC buying power. Combining regulatory resources addresses sustainability concerns. Stronger trans-Tasman agency may improve international reputation.	
<b>Costs</b>	Price increases for complementary healthcare products and medical devices, but lower than Unilateral option.	Increased compliance costs and reduced profitability for complementary healthcare products and devices, but less so than above options.	Higher medical device costs will impact on ACC and health budgets, but less so than above options. Foregone tax revenues from duty removal and firms relocating regulatory affairs to Australia.	\$8.3 million (+/- 20%) 0.5% of industry sales

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The incremental compliance costs are midpoint estimates only and do not include the changes in fiscal costs to Government or transition costs. Actual compliance costs for pharmaceuticals and complementary healthcare products would be higher as the above estimates do not include the (potentially substantial) costs of manufacturing licences and audits.

## Conclusions

Given the costs of compliance, whether any change from the Status Quo is seen to be of net benefit to New Zealand or not depends on:

- ≠ a judgement about the additional benefits to public health and safety and the value of better information to consumers; and
- ≠ a judgement about the value to New Zealand of potential additional trade opportunities, and improved trans-Tasman and international relationships.

This trade-off is not that clear for medical devices and complementary healthcare products, where it strongly depends on a judgement of the emerging risk profile, whether added regulation in New Zealand can influence this, and how much society values the risk reduction. No data is available to assess the magnitude of these factors.

Given the degree of uncertainty, the decision on whether the regulatory framework needs to be extended involves a qualitative assessment about how well consumers are equipped to deal with the risks (whatever the scale), the ability to rectify harm and the relevance of the precautionary principle, the perceived bias of producers to understate risks or regulators to over-regulate, how much risk reduction is valued, and different notions of liberty and responsibility.

The personal and social costs of a specific incident can be enormous. We do not have precise data on the magnitude of those costs. ACC payouts for medical misadventures, for example, cover treatment and rehabilitation costs, but do not reflect other costs such as lost productivity or mental anguish. There are some data we could use as *broad* indicators of how much people are willing to pay to avoid serious harm or death. This would help to put the costs of the regulatory options (including the Status Quo) in perspective.

In the transport sector, a survey of people's willingness to pay for road traffic risk reduction implicitly puts the statistical value of life at \$2.55m. From health services research we know that people compare the cost of most serious deteriorations in the quality of life in a similar way as death. Using this statistical value, an additional 4.5 adverse incidents, resulting in premature death or serious harm from sub-standard medical devices or complementary healthcare products, would need to be avoided each year to cover the incremental compliance costs of extending the regulatory regime, assuming the JTA regime.<sup>3</sup> This does not account for any trade benefits.

The JTA would contribute most to CER objectives. Compared to the other options, and given the experience of trade-liberalisation more generally, a single regulatory regime

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<sup>3</sup> In Australia, where people can sue for medical negligence, the average settlement is around \$A500,000. Settlements for the most serious incidents are around \$A1.5-2m. These settlements take into account the legal system's assessment of the full personal cost, ongoing support costs, lost productivity, and legal costs. They do not capture the number of less serious incidents that do not make it to court. It is very difficult to extrapolate from other systems in a relevant manner, but for illustrative purposes, assume that the average social cost of moderate harm from substandard therapeutic products would be \$500,000. If so, then regulation under a JTA regime would need to reduce incidents or their impacts by an additional 20 per year in order to cover the additional compliance costs (not accounting for trade benefits).

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is likely to promote Trans-Tasman trade, particularly in the medium to long term. But the immediate impact will be small given the reliance on imports from elsewhere. A trans-Tasman regulator with international credibility may make it easier for local manufacturers to break into export markets.

Added compliance costs for manufacturers of medical devices and complementary healthcare products would raise costs, which can affect profitability if they cannot pass the costs on to consumers. For most pharmaceutical firms, compliance costs may decrease, because of the opportunity to submit only one data package, obtain and pay fees for a single product licence, and maintain only one regulatory file in order to market a product in both countries.

The JTA would establish a set of precedents for any future development of joint agencies in the context of CER. The successful establishment and operation of this agency could have a significant influence on the attitudes of both the New Zealand and Australian governments towards options for the extension of CER in the future.

Overall, the conclusion is that relative to the three other regimes considered here, a move to a JTA has the potential to yield a small net benefit to government, industry, consumers and other stakeholders in both countries.

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# 1. INTRODUCTION

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## 1.1 Purpose

This report provides an economic evaluation of the proposal for a joint therapeutic products agency (JTA) to harmonise therapeutic products regulation for Australia and New Zealand, compared to the main alternative regulatory options being considered for pharmaceuticals, medical devices and complementary healthcare products.

Therapeutic products regulation has been temporarily exempted from the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The options being considered to resolve the special exemption include harmonisation of product and manufacturing standards and conformance assessment requirements, and permanent exemption.

New Zealand has also been considering bolstering therapeutic products regulation to capture medical devices<sup>1</sup> and therapeutic-type dietary supplements<sup>2</sup>, separately from consideration of the joint agency. Officials regard bolstered regulation as a precondition to harmonisation, given the complex interfaces between product groups.

## 1.2 Current regulatory regime

A detailed discussion of the current regulatory arrangements for therapeutic products in Australia and New Zealand is provided in our previous report (October 2000), and the Discussion Paper on the Joint Therapeutic Products Agency produced by the trans-Tasman working group (June 2002).

The Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand undertake broadly the same activities in relation to medicines with the aim of managing health and safety risks from their use through:

- €# Pre-market evaluation and approval of products intended for supply in Australia or New Zealand;
- €# Licensing of manufacturers;
- €# Post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries;
- €# Setting and monitoring standards.

Both agencies also undertake other divergent activities, which are outside the scope of this report.

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<sup>1</sup> These include a very wide range of products from rubber gloves, syringes and diagnostic kits, to prostheses and implants such as pacemakers.

<sup>2</sup> These include herbal medicines, vitamins, minerals, nutritional supplements, aromatherapy oils and certain homoeopathic medicines. These products are referred to in Australian legislation as “complementary medicines”. For convenience, the term “complementary healthcare product” is used in this report.

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### 1.2.1 The Australian regime

The *Therapeutic Goods Act 1989* (the TG Act) and its associated Regulations cover medicines (including prescription, over-the-counter and complementary medicines), and medical devices. This legislation is administered by the TGA.

This report anticipates the implementation of new legislation from October 2002 to regulate medical devices in accordance with Global Harmonisation Task Force (GHTF) recommendations, which encourage convergence of medical devices regulation.

The TGA has a staffing complement of around 350-390 persons. It has an annual budget of \$A50 million and operates on full cost recovery, collecting fees from industry primarily through annual charges, evaluation fees and licence charges.

### 1.2.2 New Zealand

In New Zealand, different arrangements exist for pharmaceuticals, medical devices and complementary healthcare products.

*Medicines* are regulated by the Medicines Act 1981 and the Misuse of Drugs Act 1975. Medsafe is responsible for administering these statutes and regulations made under them. The Medicines Act 1981 regulates prescription and over-the-counter medicines and some herbal and homoeopathic medicines and prohibits the distribution of products for a therapeutic purpose without the consent of the Minister of Health.

*Medical devices* in New Zealand are currently not subject to pre-market regulation, with some exceptions, and Medsafe's role is restricted to post-market monitoring.

Most *complementary healthcare products* are currently regulated as dietary supplements under regulations under the Food Act 1981 (the Dietary Supplements Regulations 1985). The Regulations state the maximum daily doses for some nutrients, list food additive permissions and labelling requirements. It is the manufacturer's/importer's responsibility to ensure products are safe and comply with the legal requirements (i.e. no approval is required).<sup>3</sup> The regulations do not permit therapeutic claims to be made for dietary supplements. This legal requirement is only lightly enforced and many dietary supplements are marketed with illegal therapeutic claims.

Dietary supplement manufacturing premises must be registered under the Food Hygiene Regulations 1974 or have an Ministry of Health approved Food Safety Programme (FSP) under section 8F of the Food Act 1981.

The principles embodied in FSPs are similar to the principles of Good Manufacturing Practice proposed for therapeutic products. FSPs are currently voluntary but are likely to be phased in as a mandatory requirement for food producers over the medium term. This means that manufacturers currently do (or will) face compliance costs. While there are similarities, FSPs and GMPs address different risks. FSP is focused on hygiene while GMP is focused on each batch of a product consistently meeting quality standards on purity, potency and identity.

Therapeutic claims are also covered by the Fair Trading Act (FTA), which prohibits misleading advertising, including an absence of supporting evidence. The Commerce Commission, in its role of enforcing the FTA, has sought to police therapeutic claims made by dietary supplement suppliers in the past, including scrutinising any research

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<sup>3</sup> Ministry of Health website refers, [www.moh.govt.nz](http://www.moh.govt.nz).

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behind claims. However, the Commission does not have the necessary technical capacity to interpret the available medical evidence and determine whether claims are justified.

Medsafe employs 52 staff and has a budget of \$6.7 million.<sup>4</sup> Currently, 51% of Medsafe's budget is funded from evaluation fees and other third party revenue, and the remaining 49% from Crown funding. Some of the agency's corporate functions are provided by the Ministry of Health.

## 1.3 Context

There are a number of important drivers that are impacting on the efficiency and effectiveness of the current New Zealand regulatory regime, and the costs and benefits of alternative regulatory options. Below we briefly summarise key trends and issues relevant to this analysis.

### 1.3.1 Technological developments

Emerging technologies and scientific advancements are enabling the development of increasingly sophisticated and specialised products. As a result, the technology and expertise required to evaluate such products is becoming increasingly sophisticated and specialised. Such expertise is scarce globally, particularly for those products at the cutting edge of science and technology, and Medsafe reports that already New Zealand is finding it difficult to access domestically the expertise needed to evaluate some biological products.

### 1.3.2 Globalisation

Globalisation, or the increasing integration of the global economy, has implications for the regulatory arrangements. Information, finance and technology are becoming increasingly accessible to consumers and firms around the globe. Some of the consequences are:

- leakage of products from countries with different standards;
- global rationalisation of firms, particularly in industries facing high sunk costs in bringing product to market, such as pharmaceutical companies; and
- increased pressures to harmonise regulation to reduce trade-barriers and improve cost-effectiveness of regulation.

### 1.3.3 Closer Economic Relations (CER)

The proposal to establish a joint therapeutic products agency arose in the context of wider economic integration between Australia and New Zealand through CER.

CER originally covered the elimination of tariffs on trade in goods between Australia and New Zealand. It was subsequently extended to services in 1988, via the Protocol on Trade in Services to the ANZCERTA.

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<sup>4</sup> Unless otherwise specified, financial amounts in this report refer to New Zealand dollars.

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In the CER context, the focus of both governments is now on so-called ‘third generation’ matters. This refers to ‘within border’ barriers to trade, including taxation issues, business law, and various regulations. The Trans-Tasman Mutual Recognition Arrangement (TTMRA) has now been in force for several years, and encompasses the mutual recognition of goods for sale and registration of occupations.

The Joint Foods Standards Treaty (1995) is one example. The establishment of a joint foods standard system and the Australia New Zealand Food Authority involved New Zealand joining an already existing Australian system regulated at the state level. It involves New Zealand working with the governments of the eight states and territories as well as the Commonwealth Government.

The proposed Joint Therapeutic Agency offers an opportunity to develop a new type of trans-Tasman organisation that would be governed by two jurisdictions – the Australian Commonwealth and the New Zealand Governments. This is facilitated by therapeutics being regulated in Australia at the Commonwealth level. It would be an innovative step for CER in a number of ways, including its governance arrangements and in the relationship between the two national governments and parliaments.

The decision on whether or not to harmonise therapeutic products regulation is therefore regarded as a test case for the future evolution of some important aspects of CER. The successful establishment and operation of the proposed JTA as a vehicle for harmonisation could impact on the attitudes of both governments toward extending CER in the future.

#### **1.3.4 Features of the public health care and accident insurance system**

Other health sector features impact on the costs and benefits of the different regulatory options. While these impacts are taken into account, this report takes the features as given.

##### ***a) Government funding arrangements for pharmaceuticals***

As in the rest of the OECD, both Australia and New Zealand Governments subsidise pharmaceuticals to ensure people have access to appropriate health care regardless of individual ability to pay. Regulatory decisions concerning the safety of therapeutic products are independent of decisions to subsidise any or all of the therapeutic products. For this reason, pharmaceutical funding arrangements – currently operated by PHARMAC in New Zealand and the Pharmaceutical Benefit Scheme in Australia – are outside the scope of this report.

Some pharmaceutical firms are concerned that regulatory options under consideration, particularly the joint regime, will promote parallel importing. Firms argue they may then decide they would be better off if they did not market products in one market (i.e. New Zealand, to the cost of consumers) to protect profits in the other (i.e. Australia). None of the schemes considered will seek to facilitate parallel importing.

##### ***b) Professional practice and regulation***

The nature and effectiveness of professional (statutory or self) regulation is an important part of the wider consumer safety framework. While consumers may decide independently on the use of therapeutic products, in a number of cases they rely on the

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advice of health professionals such as doctors, pharmacists, and specialists such as herbalists and naturopaths, and in other cases access to products is controlled or determined by providers (e.g. consumption of most medical devices is mainly controlled by providers, and specialist herbal medicines are made available only under guidance of a herbalist). This affects the risk that consumers are exposed to, and so the added benefits of therapeutic products regulation.

### **c) The public health care and accident compensation system**

Public healthcare funding and accident compensation scheme insure New Zealand consumers against accident and injury, and reduce the possibility of litigation arising from adverse events. While this has clear benefits for current and potential patients, and reduces transaction costs through avoiding litigation, it suffers the same drawback as other insurance, namely “moral hazard” – where persons do not suffer the costs of their actions so that their incentives to minimise those costs are reduced. The effect of this in relation to therapeutic products is:

- €# suppliers have less incentive to ensure products are safe, as they are less likely to face the cost and reputational damage of court action if something goes wrong; and
- €# consumers have less incentive to ensure the safety of products, as any harm they suffer as a result is likely to be covered by ACC (although this does not eliminate the costs – including personal trauma – that may arise, it does reduce those costs).

## **1.4 Previous report**

The report builds on an earlier NZIER/ Applied Economics report *Regulatory impact analysis: A joint Australia and New Zealand therapeutics goods agency*, and subsequent policy work in the two countries.

The key conclusions from our previous report on the regulatory impacts were that, relative to alternative regimes, a move to a JTA has the potential to yield a small net benefit to government, industry, consumers and other stakeholders in both countries. The more important support for the proposal came from its potential contribution to: the collective regulatory capacity of the two countries in the medium and longer term; bilateral trade relations; and the development of the Australian therapeutics industry from shoring up the regional standing of the regulatory arrangements. The findings of our initial report are summarised in Table 2.

**Table 2: Impact of JTA – previous findings**

	<b>Costs</b>	<b>Benefits</b>
New Zealand	<ul style="list-style-type: none"> <li>€# New regime means additional costs to meet regulatory requirements for medical devices and complementary healthcare products.</li> <li>€# Cost recovery shifts costs to producers and consumers, and may lead to rationalisation of product lines.</li> <li>€# Cost of transition to JTA estimated at \$A10m over 3 years, shared with Australia.</li> <li>€# Unilateral recognition regime would risk losing regulatory co-operation from Australia.</li> </ul>	<ul style="list-style-type: none"> <li>€# Enhanced regulatory capacity, and faster approval times, resulting in:               <ul style="list-style-type: none"> <li>€# Higher safety/quality standards.</li> <li>€# Additional trade opportunities, consistent with CER objectives.</li> </ul> </li> </ul>
Australia	<ul style="list-style-type: none"> <li>€# New requirements on medical devices and complementary healthcare products in NZ would impact on some Australian exporters.</li> <li>€# Transitional costs of \$A10m over 3 years shared with NZ.</li> </ul>	<ul style="list-style-type: none"> <li>€# Some economies of scale may lead to lower fees.</li> <li>€# Some additional trade benefits from lowering regulatory barriers (85% of medicine approvals are shared).</li> <li>€# Enhanced regulatory capacity and international standing</li> </ul>

## 1.5 Caveats

The relative merits of options depend on precisely how they are implemented. The detail continues to evolve, and therefore the regulatory impacts of these options, including compliance costs on business, are estimates based on our understanding of the options as at June 2002.

In some areas reliable data are not available – particularly in relation to complementary healthcare products and medical devices. The industry data contained in this report are constructed from a range of official sources and industry, and should be viewed as indicative only.

Some costs and most benefits could not be quantified. This does not mean they are insignificant – instead, drawing conclusions requires careful balancing of qualitative and quantitative information.

Given the range of products and firms within the sectors covered by this proposal, we cannot assume that the general assessments contained in this report will apply equally to all products and all parts of these sectors.

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## 2. ANALYTICAL FRAMEWORK

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### 2.1 Methodology

In deciding whether or not to proceed with:

- €# extending the scope of therapeutic products regulation to cover medical devices and complementary healthcare products, and
- €# a joint therapeutics agency,

policy-makers need to assure themselves that:

- €# the proposals are the best available alternative to meet the stated objectives; and
- €# the proposals deliver net benefits to society, i.e. improve on the status quo.

To meet the information requirements for a Regulatory Impact Statement, we use the Cost Benefit Analysis framework. We assign values where possible, and other impacts are considered by way of a systematic qualitative review of the impact of each option on the Government's policy objectives. This provides a cost-benefit assessment to assist policy-makers to select the proposal that would yield the greatest net benefit to society.

#### 2.1.1 Distributional effects

Another consideration is who bears the benefits and costs of the different options.

There are three broad groups that are affected by changes to the regulatory framework for therapeutic products:

- €# consumers;
- €# industry (manufacturers and distributors of pharmaceuticals, medical devices and complementary healthcare products sectors); and
- €# government (as agent for the wider community and taxpayers).

The table below summarises where the potential costs and benefits fall.

**Table 3 The incidence of regulatory costs and benefits**

Perspective	Benefits	Costs
Consumers	Health benefits from safer products and more informed choice	Higher prices and reduced choice (product differentiation)
Industry	Recognised regulatory seal of approval may facilitate domestic and export trade	Additional production and compliance entry standards shield incumbents from competition Business compliance costs reduce profitability or raise prices (see above)
Government and wider community	Reduced costs of restorative care (as main funder of health care)  In relation to JTA, potential wider benefits for economic and political relations	Fiscal costs of higher prices, and administering the regulation

### 2.1.2 Market failure vs. regulatory failure

In a range of circumstances, markets will fail to deliver the best possible outcome for society. Government can intervene to improve overall outcomes, using tools such as regulation. However, regulation can also fail, and inadvertently lead to worse outcomes than without any intervention.

If the regulatory test is 'that the product is safe', there are two types of regulatory failure:

⌘ Type 1 errors: products are rejected even though they are safe; and

⌘ Type 2 errors: products are approved even though the risks outweigh the benefits.

A key issue is whether it is better to err on the side of over- or under-inclusiveness in the face of uncertainty. There are different reasons why policy-makers may wish to err on either side of caution, including their perception of consumers' ability to deal with the risks, ability to rectify harm (and the relevance of the precautionary principle<sup>5</sup>), the perceived bias of producers to understate risks or regulators to over-regulate, and different notions of liberty.<sup>6</sup> As inevitably there is uncertainty about the underlying risk profile, this qualitative assessment will be central to the choice between options.

<sup>5</sup> A precautionary stance may be adopted where avoidance of or attainment of certain objectives takes absolute priority over other considerations. A prerequisite for this type of treatment is irreversibility, i.e. once a policy is implemented, and its results have occurred, it is not possible for the policy to be reversed and the situation to return to its original state.

<sup>6</sup> Baldwin R & M Cave (1999). *Understanding Regulation. Theory, Strategy and Practice*. Oxford University Press: Oxford

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## 2.2 Business compliance costs

Business compliance costs need to be considered as part of the regulatory impact statement. We use a relatively broad definition of the term “compliance costs” to include all costs to affected parties of the regulatory regime. This includes the costs to affected parties of:

- €# Understanding their obligations;
- €# Processing and providing information to the regulatory agency;
- €# Any regulatory fees incurred;
- €# Training requirements; and
- €# Costs associated with any delays in time to market, or changes to production processes required by the agency/regulatory regime.

Compliance costs include direct financial costs, costs of management and staff time and intangible costs. Quantitative estimates of compliance costs in this report include regulatory fees, the cost of management and staff time spent on compliance activities, and an estimate of lost profits from delays to market as a result of regulation.

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## 3. PROBLEM DEFINITION

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The regulatory options being assessed in this report relate to three issues:

- €# concerns that the New Zealand regulatory regime is inconsistent with that of other developed countries and inadequate in the management of health and safety risks from the use of medical devices and complementary healthcare products;
- €# a concern that, due to the increasing difficulty and cost of attracting and retaining appropriately skilled staff, New Zealand will find it increasingly difficult to meet its regulatory objectives for pharmaceuticals to appropriate standards and within acceptable time frames; and
- €# differences in therapeutic product regulation stand in the way of stated policy objectives to remove trans-Tasman trade barriers and integrate the New Zealand and Australian economies under the Trans Tasman Mutual Recognition Arrangement (TTMRA). In relation to the regulation of therapeutic products, the TTMRA has a special exemption that needs to be resolved by 2003.

The first two concerns point to selecting a regulatory arrangement for New Zealand that results in an efficient and sustainable level of risk management in the future, balancing public health and safety and trade benefits<sup>7</sup> with the costs of regulation.

The third concern is about the trade-off between, on the one hand, the benefits from an aligned regulatory regime in the two countries (the additional contributions to trans-Tasman trade and economic integration and the more efficient use of scarce regulatory resources), and on the other hand the potential cost of a reduced ability to regulate according to the specific conditions and preferences of each nation.

### 3.1 Risk

The nature and magnitude of risk varies widely across the range of therapeutic products. Many therapeutic products have few risks for users, whereas others can have severe even fatal adverse effects if improperly used or defective.

People face and deal with risks<sup>8</sup> in all their daily activities. Often individuals are best placed to manage the risks that affect them, as each individual places a different value on the costs, risks and benefits of their actions. However, this may not be the case in the presence of:

- €# *Incomplete information* – where consumers may not have easy access to sufficient information to verify claimed therapeutic benefits, or the nature and magnitude of risks.
- €# *Externalities* - where the actions of individuals affect others (e.g. if improper use of a substance imposes costs on other individuals and the wider community). If these effects are not taken into account then decisions made by individuals may not be in the overall interest of society

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<sup>7</sup> Approval by a regulator signals to prospective consumers that the good or service has met some minimum standard, which may assist trade and informed choice. Some regulatory options contribute more to such objectives than others.

<sup>8</sup> Risk is the probability of an event occurring multiplied by the impact of the event.

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€# *Moral hazard* – where because of publicly funded health care and the ACC system, persons do not suffer the full costs of their actions so that incentives to manage those costs are reduced.

The question is not about whether all risks should be completely eliminated, but what level of risk individuals are willing to accept in return for the benefits offered by the goods they consume or activities they undertake, and whether they are able to make those trade-offs themselves.

Efficient risk management means that the response is proportionate to the magnitude of that risk, as distinct from risk minimisation. If hurdles are set too high, the social outcome may be worse than if there was no intervention.

### **a) Pharmaceuticals**

Medicines used appropriately can have real health benefits. However, inappropriate use of some pharmaceuticals can be dangerous and even fatal. For this reason, pharmaceuticals are subject to pre- and post-market regulation around the world. In common with other regulators and consistent with WHO recommendations, Medsafe uses a number of tools to manage risks from pharmaceuticals, including:

- €# pre-market approvals
- €# licensing of manufacturers
- €# scheduling to regulate through whom certain pharmaceutical products can be accessed
- €# post-market activity through monitoring adverse reactions, testing product quality, and recalling products.

Other than regulatory capacity, we are not aware of any substantial issues or problems with the current regulatory framework for pharmaceuticals, and there are no proposals to substantially change it. The treatment of pharmaceuticals under a harmonised environment would be similar to the status quo.

### **b) Complementary healthcare products**

There is no comprehensive data on illness, disabilities or death in New Zealand that could be attributed to complementary healthcare products. But this does not mean that there are no risks or issues.

Most, but not all, complementary healthcare products are low risk products, relative to other types of therapeutic good. Some complementary healthcare products available in New Zealand have health risks (such as products that may trigger allergic reactions in some individuals, or cause organ damage if too much is taken or wrongly used). Internationally, there have been instances of death or severe harm, including liver or kidney damage.<sup>9</sup> But ingredients are not the only source of risk.

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<sup>9</sup> See, for example, [http://www.senate.gov/~gov\\_affairs/ogm.htm](http://www.senate.gov/~gov_affairs/ogm.htm), U. S. Food and Drug Administration warnings and safety information at <http://www.cfsan.fda.gov>, U. S. Food and Drug Administration (1993) *Illnesses and Injuries Associated With the Use of Selected Dietary Supplements*, at <http://vm.cfsan.fda.gov/~dms/ds-ill.html>

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Risk may arise from:

- ⌘ lack of efficacy for the claimed indication (especially for serious diseases);
- ⌘ false or misleading claims;
- ⌘ interactions with prescribed or OTC medicines;
- ⌘ lack of, or inappropriate, consumer information;
- ⌘ the manufacturing process (poor hygiene, inaccurate labelling, batch-switching, and incorrect dosage);
- ⌘ innovative high potency products for which there is little or no history of use in traditional medicine;
- ⌘ adulterated products<sup>10</sup>; and
- ⌘ the lack of a standard nomenclature for many ingredients, which may lead to consumers over-dosing on an ingredient that is referred to by different names.

Internationally, reliance on complementary healthcare products is high, and appears to be increasing.<sup>11</sup> This trend is reflected in New Zealand; over half of New Zealand's population uses complementary healthcare products.<sup>12</sup> Increasing use of these products, combined with increasing potency of active ingredients and instances of adulterated products, increases the potential for adverse reactions to occur. In light of these factors, the World Health Organization (WHO) is encouraging members to establish national regulation and registration of herbal medicines, to ensure authenticity, safety and efficacy.<sup>13</sup>

While there are many specific examples of harm or potential harm (stemming, for example, from ingredients, formulation, or use by consumer), safe and good quality complementary healthcare products can increase health and wellbeing. Depending on the design, regulation could reduce access to those products. This cost would need to be traded-off against the potential benefits of reducing the risk from complementary healthcare products. We have, however, not found conclusive data that would help identify the extent of risk or quantify by how much regulation would reduce the risks to consumers.

### **c) Medical devices**

Medical devices include a wide range of products from very low risk (e.g. walking aids, non-sterile examination gloves) through medium risk (e.g. products required to be sterile), to high-risk products, which, if faulty, could lead to severe harm or death (e.g. heart valves). For example, in the three years to 1997/98, nine deaths and 55 serious injuries in the United Kingdom were directly related to failures of medical devices, or their misuse.<sup>14</sup>

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<sup>10</sup> For example, the FDA recently issued a warning to consumers to cease using two products sold as herbal supplements in the United States, as they contain prescription drugs. (Reuters, 9/2/02 *FDA Issues Warning on 2 Herbal Products*). Also, the Senate website [http://www.senate.gov/~gov\\_affairs/ogm.htm](http://www.senate.gov/~gov_affairs/ogm.htm) contains expert submissions about the risks associated with some complementary healthcare products and the differences between vitamins and minerals, potent herbal products that act like drugs, animal derivatives, and steroid precursors, currently all marketed as dietary supplements.

<sup>11</sup> See for example WHO (2002) *WHO Traditional Medicine Strategy 2002-2005*, section 1.2.

<sup>12</sup> Ministry of Health (1999), *NZ Food: NZ People - Key results of the 1997 National Nutrition Survey*, page 79.

<sup>13</sup> *WHO Policy Perspectives on Medicines*, No. 2 May 2002.

<sup>14</sup> United Kingdom Select Committee on Public Accounts, Twentieth Report, *NHS Executive: The Management of Medical Equipment in NHS Acute Trusts in England*.

In New Zealand, there is no requirement for medical devices to be approved before being marketed. This contrasts with most other countries. Medsafe deals with safety issues as they emerge. Because there is no register of devices, recalling or withdrawing devices, and/or the co-ordination of remedial action is a difficult and costly exercise.

Somewhere between 65% (official statistics) and 95% (industry sources) of medical devices used in New Zealand are imported, mainly from the US, Europe, Japan, and Australia. It is therefore likely that most internationally marketed medical devices already meet safety standards that are adequate for New Zealand, particularly as world standards converge around the Global Harmonisation Task Force requirements.

Hospitals and other medical institutions, as the largest consumers of medical devices in New Zealand, have incentives to seek evidence that relevant standards elsewhere have been met before purchasing high-risk devices. At least half of the District Health Boards have processes to check safety and effectiveness of medical devices, although smaller rural and some private hospitals may not have such systems.

This suggests that key safety risks are managed to an extent. But these institutions may not have sufficient information on the adequacy of some codes of practice or standards. A national register may be a more cost-effective way of assuring the safety of medical devices marketed in New Zealand. There is also a concern that, without regulation in New Zealand, poor quality product that does not meet international standards and cannot now be sold overseas will be brought into New Zealand, with subsequent implications for public health and safety.

There are no data on the extent of that problem, or more generally the availability of devices with higher risk than New Zealanders would be willing to accept. The only readily available indicator, other than anecdote, is the numbers of alerts to Medsafe concerning potentially faulty medical devices (see Table 4). Within the context of industry sales of over \$600 million per annum and approximately 40,000 different medical devices available in New Zealand, the incidence seems low, although it does not tell anything about the extent of the potential harm.

The Ministry of Health considers that, consistent with international practice, the costs of current and emerging risks are likely to be significant enough to warrant a risk-based regulatory regime for medical devices.

**Table 4: Medical Device alerts and product recalls / withdrawals**

Year	Alerts	Recalls and product withdrawals
1991	167	16
1992	208	22
1993	151	17
1994	157	26
1995	171	46
1996	189	36
1997	242	39
1998	226	51
1999	286	45
2000	352	52
2001	334	71

Source: Ministry of Health

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## 3.2 Efficient use of scarce regulatory resources

Adequate regulatory capacity is clearly an important prerequisite for an effective pre-market licensing regime for therapeutic products. A lack of capacity leads to poor regulatory decisions, delays to market, loss of reputation. This can have adverse effects on public health outcomes and trade.

Expansion of the range and complexity of therapeutic products means that regulators in New Zealand and Australia need to be able to access a wider and more specialised range of assessors. This expertise is in short supply globally as evidenced by reports of hard-to-fill vacancies at large therapeutic products regulators around the world.

Without further analysis of the extent to which the global labour supply of assessors will respond to this excess demand, New Zealand will find it increasingly costly and difficult to build and maintain that expertise in-house or even to commission it domestically and internationally.

Medsafe has a performance target of completing the initial evaluation of 80% of applications to market new prescription medicines (other than generics) in 440 days. This is being achieved, but is being assisted by the use of evaluation reports from Australia. However, the international trend is towards achieving approvals within six months of application.

Combining resources might enable the regulators to maintain sufficient capability by reallocating some of the resources engaged in duplicate regulatory and management activities, and capturing other economies of scale. In addition, the improved international standing that a joint regulator is expected to enjoy would increase the potential to develop mutual recognition agreements with other regulators which would help to alleviate the capacity constraint.

Alternatively, the capacity constraint would need to be addressed by increasing the resources allocated to the regulatory function (by raising industry fees or government funding), or by relaxing approval times, or by accepting greater risks (e.g. by only fully assessing the products with the highest risks, and have lower level requirements on other products). This is part of the choice between the options being considered.

## 3.3 Resolving the special exemption on TTMRA

A special exemption from the TTMRA is currently in force for therapeutic goods. Some government action is needed to address the status of therapeutic goods under the TTMRA before the special exemption expires in 2003.

The options to resolve the special exemption on the TTMRA involve a choice between the potential benefits from trade, reduced compliance costs, and more efficient use of scarce regulatory resources against a perceived reduction in the ability to regulate according to the specific conditions and preferences of each nation. The premise of CER is that similarities are more important, even though there are instances now where some pharmaceutical products are permitted on the market in only one of the two countries. The options under consideration for resolving the special exemption are harmonisation or a permanent exemption from the TTMRA. While mutual recognition

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is theoretically an option, Australian and New Zealand Health Ministers have ruled it out, given the significant differences in the two current regulatory regimes.<sup>15</sup>

Aligning regulation between New Zealand and Australia would bring advantages from:

- €# Greater specialisation and division of labour;
- €# Scale economies and dynamic efficiencies; and
- €# Administrative efficiencies in the proposed new regulatory regime.

Trans-Tasman harmonisation of therapeutic product regulation could offer gains from trade of the kind well documented for tariff and product standards reform in international trade policy, and which provide the basic rationale for CER.

Harmonisation of therapeutic product regulation (or some other solution with a similar effect, such as introducing a single regulatory regime, or a commitment to co-ordination) may contribute more widely to strengthening and improving trans-Tasman relationships, such as envisaged in the recent *Inquiry into New Zealand's Economic and Trade relationship with Australia*.<sup>16</sup>

### **a) Pharmaceuticals**

Currently there is considerable duplication in the regulation of pharmaceuticals between New Zealand and Australia. Under the current arrangements pharmaceutical companies marketing products in both Australia and New Zealand must:

- €# Maintain staff that are proficient in the regulatory requirements of both Australia and New Zealand;
- €# Seek regulatory approval for their products in both countries, resulting in duplication of the associated compliance costs; and
- €# Develop different packaging, labelling and advertising for the two different markets. Differences in scheduling requirements can lead to different notices being required on product labels, which increases not only printing costs, but also the costs of packaging, as additional checks are needed to ensure correct labelling.

While most pharmaceuticals in New Zealand are imported, harmonisation would benefit local manufacturers who export to Australia, importers from Australia, and local distributors and consumers.

### **b) Complementary healthcare products**

There is little pre-market regulation for complementary healthcare products in New Zealand. This means that there are almost no regulatory barriers to trade from Australia to New Zealand.<sup>17</sup> New Zealand firms must meet Australia's regulatory

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<sup>15</sup> 1999 Therapeutic Goods Co-operation Program Report to the Council of Australian Governments including New Zealand.

<sup>16</sup> Report of the Foreign Affairs, Defence and Trade Committee. 2002

<sup>17</sup> The only such barrier is the prohibition on therapeutic claims for dietary supplements. Complementary healthcare products that have been approved for supply in Australia are permitted to make such claims, so legally such medicines would need different labelling for supply in New Zealand. However, the level of enforcement of the New Zealand prohibition is light, so the actual impact of this restriction is likely to be relatively minor.

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requirements in order to export to Australia. This raises the costs for New Zealand firms wanting to export to Australia.

Several of New Zealand's larger dietary supplement manufacturers have already upgraded their plant to meet Australian GMP standards (or are in the process of doing so) and market products in Australia. As there are no regulatory costs for market entry in New Zealand, there is currently no issue of cost duplication.

The absence of domestic regulatory compliance costs makes New Zealand exports price competitive relative to competing exporters with a regulatory regime. However, it makes it more difficult for exporters to obtain the export certification increasingly being required by importing countries.

Pre-market regulation of complementary healthcare products would impose new compliance costs. In the absence of regulatory co-ordination across the Tasman, regulatory costs would be duplicated for products traded across the Tasman.

### ***c) Medical devices***

There is no pre-market regulation for medical devices, so that there are no regulatory barriers to import from Australia. New Zealand firms must meet Australia's regulatory requirements to export to Australia. This raises the costs for New Zealand firms wanting to export to Australia. The absence of domestic regulatory compliance costs makes New Zealand exports cost competitive relative to competing exporters based in countries with regulatory regimes. This is so because all face the same regulatory requirements and fees in the destination country.

As for complementary healthcare products, pre-market regulation of medical devices would impose new compliance costs, which would be duplicated for products traded across the Tasman, without some form of regulatory co-ordination.

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## 4. OBJECTIVES

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We assume that the overarching objective of both the Australian and New Zealand governments is to maximise their respective nations' welfare. In relation to therapeutic products it can do so by:

- ≠ managing risks to health and safety from the use of therapeutic products; and
- ≠ minimising barriers to trade in therapeutic products created by differences in domestic regulation.

### 4.1 Health objectives

The primary policy objective of therapeutic products regulation is to manage risks to public health and safety over time by ensuring that therapeutic products meet appropriate standards of safety, quality and efficacy.

This is the core objective of TGA and Medsafe, and would be the primary objective of a JTA for therapeutic products. Closely related objectives are to:

- ≠ provide timely and effective evaluation of therapeutic products over the long term, by ensuring a sustainable regulatory capacity for therapeutic products in Australia and New Zealand;
- ≠ ensure public and health professional confidence in the regulator and regulatory scheme;
- ≠ have the capacity to influence regional and global standards and conformance assessment of therapeutic products. This will assist in shaping regional and global standards that are appropriate for the local populations and health systems.
- ≠ have the confidence of key overseas regulators to facilitate sharing of regulatory information, technical assessments and mutual recognition. This would assist in reducing duplication of product assessments and lowering compliance costs.

### 4.2 Wider social and economic objectives

Officials have also articulated the following additional objectives relating to trade and industry development to:

- ≠ facilitate trans-Tasman trade in therapeutic products;
- ≠ facilitate exports of therapeutic products beyond Australia and New Zealand;
- ≠ provide an environment that supports the ongoing development of the therapeutic products sector and investment in the therapeutic products industries in Australia and New Zealand, including research and development;
- ≠ enhance Closer Economic Relations between Australia and New Zealand.

## 5. REGULATORY OPTIONS

### 5.1 Options for New Zealand

Figure 1 shows the options we were asked to consider, in the context of the range of theoretically possible options. The blank cells represent other possible options. But policy makers do not consider these to be feasible, as they would not provide a consistent approach to all products claiming a therapeutic purpose.

Table 5 below summarises the regulatory arrangements under each option. The new options could be funded in different ways, but in this paper we assume full cost recovery through a range of fees including application and audit fees and annual charges on industry.

**Figure 1: Summary of options for New Zealand**

Administrative Option →	Status Quo*	Enhanced Medsafe	Unilateral Recognition	Joint Agency
Pre-market regulation of: ↓				
Pharmaceuticals only	Option 1	Option 2a		
Pharmaceuticals & Complementary healthcare products	Not applicable			
Pharmaceuticals & Devices				
Pharmaceuticals, Complementary healthcare products & Devices		Option 2b	Option 3	Option 4

\* Status quo = Medsafe with pre-market assessment of pharmaceuticals only.

#### 5.1.1 Option 1: Status Quo (The Counterfactual)

Medsafe would continue as a small agency with about 52 staff and a budget of \$6.7 million, of which 43% would be Crown funded.<sup>18</sup> Some corporate functions would continue to be provided by the Ministry of Health. Medsafe would have responsibility for assessing and approving pharmaceuticals for supply in New Zealand, and carrying out post-market activities. It would continue to rely on TGA and EC regulators' reports where feasible.

There would be no additional regulation of medical devices. At the time of writing consultation is underway on a proposal to amend to the Medicines Regulations to require suppliers to register medical devices marketed in New Zealand. The register would be used to facilitate post-market surveillance, but Medsafe would not check the conformity assessment of the devices to ensure they met performance and safety standards. This step would require new legislation, which would be introduced following the Government's decision on which of the options (Joint Agency, Enhanced Medsafe or Unilateral Recognition) it will follow.

Dietary supplements – a subset of complementary health care products – would be regulated in essentially the same way as under the current Dietary Supplement Regulations (even though the current regulatory framework for dietary supplements

<sup>18</sup> Based on 2000/01 figures.

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would be replaced).<sup>19</sup> Thus we assume complementary healthcare products would not be subject to pre-market regulation unless they made therapeutic claims, in which case they would face the same registration process as pharmaceuticals.

### **5.1.2 Option 2: Enhanced Medsafe**

This option covers two sub-options.

- ≠ Expansion of Medsafe to regulate pharmaceuticals to stated performance targets, consistent with international standards of regulatory practice; and
- ≠ Enhancement of the regulatory framework to incorporate complementary healthcare products and medical devices.

High- and medium-risk medicines and complementary healthcare products would be subject to full local pre-market evaluation to international standards. Low risk products would be licensed based on self-certification. Evaluations by other reputable regulators would be recognised for most medical devices.

For most complementary healthcare products, suppliers could simply register their products with ingredients that appeared on Medsafe's "positive list" of approved ingredients. If a supplier wished to introduce a substance not already on the list, they would apply to Medsafe for approval to include that substance in the positive list.

Medical devices would need to meet GHTF safety and performance requirements. Much of the burden of complying with these requirements would fall on product manufacturers, rather than importers/distributors. The extent and nature of the pre-market approval process would depend on the level of risk of the product.

### **5.1.3 Option 3: unilateral recognition**

Medsafe would recognise the decisions of certain specified regulators internationally, when deciding whether to grant pre-market authorisations for the full range of therapeutic products. Regulators recognised in this way would probably include the US, UK, European Union, Canada and Australia. The list would be different for different therapeutic products and would be determined by the standards of the pre-market regulatory systems in those other countries. The requirements would be risk-related, and the emphasis of the agency would be more on post-market surveillance.

The number of products requiring evaluation solely in New Zealand would be relatively small, given the importance of imports in this sector. Most products would have been approved in Australia or elsewhere. For products marketed in New Zealand only, the supplier could either get their product(s) evaluated by a recognised regulator overseas, or apply to Medsafe to organise the evaluation.

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<sup>19</sup> Under the Australia New Zealand Food Authority (ANZFA) and trans-Tasman harmonisation of food regulation a common definition is needed of what constitutes a food. Currently complementary healthcare products are treated mainly as medicines in Australia, but regulated as foods in New Zealand. The approach being developed by ANZFA excludes complementary healthcare products from food regulation in both countries, with the exception of products that take the form of foods (e.g. energy bars, sports drinks). As a consequence, New Zealand's current regulatory regime for dietary supplements must be replaced to progress food harmonisation, regardless of whether the JTA proposal is implemented.

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#### **5.1.4 Option 4: Joint Therapeutic Products Agency**

Under this option New Zealand and Australia would implement a single regulatory regime for pharmaceuticals, complementary healthcare products and medical devices, administered by a single regulator for both countries. A Discussion Paper by the project teams in Australia and New Zealand provides full detail.<sup>20</sup>

There would be common regulatory outcomes (except under extraordinary circumstances). Existing mutual recognition agreements between Australia and New Zealand respectively, and the European Union would remain in place and enable the joint agency to rely on certain assessments carried out by the competent bodies specified in the MRAs in place of local assessments.

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<sup>20</sup> *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products -Discussion Paper (June 2002)*

**Table 5: Comparison of regulatory requirements per option**

	Status Quo	Enhanced Medsafe	Unilateral Recognition	Joint Agency
<b>Class I medicines (Low risk products such as medicinal shampoos)</b>				
Market entry requirements	Evaluation by Medsafe; local labeling rules	Sponsor submits data (fewer than status quo) and self certifies compliance; local labeling rules	Sponsor submits data (fewer than status quo) and self certifies compliance; local labeling rules	Sponsor submits data (fewer than status quo) and self certifies compliance; local labeling rules
GMP requirements	Medicine Code	Medicine Code	Medicine Code	Medicine Code
Post market requirements	Testing, adverse event monitoring, etc.			
<b>Class II medicines (Most OTCs)</b>				
Market entry requirements	Evaluation by Medsafe, Current dataset, local labeling rules	Evaluation by Medsafe, Current dataset, local labeling rules	Overseas evaluation recognised. Smaller dataset. Local labeling rules	Evaluation by JTA; Current dataset. JTA labeling rules
GMP requirements	Medicine Code	Medicine Code	Medicine Code	Medicine Code
Post market requirements	Testing, adverse event monitoring, etc	Testing, adverse event monitoring, etc	Increased level of testing	Testing, adverse event monitoring, etc
<b>Class III medicines (Prescription medicines including generics )</b>				
Market entry requirements	Evaluation by Medsafe with some reliance on overseas reports (ICH dataset); local labeling rules	Evaluation by Medsafe. (ICH dataset); local labeling rules	Overseas evaluation recognised. Much smaller dataset submitted. Local labeling rules	Evaluation by JTA (ICH dataset). JTA labeling rules
GMP requirements	Medicine Code	Medicine Code	Medicine Code	Medicine Code
Post market requirements	Testing by regulator, adverse event monitoring, etc	Testing by regulator, adverse event monitoring, etc	Increased level of testing	Testing by regulator, adverse event monitoring, etc
<b>Class I complementary healthcare products (95% of complementary healthcare products)</b>				
Market entry requirements	N/A	Sponsor submits data and self certifies compliance	Sponsor submits data and self certifies compliance	Sponsor submits data and self certifies compliance
GMP requirements	As for food products	Medicine Code (with appropriate low risk interpretation)	Medicine Code (with appropriate low risk interpretation)	Medicine Code (with appropriate low risk interpretation)
Post market requirements	N/A	Testing, adverse event monitoring, etc.	Testing, adverse event monitoring, etc.	Testing, adverse event monitoring, etc.
<b>Class II complementary healthcare products (small number of medium-risk products)</b>				
Market entry requirements	N/A	Evaluation by Medsafe, small dataset as for Class II medicines; local labeling rules	Overseas evaluation recognised, smaller dataset submitted. Local labeling rules	Evaluation by JTA; small dataset as for class II medicines; JTA labeling rules

GMP requirements	As for food products	Medicine Code (with appropriate interpretation)	Medicine Code (with appropriate interpretation)	Medicine Code (with appropriate interpretation)
Post market requirements	N/A	Testing, adverse event monitoring, etc.	Testing, adverse event monitoring, etc.	Testing, adverse event monitoring, etc.

**Class III complementary healthcare products (prescription products, products indicated for serious diseases)**

Market entry requirements	N/A	Full evaluation of all products (ICH dataset). Local labeling rules.	Overseas evaluation recognised, smaller dataset submitted. Local labeling rules	Evaluation by JTA (ICH dataset). JTA labeling rules apply.
GMP requirements	As for food products	Medicine Code	Medicine Code	Medicine Code
Post market requirements	N/A	Testing, adverse event monitoring, etc.	Testing, adverse event monitoring, etc.	Testing, adverse event monitoring, etc.

**Devices (same regulatory standards [GHTF] in all new scenarios)**

Class I	N/A	Sponsor self certifies compliance	Sponsor self certifies compliance	Sponsor self certifies compliance
Within scope of current EU MRA	N/A	EU Conformity assessment recognised, no local assessment by regulator	EU Conformity assessment recognised, no local assessment by regulator	EU Conformity assessment recognised, no local assessment by regulator
With CE mark	N/A	CE mark and conformity with requirements recognised, no local assessment	CE mark and conformity with requirements recognised, no local assessment	CE mark and conformity with requirements recognised, no local assessment
FDA approved but no CE mark	N/A	Recognise FDA work but top up assessment locally of GHTF aspects not covered by FDA	Recognise FDA	Recognise FDA work but top up assessment locally of GHTF aspects not covered by FDA
Class II and higher not approved by FDA or CE marked	N/A	Assessment by Medsafe	Assessment by third party contracted by Medsafe	Assessment by JTA
Devices containing biological material	N/A	Assessment by Medsafe	Assessment by third party contracted by Medsafe (if not already approved by another recognised agency)	Assessment by JTA
Post market requirements	N/A	Adverse event monitoring (sponsor and regulator), testing	Adverse event monitoring (sponsor and regulator), testing	Adverse event monitoring (sponsor and regulator), testing

Source: Medsafe

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## 6. KEY METHODS AND ASSUMPTIONS

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### 6.1 Basic approach

This section sets out the methodology and major assumptions adopted to quantify the agency and business compliance costs. This section does not seek to quantify the costs and benefits of the other effects, such as impacts on public health and safety, trade, and consumer welfare gains and losses from the positive and negative impacts on choice.

- €# First the likely number of licences that businesses would hold if the regulatory regime were to be extended are identified (see 6.2);
- €# Second, the cost to run a regulatory agency under each option is identified (see 6.3). New Zealand’s share of the total JTA budget is also estimated.
- €# Third, likely business compliance costs under each option are identified (see 6.4). This looks at fees paid by firms, time and wages spent by firms on regulatory affairs, and the cost of delays to market (foregone gross profits) due to license processing.
- €# Fourth, transitions costs are discussed (see 0). As precise transition details are still sketchy, further work would need to be undertaken to estimate those impacts.

We compare the differences in compliance costs at a single point in time. The basic underlying trends are unlikely to be affected much by the different regulatory options. But different options do have different dynamic effects (e.g., on trade and number of products marketed). These could not be quantified meaningfully so the dynamic consequences have been presented in a qualitative form.

### 6.2 Number of product licences

Table 6 sets out the basic data about the expected number of applications for new licences or variations and annual licence/registration fees. These form the basis of our calculations.

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**Table 6: Number of product licences in New Zealand**

Estimated numbers per year under extended regulation

<b>Pharmaceuticals</b>	<b>New licence applications</b>	<b>Licence variations</b>	<b>Total licences</b>
High risk	350	1400	3,000
Low risk	150	600	2,500
<b>Comp. healthcare products</b>	<b>New licences and variations</b>		<b>Total licences</b>
High risk		150	750
Low risk		2850	14250
<b>Medical devices</b>			
High risk		100	7500
Low risk		900	2500

Source: Medsafe, TGA

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The numbers for pharmaceuticals are based on Medsafe’s records. The data for the other product groups are based on data from TGA performance reports and forecasts,

and adjusted using New Zealand official statistics and industry sources. In particular, industry sources maintain that there are likely to be a wider range of products on the market in New Zealand than in Australia, due to fewer regulatory barriers. Added regulation is likely to reduce the range somewhat, including choice within product groups.

As the activity levels for the three therapeutic product groups are estimates only, we have conducted a sensitivity analysis by choosing different activity levels. The impacts are reflected in the final costs (Table 9).

The risk classifications are based on Medsafe and TGA data. For medical devices we adopted the breakdown presented in recent fees and charges modelling for the TGA by Price Waterhouse Coopers to reflect the shift to the GHTF regime. That is, about 10% of medical devices fall in the high risk Class III +AIMD group, 60% in Class II, and 25% in the low risk Class I. Classification is important as it determines the compliance requirements.

Table 7 outlines the estimated processing times that underpin agency and business compliance cost estimates.

**Table 7: Licence application processing times**

Estimated average working days

	Medsafe	Enhanced Medsafe	Unilateral Recognition(4)	JTA (5)
<b>Pharmaceuticals (1)</b>				
High risk products	420	360	139	119
Low risk products	230	70	69	49
<b>Complementary healthcare products (2)</b>				
High risk products	230	70	69	49
Low risk products	0	0	0	0
<b>Medical devices (3)</b>				
High risk products	0	66	66	66
Low risk products	0	15	15	15

Notes: (1) Based on actual (Medsafe) and estimated time taken to process applications delays.

(2) Assume all high risk complementary healthcare products would be evaluated as low risk pharmaceuticals under the Counterfactual. Low risk times provided by Medsafe.

(3) As the approach is the same across options, assume Enhanced Medsafe and Unilateral Recognition processing times is same as JTA.

(4) Processing times under unilateral recognition (with the exception of medical devices and low risk complementary healthcare products) are assumed to be sum of the time taken to obtain full regulatory approval in an approved agency (the TGA) plus NZ processing time of 20 days.

(5) For the JTA we assume processing times would be maintained at levels that match or better the current TGA approval times (2000/01 TGA performance report).

Source: Medsafe, TGA

## 6.3 Regulatory Agency Costs

Medsafe provided estimates of how much it would cost to run the agency under each scenario (Table 8). These costs were based on its estimates of the number of technical and support staff that would be required to process the volumes in Table 6. It also estimated the requirements for corporate staff. Budgets presented here reflect Medsafe as a stand-alone agency with its own infrastructure under all scenarios.

**Table 8: Assumed agency costs**

NZ Dollars per year

	Medsafe Status Quo (1)	TGA Status Quo (2)	Enhanced Medsafe	Unilateral Recogn.	JTA (3)	JTA - NZ Industry share (4)
Total cost	\$8m	\$60m	\$43m	\$29.4m	\$68m	\$20m
Total activities (5)	8000	n/a	37000	37000	n/a	n/a
Cost per activity	\$1000	n/a	\$1162	\$795	n/a	n/a
Staff	62	370	319	211	420	n/a
Cost per staff	\$0.128m	\$0.163m	\$0.135m	\$0.139m	\$0.158m	n/a

Notes: (1) Medsafe budget of \$6.7m is adjusted to allow for corporate costs still subsumed in Ministry of Health (e.g. legal, HR, communications, IT). It assumes 1 corporate staff for every 4 regulatory staff.

(2) The relevant TGA budget is about \$A50m, for 370 staff, and has been converted to NZ\$ using exchange rate of 0.83 (ie \$NZ60m).

(3) Current TGA budget plus extra activity or Medsafe budget (Source: Australian RIS, NZIER 2000).

(4) An estimate of share of JTA cost that would fall on NZ, through fees etc. We assume NZ share is 30%.

(5) Activities include the total annual number of applications, variations and annual renewals, and includes GMP audits and post market surveillance activities.

Source: Medsafe, TGA

### a) Status Quo

Medsafe's current budget does not fully reflect the cost of running the agency. In particular, as a business unit of the Ministry of Health, some of Medsafe's corporate costs are captured in Ministry accounts, not Medsafe's operational budget. To be able to compare the *Status Quo* agency costs with those of other options, Medsafe budget must be adjusted upward. As a rough estimate, we assumed that 4 regulatory staff are supported by 1 corporate staff and overheads. Accounting for this would increase Medsafe's staff by 10. The budget has been scaled up accordingly.

### b) Enhanced Medsafe & Unilateral Recognition

Agency costs for these options are based on estimates of the number of staff times an estimate of their average wage, plus overheads and other expenses of around 70% of total wage & salary bill. This ratio of overhead costs is based on historic ratios from the Ministry of Health and other regulatory agencies. Medsafe assumes between 2.25 and 3.25 regulatory staff per corporate staff. The agency cost per staff member comes to about \$140,000 per annum.

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We regard these estimates as an upper bound on the ratio of corporate staff. A ratio of technical to corporate staff of 4:1 or 5:1 is more usual. It is always difficult to draw comparisons with other organisations, but in its annual report for 2000/01, the Medicine Control Agency (UK) reported that of its permanent employees, 366 were engaged in licensing and inspection, and 70 in admin and finance (i.e., a ratio of 5 regulatory staff for each corporate staff). But its overhead costs were 100%, rather than 70%, of salary costs.<sup>21</sup>

As part of the sensitivity analysis, we assumed a ratio of 5 regulatory to each corporate staff. The impact on the agency budget was -8% for Enhanced Medsafe, and -13% for Unilateral Recognition. Increasing overheads also, from around 70% of salary costs to 100% of salary costs, increased total agency costs by 9% and 1% respectively. The estimates are very sensitive to the number of technical regulatory staff: Every 10% reduction in technical staff is matched by a cost reduction of 8%.

### **c) JTA Budget**

The JTA budget estimate is derived in two ways. The Australian Regulatory Impact Statement (2002) assumed the current TGA budget and added an estimated net 15% increase in activity to take account of New Zealand-related activities. The 15% was selected because it reflected the estimated 85% overlap in pharmaceutical product regulation, the New Zealand share of total Australian-New Zealand industry sales, and New Zealand's share of the combined population. The alternative approach is to add the TGA and Medsafe budgets together, once converted to the same currency. The resulting agency costs are about the same (\$68m-\$69m).

The agency cost does not take into account the expected administrative efficiency gains, or the degree of rationalisation in applications and annual renewals that a JTA would allow. This is unlikely to be as large for medical devices and complementary healthcare products as it will be for pharmaceuticals. (The earlier NZIER / Applied Economics report estimated direct agency cost savings of between A\$6.5 and A\$11.5m, based on a cessation of duplicated evaluation functions, and avoided training costs and future salary increases.<sup>22</sup>)

### **d) New Zealand's share of total JTA costs**

For the cost-benefit analysis, a key issue is what part of the cost of running a JTA will fall on New Zealand. One way to look at this is to argue that, as the regulatory costs will be passed on to consumers, then the share of the JTA budget will be the same as the ratio of New Zealand's population to the total Australian and New Zealand population, that is, about 15%.

Our view is that this will be true for pharmaceuticals, but not for the other product groups, where the New Zealand share of costs depends on the extent to which companies market their products in both Australia and New Zealand or hold separate

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<sup>21</sup> That agency has 529 FTE staff, with annual expenditure of around 37.2 million pounds. Medical devices are regulated by a separate agency of 140 staff, with a budget of 9.6 million pounds. 16% of that agency's budget was for service agreement with the Department of Health for corporate services (finance, legal, HR, accommodation, and IT).

<sup>22</sup> TGA *Trans-Tasman Regulatory Reform For Therapeutic Goods: Regulatory Impact Statement (Including Cost Benefit Analysis)*, 13 February 2002, page 17.

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licences etc. for each of the two countries. Overall, we have assumed that New Zealand's share of the cost will turn out to be higher, that is around 21%, at least in the medium term, because:

- €# The likelihood is that for almost all pharmaceuticals, there will be only one licence application and one annual renewal per product for both countries. The costs will therefore be shared on a per capita basis, that is 15% for New Zealand.
- €# For medical devices, the question is whether there will be rationalisation among importers, that is, a move to single distributors of devices for New Zealand and Australia combined. In this paper we argue this effect is likely to be small. 15% of New Zealand firms will not face additional fees (based on share of industry turnover of device exports to and imports from Australia). But mainly there will be duplication of licenses. About 50% of JTA costs for devices would therefore fall on New Zealand products.
- €# For complementary healthcare products, the issue is similar to that for medical devices. To the extent that rationalisation across the Tasman is efficient, we would expect it to have taken place already (particularly for products imported from Australia). But the compliance costs and lower access barriers under a JTA for New Zealand manufacturers of complementary healthcare products will induce some additional rationalisation at the margin. We therefore assume that for complementary healthcare products New Zealand's share of the costs would be up to 30%.

Combined, this means that the New Zealand's share of the JTA cost will be about 21%.

## 6.4 Business compliance costs

We assume that the agency costs discussed above would be passed on in full to the industry in the form of regulatory fees. Additional business compliance costs under each of the options were estimated by combining the following factors:

- €# Employee days per application and annual licence renewal. Applications for high risk products were assumed to take more time and effort than for low risk products, due to different requirements. Days also vary with each option due to different requirements.
- €# Annual full-time salary for a 'regulatory affairs' employee (or consultant), including overheads. The base-case is \$NZ100,000 p.a. but as part of the sensitivity analysis we also calculated scenarios using \$75,000 p.a. and \$125,000 p.a.
- €# Loss of earnings from delays to market. Each application involves some processing time by the agency (see Table 7). This time depends on the risk profile. Delays mean foregone income. In many cases, the licence application (as defined for our model) involves a variation on a product, or a replacement by an improved substance or model. We assume that this results in a 10% lift in revenue. We assume a 30% mark-up to derive a gross profit loss. This is used to work out the cost of each day's delay.
- €# For the JTA, firms that already export to or import from Australia would not face any additional compliance activities (and pharmaceuticals may face a reduction overall). This has been taken into account.
- €# The assumed overlap of products (or the decrease in number of licenses) was discussed in the section on the New Zealand Share of JTA costs.

## 6.5 Total administrative and compliance costs

**Table 9: Total Government and Industry Costs** <sup>(1)(2)</sup>

Annual costs, Midpoint estimates

	Medsafe	Enhanced Medsafe	Unilateral Recognition	JTA NZ's 'share'
<b>Administrative costs</b>				
Costs to Government <sup>(3)</sup>	\$4.2m	\$0.6	\$0.6	\$1.1m
<b>Business Compliance Costs</b>				
<b>Pharmaceuticals (+/- 11%)</b>				
Regulatory fees	\$3.8m	\$29.1m	\$14.7m	\$6.8m
Other business compliance	\$5.7m	\$4.5m	\$1.8m	\$1.3m
Total	\$9.5m	\$33.6m	\$16.5m	\$8.1m
% of industry turnover	1.1%	3.7%	1.8%	0.9%
<b>Complementary Healthcare products (+/- 30%)</b>				
Regulatory fees	\$0 <sup>(4)</sup>	\$6.3m	\$6.0m	\$1.7m
Other business compliance	\$0.2m	\$1.4m	\$1.4m	\$1.1m
Total	\$0.2m	\$7.7m	\$7.4m	\$2.9m
% of industry turnover	0.2%	7.7%	7.4%	2.9%
<b>Medical devices (+/- 30%)</b>				
Regulatory fees	\$0.1 m	\$7.5 m	\$8.5 m	\$5.9 m
Other business compliance	0	\$1.9 m	\$1.9 m	\$1.2 m
Total	\$0.1 m	\$9.4 m	\$10.4m	\$7.1 m
% of industry turnover	0.0 %	1.4 %	1.6%	1.1%
<b>Total Business Compliance Costs (\$ million)</b>				
Total	\$9.8m	\$50.7m	\$34.3m	\$18.1m
% of sector turnover	0.6%	3.1%	2.1%	1.1%

Notes: (1) Quantifiable compliance costs only.

(2) Distribution of compliance costs may change as design of options develops. Compliance costs are sensitive to any change in the overhead allocation methodology.

(3) Administrative costs of \$4.2 million under the Status Quo is made up of Crown funding of Medsafe plus corporate services provided by the Ministry of Health to Medsafe. Under all other options there are ongoing fiscal costs of \$0.6 million for Crown funded medicine control activities. Under the JTA, there is also the additional cost of monitoring the JTA.

(4) Under the Status Quo some complementary healthcare products are treated in the same way as low risk pharmaceuticals. Regulatory fees, which would be low, are included under pharmaceuticals.

Source: NZIER

Fiscal costs are unclear. Each option has elements that both increase and decrease fiscal costs. The net change is ambiguous across options. While it would require a decision from Cabinet, we have assumed that, if complementary healthcare products are regulated as medicines rather than food, they would no longer be required to pay the current 7% Customs duty on imports. This would reduce import costs, but also tax revenue. The loss of revenue would be offset by the reduction in Government funding for Medsafe under full cost recovery.

A business compliance costs statement requires compliance costs to be presented as incremental costs, i.e. the difference between the costs of a given option and the status quo. This information is presented for the Enhanced Medsafe, Unilateral Recognition and JTA options in Table 10 below.

**Table 10: Incremental Compliance Costs**

Annual costs, Midpoint estimates, excludes costs to Government

	Enhanced Medsafe	Unilateral Recognition	JTA NZ's share
<b>Pharmaceuticals (+/- 11%)</b>			
Regulatory fees	\$25.3m	\$10.9m	\$3.0m
Other business compliance	(\$1.2m)	(\$3.9m)	(\$4.4m)
<b>Total</b>	<b>\$24.1m</b>	<b>\$7.0m</b>	<b>(\$1.4m)</b>
% of industry turnover	2.7%	0.8%	(0.2%)
<b>Complementary Healthcare products (+/- 30%)</b>			
Regulatory fees	\$6.3m	\$6.0m	\$1.7m
Other business compliance	\$1.2m	\$1.2m	\$0.9m
<b>Total</b>	<b>\$7.5m</b>	<b>\$7.2m</b>	<b>\$2.6m</b>
% of industry turnover	7.5%	7.2%	2.6%
<b>Medical devices (+/- 30%)</b>			
Regulatory fees	\$7.4 m	\$8.4 m	\$5.8 m
Other business compliance	\$1.9 m	\$1.9 m	\$1.2 m
<b>Total</b>	<b>\$9.3 m</b>	<b>\$10.3 m</b>	<b>\$7.0 m</b>
% of industry turnover	1.4 %	1.6%	1.1%
<b>Total Sector</b>			
<b>Total</b>	<b>\$40.9m</b>	<b>\$24.5m</b>	<b>\$8.3m</b>
% of sector turnover	2.5%	1.5%	0.5%

Source: NZIER

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## 6.6 Transition costs

There are three major sources of transitional costs to the industry under each option for change:

- €# finding out about the new regime: we are unable to quantify this cost, but expect it would be relatively small for larger firms who are already familiar with the general tenor of proposals. This may be a more substantial cost for smaller firms, but could be minimised by the agency providing clear advice;
- €# registration of existing products; and
- €# implementing GMP.

The discussion paper describes the principles and broad approach of the transition, but the detailed requirements or the period over which the transition will take place have not yet been determined (See Discussion Paper, op cit.). We assume that similar transition arrangements will apply under the other options considered here.

Under the current proposals for the JTA, sponsors of products that are legally on the market but have not undergone any pre-market approval process (i.e. complementary healthcare products and medical devices marketed in New Zealand) will have to go through a process to apply for a joint agency product licence. But they do not have to apply for a dual country licence to continue to supply the product in New Zealand only. Therapeutic products that have already gone through the relevant pre-market approval process in either country will be automatically given an interim product licence for the country in which they currently market the product. The interim licence will lapse at the end of the transition period when the sponsor will have to apply for a joint agency licence. The transition period gives sponsors the time to learn about the requirements, compile the required information, and adjust their production, labelling and distribution processes.

In addition to the industry transition, significant set up costs would be involved in establishing the JTA. These would include the costs of building refits, computer hardware and software development, and implementation. The previous NZIER / Applied Economics report estimated these transition costs for a joint agency would be in the order of \$A 3 million per annum over three years, and \$10 million in total.<sup>23</sup> The allocation of this cost is subject to negotiation. It is likely that the cost would be split between Australia and New Zealand. We assume a 50:50 split, in which case the cost to New Zealand would be \$NZ6 million over three years, and we assume that this cost would be borne by Government. There may be some offsets for the New Zealand Government, such as reduced investment in the existing regulatory capacity that would have occurred in the absence of a movement to a JTA.

Medsafe anticipates that set up costs would exceed \$NZ5m for the *Enhanced Medsafe* and *Unilateral Recognition* options.

Industry transition costs will include the costs of finding out about new requirements (which we have not been able to quantify), and the costs (if any) of registering complementary healthcare products and medical devices that are on the market but not currently registered. At this stage, the preferred option appears to be that there will be no charge for the initial registration of products that are already on the market. That raises the distributional issue as to who bears the cost of running the agency.

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<sup>23</sup> See TGA, *Trans-Tasman Regulatory Reform for Therapeutic Goods: Regulatory Impact Statement (Including Cost Benefit Analysis*, 13 February 2002.

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## 7. COST BENEFIT ASSESSMENT

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### 7.1 Option 1: Status Quo

A continuation of the status quo would suffer from the issues identified in the problem definition.

The advantage of this option is that it is a low cost way to manage the public health and safety risks associated with pharmaceuticals. The disadvantage is that it does not address the concerns about inadequate regulatory capacity, nor does it adequately manage the risks from medical devices or complementary healthcare products, where reliance is placed on overseas regulatory arrangements reducing the risks of imported therapeutic products that are not evaluated locally. New approaches within the current regulatory framework (i.e. the planned medical device register) will help mitigate some of the risks. But without added resources Medsafe could not assess the safety and performance of medical devices and would find it hard to enforce the existing prohibition on health claims for complementary healthcare products.

Low domestic compliance costs benefit New Zealand's export competitiveness (particularly for complementary products and medical devices), and also keep prices of locally manufactured product and imports down. This benefits consumers. Exporters would still need to meet any health and safety regulations of the importing countries, and may be disadvantaged if they cannot locally obtain export certification when this is increasingly being demanded by importing countries.

However, the regulatory regime would be out of step with that of most other countries, and the potential for harm to consumers (which is thought to be rising) would remain. The regime will continue to rely on the ability of purchasers to make good judgements about the safety of complementary healthcare products and medical devices. As products become increasingly sophisticated and technical possibilities grow the risks from some products will become more pronounced, and consumers and health professionals may find it harder to assess the safety and quality independently at reasonable cost. This raises the prospect of poorer decisions, and with an adverse but unquantifiable impact on health.

In addition, there would be increasing delays in approving new and improved pharmaceutical products, as Medsafe lacks sufficient capacity to conduct all evaluations in a timely fashion. This also has public health costs. Medsafe would find it increasingly difficult to attract and retain regulatory expertise. Similarly, it will find it increasingly hard to access overseas reports (the TGA, for example, has already indicated that it cannot continue to freely share costly evaluation reports paid for by the Australian industry).

The Status Quo is also inconsistent with Government's objectives for trans-Tasman economic relations and trade.

### 7.2 Option 2: Enhanced Medsafe

This option covers two sub-options.

€# Option 2a- an expansion of Medsafe's capacity to carry out in full its functions under the current regulatory framework, and within a reasonable timeframe; and

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≠ Option 2b – the enhancement of the regulatory framework to incorporate complementary healthcare products and medical devices.

The net impact of option 2a is covered by the discussion of the pharmaceutical sector.

### 7.2.1 Summary

In principle, the *Enhanced Medsafe* option would contribute to the Government's health objectives. It would provide for quicker and more thorough approvals and surveillance – improving industry profitability and consumer health and safety.

For medical devices and complementary healthcare products, the key issues are how much extending the regulatory regime would reduce public health risks, and how much that reduction is valued by consumers.

Most medical devices used in New Zealand are imported, mainly from the US, Europe, Japan, and Australia, where they are required to meet safety standards for those markets. But they do not regulate the standard of export products. While it is likely that medical devices imported from those countries meet standards that are adequate for New Zealand, this cannot be guaranteed, nor is it certain that future imports come from those countries. Likewise, there is nothing to prevent poor quality medical devices from other unregulated markets from being sold here. This poses risks to the public health and safety. There would, therefore, be additional risk reduction benefits from adding pre-market requirements in the devices sector, but these may not be large.

Although local manufacturing and trade with Australia is relatively more important for complementary healthcare products, many products are sourced from countries that do not adequately regulate the safety and quality of these products. Examples include the USA and some Asian countries. While most products would be considered low risk, consumers are exposed to potentially significant risks from poor quality or adulterated products or from toxic ingredients.

The size of the health benefits of extending regulation to be more in step with international approaches could not be quantified and remains a matter of judgement. The main benefit of pre-market registration would be that it makes post-market regulatory activities more cost-effective, particularly for medical devices, but also for complementary healthcare products. It would also reduce evaluation costs incurred by hospitals and aged care facilities purchasing medical devices.

There would be a significant increase in compliance costs, estimated at \$43.3 million per annum – \$24.4M for pharmaceuticals, \$10.4M for medical devices and \$8.5M for complementary healthcare products. Full cost recovery means these costs would be passed on in higher prices and/or reduced volumes to consumers of healthcare and to Government, as the main funder of pharmaceuticals and healthcare. This would be the main effect on the pharmaceutical sector. The added compliance costs would also cause rationalisation in the complementary healthcare products sector relative to the status quo, and in the medical devices sector.

The option would not support the Government's trade objectives. Proof of compliance with safety standards from a reputable regulator may reduce the marginal cost of breaking into export markets and so improve future trade outcomes for domestic producers. But new or increased domestic compliance costs (e.g., local annual fees) reduce international competitiveness. Neither would this option be consistent with the Government's overall objective of Closer Economic Relations with Australia.

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The option seems unsustainable and even unrealistic, given the reported international scarcity of therapeutic product regulatory expertise. Difficulty in recruiting the desired number would drive up wages (and costs) and/or cause delays in approving new or improved products for the New Zealand market, with subsequent foregone health benefits.

## 7.2.2 Pharmaceuticals

Medsafe estimates that the agency's budget would need to increase by around \$25.3 million to achieve current approval time standards for pharmaceuticals (putting aside the issue of the trend in applications, which would be similar under any scenario). This estimate also recognises the additional costs that would arise from losing free access to TGA expert reports.

### a) Impact on industry

We would expect compliance costs to increase relative to the *Status Quo*, our midpoint estimate of this increase is around \$24 million (2.7% of industry turnover). This increase is primarily made up of increases in regulatory fees due to the move to full cost recovery. Some (around \$4.2 million) of the increase in regulatory fees is a transfer of the burden from taxpayers to industry, and so is not a real resource cost to society. The balance reflects an increase in the number of product applications and variations that can be processed per annum with full capacity.

Considerable progress has been made to date toward harmonising scheduling requirements between Australian and New Zealand – 90% of products are now harmonised in this way. This decreases production costs by:

- €# reducing duplication in the cost of labelling; and
- €# reducing production down-time - GMP requires considerable checking between packaging products with different labelling requirements, in order to ensure the correct labels are used.

However, in the absence of a formal mechanism, Medsafe and the TGA are concerned that it would be difficult to maintain the level of commonality achieved to date. The result would be a slow increase over time in production costs associated with labelling, which would further contribute to gradual price increases. It is not clear how significant this risk is. The savings on production costs are a strong incentive for the industry to pressure for the same scheduling standards to be applied in the future. In other words, continued willingness of both regulators to support this kind of co-ordination would be the key.

Firms' responsiveness to any decrease in margins due to regulatory fees depends on company strategy. Some firms indicated they would withdraw products that no longer make a profit, while others said that these are strategic marketing decisions that depend on the parent company's global strategy. Changes in regulatory costs will make a difference on the margin, but regulatory fees and related compliance costs (other than labelling) are usually small compared to the overall investment of bringing a product to market.

The most reasonable assumption, however, is that firms will respond on the margin to changes in profitability. A rise in compliance costs would lead to price rises or reduced supply on the margin. The key impact will be on low value/volume products, and thus

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depends much on the precise structure of fee exemptions. Any such exemption would shift the regulatory burden to producers and consumers of other (non-exempt) medicines.

### ***b) Impact on consumers***

Firms will try to pass on cost increases to consumers of pharmaceuticals, which will also affect those seeking other publicly funded healthcare.

Any price rises will reduce the overall purchasing power of consumers and funders of healthcare. The international literature indicates that a 10% increase in the price of a prescription medicine to consumers (co-payments) leads to a decrease in spending on those medicines of about 2 to 5%. People are likely to be more sensitive to a change in price of over-the-counter medicines, compared to prescription medicines.

Most of any price increases would be faced by PHARMAC, which either needs to seek an increase in budget (in which case DHBs and the Ministry of Health would need to make trade-offs with other health services or seek more baseline funding) or raise the health benefit threshold at which medicines would be publicly funded. This would partly offset the health benefits from reducing the time it takes to bring new and safer medicines on to the market. We assume that trade-offs are made somewhere within the health budget, impacting on consumers of public healthcare.

### ***c) Impact on Government***

At 2000/2001 figures this option would reduce direct fiscal costs to the Government by approximately \$3 million. This fiscal saving may be off-set by an increase in Vote Health if the likely price rises faced by PHARMAC impact on the CPI. If not, then trade-offs would need to be made within Vote Health, which could affect other Government objectives in this portfolio.

Even with increased financial resources, Medsafe would find it difficult to access the specialist expertise needed to evaluate new pharmaceutical products, due to a reported difficulty regulators have world-wide to attract the people with the necessary skills. This suggests that pursuit of this option will lead to further upward pressures on wage costs and so fees, and the inability to process some applications.

## **7.2.3 Complementary healthcare products**

### ***a) Impact on industry***

As most complementary healthcare products would be registered based on a simple self-assessment by the supplier, submitted and verified electronically in real time, there would be only very minimal delays to market from registration.

The disadvantage of this option is that it would increase compliance costs for industry:

€# For each new product, the sponsor would incur application costs for approval to market the product;

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- €# For factories in Australia and New Zealand and those overseas sites not already inspected by a recognised local regulator there would be audit costs each 1-2 years (associated with pre-licensing audits);
  - €# For each significant variation to the product, such as a change of manufacturer, the sponsor would incur an application fee; and
  - €# Each licensed product (i.e. all products on the market) would incur an annual fee to cover the cost of surveillance.

Our midpoint estimate of regulatory fees is around \$6 million. Other compliance costs would also increase, with a midpoint of approximately \$2 million. Total compliance costs would be in the order of 8.5% of estimated industry turnover. The extent to which suppliers absorb the additional costs of regulation, or pass these costs on to consumers will depend on the market. Demand for complementary healthcare products appears to be price sensitive, which constrains the ability of suppliers to pass costs on. Thus we would expect suppliers to absorb part of the cost increase, and pass the remainder on to consumers. Those unable to do so may exit the market.

If an ingredient is not on the approved “positive list”, a supplier wishing to market a product containing that ingredient could apply to have the substance added to the list and pay a fee for the safety evaluation. However, once the substance is approved in this way, other suppliers could use it without facing the additional cost.<sup>24</sup> This kind of arrangement would put in place incentives to hold off introducing a product, causing delays in introducing new substances unless moving first provides a sufficiently large return. The social cost is not thought to be large, as the one-off fee is modest compared to other manufacturing, marketing and distribution costs, so that this dynamic is likely to only affect low volume/value products (implying that the benefits foregone will also be small).

Overall, the increase in compliance costs may lead to a reduction in the range of low value/low volume products, affecting small domestic manufacturers and importers in particular. This will affect the number of people employed in the sector and possible related industries, such as labelling suppliers, bottle suppliers, or suppliers of raw materials.

### **Manufacturers**

Manufacturers would incur the additional cost of meeting higher GMP standards compared to the current food safety and hygiene requirements.

There are no reliable sources of information about the number of manufacturers. From industry and other sources we have identified about 10 large to medium sized manufacturers. They account for most of the domestic manufacturing, around 6 of those having a turnover greater than \$10 million. In addition there are an unknown number (possibly 100) of small cottage-type manufacturers, each producing a very small number of product lines.

We understand that at least 5 of the larger manufacturers have already implemented GMP standards in order to export product to Australia and other markets, and two more are in the process of doing so. Those manufacturers who have not done so could face substantial upgrade costs. From our discussions with industry, these costs could range from hundreds of thousands of dollars to millions of dollars, depending on

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<sup>24</sup> Other options to share costs are also being considered such as a cost-sharing and rebate system.

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factors such as the size of the operation, and the type of manufacturing activity (e.g. whether packaging for full manufacturing; low risk or higher risk products).

Discussion with industry and our own estimates indicate that two of the medium firms may decide that the cost of upgrading is too high. The unknown number of smaller, volume manufacturers would also be affected. They may choose to cease manufacturing and contract with another licensed manufacturer. Alternatively, they may exit the market, unless they are able to grow their income by exporting to Australia and other markets. Once firms comply with GMP the marginal cost of entering export markets would be lower. But the fact that each product would now also incur an annual domestic licence fee, raises its average cost, reducing cost competitiveness.

### **Importers**

Registration fees are likely to affect importers more severely than manufacturers. Importers generally market a wide range of low volume products, compared to manufacturers, and report lower margins. While there may be annual fees exemptions for low value/volume products, the cost would be shifted to high volume/value products.

Importers source products from a number of manufacturing sites. If a site has been GMP certified by a recognised overseas regulator, then there will be no additional costs. If not, the importer will face the regular cost of an audit to assess the standard (consisting of the cost of an airfare and around 3 days time). Increasingly, overseas countries are planning to introduce GMP requirements for complementary healthcare products so that in the short to medium term, more and more overseas manufacturing sites will have recognisable GMP certification from their local regulator.

We understand that, under the new regulatory environment, complementary healthcare products would be exempted from the existing 7% import duty. Separate data of the actual amount affected is unavailable. We estimate the cost saving to the sector would be up to \$3.5 million per annum, based on imports of \$50 million. This would at least partly offset the increased costs to importers of regulation. However, as this effect is a transfer from the Government it does not directly affect the net benefits of regulation. Some (possibly many) low value products would still be likely to exit the market.

### **b) Impact on consumers**

The benefit of regulating complementary healthcare products would come from the positive health impacts of being better able to manage the higher risks from high potency and innovative products (including more effective recall), and to exclude harmful and poor quality products from entering the market. The framework would also give consumers better information on which to base decisions, with potential for subsequent health and other consumer benefits. While it is difficult to assess the marginal benefit of this, the cumulative effect could be significant as over half New Zealand's population uses complementary healthcare products.<sup>25</sup>

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<sup>25</sup> Ministry of Health (1999), *NZ Food: NZ People - Key results of the 1997 National Nutrition Survey*, page 79.

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The disadvantages come from the impact of price increases as some suppliers would seek to pass on part of the increased costs, and some reduction in the range of beneficial products.

Product by product, the social impact of the latter is by definition small as mainly low value and volume products would be affected. The key issue is whether there are close substitutes available, so that welfare loss is minimal. However, the cumulative effect may be more significant. Of course, to the extent that harmful or ineffective products disappear, the effect would be beneficial.

### ***c) Impact on Government***

The direct fiscal cost of this option to Government is low. There would be no additional administrative cost from extending pre-market regulation to complementary healthcare products, as these costs would be fully funded from fees.

Pre-market registration of complementary healthcare products would make post-market surveillance, including product recall, more cost-effective.

Removing the import duty on complementary healthcare products would have a fiscal cost, which we estimate to be in the order of \$3.5 million (see above). While this would be a fiscal cost to Government it is not a cost to the economy, as importers would receive an equivalent benefit.

## **7.2.4 Medical devices**

### ***a) Impact on industry***

The medical devices sector is highly diverse. According to industry sources, however, most of the 170 firms in the medical devices industry could be characterised as importers with an average turnover of around \$3.5million, typically marketing around 1,000 product items of mainly medium risk. Approval would not be needed for individual items. Often submissions can be made for groups of closely related items, which reduces the onus.

Extending the regulatory regime will affect industry through increases in regulatory fees, a firm's compliance costs and lost revenues from some delays to market. Over 50% of future applications would fall in the lower risk categories (Price Waterhouse Coopers fees and charges model), keeping requirements down. As most devices are imported, the necessary documentation would often already be available from manufacturers, and the compliance costs on importers from compiling information and waiting for approval would generally be minor.

### ***b) Impact on consumers***

Individual consumers would benefit from regulation to the extent that risks are reduced. This benefit would include the reduction in ill-health and loss of earnings that may be attributable to avoiding faulty medical devices. Society in general would benefit from any reduction in lost productivity if regulation reduced risk. There is no data to estimate the magnitude of this. These benefits would be offset to the extent that any price increase is passed on to consumers, and choice reduced.

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### **c) Impact on Government**

The impact on government comes primarily on the impact of price increases on its Health and ACC budgets, as Medsafe would be fully funded by industry. Compared to the counterfactual of no regulation, there are no offsetting savings, as Medsafe's current budget relates primarily to pharmaceuticals.

Statistics NZ's quarterly *Public Health Financial Statistics* indicate that 'medical supplies and other expenses' make up about 30% (or \$1.2B for 2001) of the costs of providing public hospital services. A significant portion of those expenses is in relation to medical devices. More detailed accounts provided by the Ministry indicate about \$475 million ex GST per annum is in relation to medical devices – diagnostic tools, implants and prostheses, instruments, patient appliances, disposables and some blood products (which could not be separated out).

As the health budget is currently adjusted for general price level (CPI) movements (as well as demographics), the impact on government depends on whether the device price rise pushes up the CPI or not. If it does not, care providers and consumers will feel the pinch through reduced margins or reduced volumes of health services as the purchasing power of district health boards falls, unless Vote Health Baselines are increased. However, the effect is marginal given a total health budget of \$7.4 billion for 2001/02.

Any increase in costs to health institutions may be off-set by reducing part of the evaluation costs some of the individual institutions incur each time they investigate whether a medical device meets safety and quality standards (they would still test suitability to local clinical requirements and preferences).

An increase in domestic regulatory costs would raise average cost, and thus cost-competitiveness, even if the marginal cost does not change. In this way it may affect export competitiveness of the few New Zealand medical device manufacturers. The impact is small as most medical devices are imported, New Zealand's exporters of medical devices already incur the cost of complying with overseas regimes, they may be able to avoid passing on regulatory costs to export markets to remain competitive ('price discrimination') and in any case most products would be low risk and so would incur a low fee.

## **7.3 Option 3: Unilateral Recognition**

### **7.3.1 Summary**

Given the importance of imports, this option would meet many of the Government's health objectives at lower compliance costs than *Enhanced Medsafe*, as long as New Zealand could access decisions from regulators that impose similar or higher standards than those of New Zealand.

This is particularly true for pharmaceuticals, where greater reliance on overseas evaluations means industry could submit fewer data for high-risk medicines, for example.

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For complementary health care products and medical devices, compliance costs would rise compared to the status quo. The effects would be similar to those described above, mainly because the functions (and thus staffing and costs) of the regulatory agency would be similar under any of the new options for these two sectors. Domestic manufacturers that do not export would be at a greater disadvantage than under option 2, however.

Local manufacturers would be subject to the same requirements as under Enhanced Medsafe, except that they would need to get approval through other recognised regulators (or Medsafe would need to on their behalf). Much would depend on the willingness of other regulators to collaborate. In other words, it may make it more difficult for domestic manufacturers to organise approvals for the local market and for developing exports.

*Unilateral Recognition* would relieve some of the capacity constraints that are unfolding, particularly for pharmaceuticals.

It would not achieve CER-related objectives, and this could disadvantage local manufacturers. New Zealand may also find it difficult to get co-operation from other regulators if it has little to offer them in return. As a small market, New Zealand cannot use 'export earning potential' or withdrawal of 'recognition privileges' as an effective lever. Compared to option 2, it would reduce trade barriers faced by manufacturers in countries whose regulatory regimes are recognised, but this may not provide enough returns to those countries to avoid the possibility that New Zealand is regarded as "free-riding" on others' regulatory regimes.

### **7.3.2 Pharmaceuticals**

#### ***a) Impact on industry***

The impact on industry compared to the *Status Quo* would be similar as discussed under *Enhanced Medsafe*. But the overall increase in compliance costs would be considerably lower than under *Enhanced Medsafe* – around \$7 million (0.8% of turnover) plus or minus 11%. This is because Medsafe would rely on evaluations from recognised overseas regulators, with only a small dataset required to accompany the application. This would apply in most circumstances as most pharmaceuticals are imported from countries with safety standards that are the same as or higher than those of New Zealand. As a result a lower number of technical regulatory staff is needed, which is reflected in the lower agency cost than *Enhanced Medsafe*.

There are concerns that this option increases the risk of counterfeit imports, compared to the other options considered. For this reason there would be more emphasis on post-market surveillance, which has also been reflected in Medsafe's budget estimates. The existence and magnitude of any additional risk from counterfeits, compared to the other available options, is unclear. Under this option, the regulator would adopt a precautionary approach. This means that, if two regulatory agencies arrive at different conclusions (where one approves and the other declines an application), Medsafe would also decline the application.

The impact on scheduling or GMP licensing would be the same as under the status quo.

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Overall, we estimate the increase in compliance costs to the pharmaceutical industry compared to the status quo to be in the order of \$7.3 million per annum. Given the small magnitude of additional compliance costs, and factors discussed above, the impact of regulatory fees on firm behaviour is likely to be negligible overall.

#### **b) Impact on consumers**

The impact would be similar to that for *Enhanced Medsafe*, although substantially less pronounced. Consumers may face some additional costs, depending on the likelihood that the regulator adopts a precautionary approach, as explained above, which would make it more likely that some beneficial products would not be approved (the Type I error discussed earlier). At the same time, regulatory delays to market would be shorter than under *Enhanced Medsafe* or the *Status Quo*. The overall impact on consumers is ambiguous.

There are concerns that *Unilateral Recognition* might lead to pressure from purchasers, product traders and special interest groups to accept products approved in countries with standards lower than New Zealand would try to maintain under other options. This could undermine consumer confidence. It seems unlikely that this pressure would be different under any of the options, or that the regulator would be any more or less inclined to accede.

#### **c) Impact on Government**

The fiscal impact would be similar as described under *Enhanced Medsafe*. But the risk of 'pass through' of compliance costs is much smaller.

While most of the industry relies on imports, the impact on pharmaceutical exports is likely to be negative more generally.

### **7.3.3 Complementary healthcare products**

#### **a) Impact on industry**

The impact of this option on industry would be broadly similar to those discussed for *Enhanced Medsafe*. The key differences would be as follows.

Where a product had been approved already by an overseas regulator, and recognised by Medsafe, the product approval process and associated fee would be abbreviated, and the registration fee consequently reduced. However, where a product did not already have a recognised approval, Medsafe would contract out the evaluation of that product to another regulator. The resulting registration fee would be higher. The total regulation fees for the sector may not be significantly different from *Enhanced Medsafe* (depending on how Medsafe allocates costs between sectors), but there may be a substantial shift of the cost burden from importers to domestic manufacturers.

We estimate total compliance costs to the industry would be in the order of \$7.9 million, or 7.9% of turnover, plus or minus 30% (see Table 10).

#### **Manufacturers**

The costs of registration would potentially be higher for domestic manufacturers under this option than under any of the other options under consideration. On the margin,

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manufacturers would be discouraged from developing product specifically for the New Zealand market, as they would either have to register the product first in a recognised overseas jurisdiction, or pay the higher fee for Medsafe to commission a product evaluation. This would reduce the competitiveness of New Zealand manufacturers' products relative to those of importers.

As a result we would expect the manufacturing base in New Zealand to contract, leaving only a small number of large manufacturers focussed on export as well as domestic markets.

### **Importers**

The cost of this option for importers would be lower under this option than under Option 2. There would be some additional costs over the status quo, although if the Customs duty was removed this would (possibly completely) offset these costs.

If we assume products marketed in Australia, Canada and Europe were recognised under this option, then the reduction in the range of product imported from these countries would be small. As under Option 2, without exemptions low value products might exit the market due to the impact of the annual registration fee. The range of products imported from countries whose regulator is not recognised is likely to fall substantially. This would particularly affect imports from Asia, and possibly the US.

### **b) Impact on consumers**

The general impacts would be similar to those outlined under Option 2. The major differences would be on product choice and consumption patterns:

- €# the availability of products designed specifically for New Zealand conditions would fall, or their prices would increase, substantially;
- €# the availability of products from non-recognised countries would also fall, or their prices increase, substantially. This would affect small groups of consumers, e.g. users of Chinese herbal remedies, and possibly those sourced from the US;
- €# prices might increase overall due to a reduction in the competitive pressure on importers from local manufacturers, due to higher relative cost increases for New Zealand only products. This would make it easier for importers to pass on cost increases such as freight costs and exchange rate fluctuations.

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### **c) Impact on Government**

As outlined for *Enhanced Medsafe*.

## **7.3.4 Medical Devices**

### **a) Impact on industry, consumers and government**

The impact is similar as described under the *Enhanced Medsafe* option, as the regulatory requirements are almost identical. However, at \$8.5m the agency cost borne by the medical devices sector is \$1m higher than under *Enhanced Medsafe*. This is only

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because in the agency cost estimates provided to us the average corporate overhead costs are higher (there are more corporate staff per regulatory staff).

Other business compliance costs are identical (\$3m per annum). The midpoint estimate of total compliance costs is thus \$11.5m or 1.7% of industry turnover.

## 7.4 Option 4: Joint Therapeutic Agency

### 7.4.1 Summary

For pharmaceuticals, regulatory costs would increase compared to the *Status Quo*, but it would achieve safety objectives at lower cost than the other options. This is due to economies of scale and scope in the regulator, and the benefits from single application costs for two markets, and the likelihood that current co-ordination on scheduling and labelling requirements will improve and/or persist. This option would be likely to reinforce the existing trend for pharmaceutical firms to shift their activities to Australia as they rationalise their regulatory (and possibly other) activities.

For the medical devices sector, the impacts are similar as described under *Enhanced Medsafe* and *Unilateral Recognition*. However, the potential economies of scale and scope would mean lower application fees and annual charges. It is also possible that a single regime will stimulate more New Zealand medical device manufacturers and distributors to export to the Australian market (and beyond). But, given the reliance on imports and the relatively small manufacturing base in New Zealand, the direct trade benefit to New Zealand is likely to be small. Imports from Australia, which do not face any regulatory barriers now anyway, would become more competitive relative to imports from other countries.

Similar conclusions may be drawn for complementary healthcare products.

The JTA would enjoy economies of scale and scope, and so would improve New Zealand's access to sustainable regulatory capacity over time compared to the other options examined. As a result, regulatory activities would be more timely and to higher standards, with associated health benefits.

A trans-Tasman regulatory agency would also potentially have greater influence over international regulatory developments, and more to offer other regulators to facilitate information sharing and Mutual Recognition Agreements. Such agreements have the potential to further reduce capacity concerns and administrative costs.

Under the JTA New Zealand would share the setting of regulatory standards. This may mean that standards do not fully reflect New Zealand's own circumstances and preferences. There are some examples where regulators' decisions in Australia and New Zealand have differed. However, this is rare, and the premise of CER is that commonalities of interests and preferences are more likely than differences. As noted, there is scope for accommodating such differences in exceptional circumstances.

Of all the options, the JTA would contribute most to CER objectives. Compared to the other options, and given experience of trade-liberalisation more generally, a single regulatory regime is likely to promote trans-Tasman trade, particularly in the medium to long term, but the immediate impact will be small given the reliance on imports from elsewhere. More generally, a trans-Tasman regulator with international credibility may make it easier for local manufacturers to break into export markets. But

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added compliance costs (particularly for medical devices and complementary healthcare products) also reduce export competitiveness.

The JTA would establish a set of precedents for any future development of joint agencies in the context of CER. The successful establishment and operation of this agency could have a significant influence on the attitudes of both the New Zealand and Australian governments towards options for the extension of CER in the future.

## 7.4.2 Pharmaceuticals

### **a) Impact on industry**

A single set of requirements for both countries would remove duplication of regulatory costs for the industry. Those firms trading in both countries benefit from reduced regulatory affairs costs (staff time, fees, and associated costs). Firms currently trading in a single country only will find it quicker and cheaper to enter the other.

Unfortunately, reliable data on the extent of overlap in pharmaceutical products between Australia and New Zealand is not available. Given the global nature of pharmaceutical companies, and Australia and New Zealand's reliance on imports, we would expect the level of overlap to be high. We therefore adopt the assumption made in the Australian Regulatory Impact Statement (2002) that 85% of pharmaceutical products available in New Zealand are also sold in Australia. The single regime would create an opportunity for pharmaceutical companies to rationalise their affairs and products across New Zealand and Australia to reduce overheads and avoid paying registration fees twice for products that are essentially the same. However, the extent of rationalisation is not that clear.

Some of the pharmaceutical firms consulted in preparing this report indicated that the establishment of a JTA would probably cause them to rationalise their regulatory affairs, but maintain their sales, marketing, and research activities (firms in New Zealand we spoke to had about 2-3 regulatory affairs staff each). Others suggested they might locate almost all of their activities in Australia, with a substantially reduced presence in New Zealand. Overall, our discussions indicated that for research-based firms New Zealand presence is less about the regulatory costs than about marketing and product protection:

- ≠ Many of these firms are global businesses – business decisions in New Zealand and Australia are determined more by world-wide business strategy than by domestic regulatory costs;
- ≠ Economies of scale in the manufacturing, packaging and labelling already put in place a strong incentive to align products offered in both countries. To the extent that current differences are not driven by differences in regulatory requirements, the degree of product variation between the two markets indicates the importance of different marketing approaches.

At the margin, a joint regime might encourage additional firms to join the existing trend to relocate regional offices to Australia.

Given the continued dominance of pharmaceutical imports, the alignment of regulatory regimes would have little impact on trade. The single regime will make it less costly for New Zealand and Australian pharmaceutical manufacturers (generics) to bring products to market in the other country, compared to the other options.

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Overall, we would expect compliance costs to fall slightly relative to the *Status Quo*, by around \$1 million, or 0.2% of industry turnover (plus or minus 11%).

### **b) Impact on consumers**

It is expected that due to lower compliance costs and greater competition from Australian generics manufacturers in the New Zealand market, product prices would be lower compared to those under the status quo and the 'enhanced Medsafe' option.

Lower prices compared to the counterfactual would also flow through to PHARMAC's budget and so benefit consumers of subsidised pharmaceuticals (more and/or better drugs can be subsidised), as well as consumers of other public and private health care services. These benefits could also result in improved health outcomes.

Greater sustainability of regulatory capacity would ensure ongoing timely decisions, compared to the other options. Compared to the other options, products for which there is currently low demand in New Zealand but which are marketed in Australia are more likely to be available.

### **c) Impact on Government**

Compared to the current Crown costs of \$4.2 million, the Crown would continue to face fiscal costs of approximately \$1.4 million per annum. The difference, a saving in the order of \$2.4 million, would be a transfer of cost to the industry. The ongoing \$1.4 million cost to the Crown consists of:

€# \$600,000 to retain existing Medsafe functions that would not be undertaken by the JTA (e.g. pharmacy audits);

€# an estimated \$500,000 for the Ministry of Health to monitor the JTA.<sup>26</sup>

If providers pass the drop in compliance costs through, the resulting decrease in pharmaceutical prices would lower inflationary pressures on Vote Health. At the same time, trans-Tasman rationalisation by firms would impose a cost on government in the form of tax revenues foregone.

## **7.4.3 Complementary healthcare products**

### **a) Impact on industry**

The impact of this option on the industry would be broadly similar to *Enhanced Medsafe*, with the following qualifications.

We would expect the increase in compliance costs to be lower than under either *Enhanced Medsafe* or *Unilateral Recognition*. This is largely due to economies of scale, and some reduction in duplication of compliance activity compared to those two options.<sup>27</sup> We estimate incremental compliance costs under this option would be between \$2.3 and \$4.3 million (3.3% of industry turnover at the midpoint).

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<sup>26</sup> It is assumed that there will be a small unit focused on monitoring the JTA, consisting of a team of 3 senior staff at an average salary of \$80,000 and with an overhead multiplier of 2.

<sup>27</sup> We have assumed a 20% to 30% product overlap between New Zealand and Australia.

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## **Manufacturers**

In respect of product not currently registered in Australia, and for those manufacturers who do not export to Australia, costs would increase compared to the status quo. Those manufacturers who already export product to Australia would face less of a cost increase than under *Enhanced Medsafe*, as they already meet GMP requirements, and are already registered. Compared to *Enhanced Medsafe*, New Zealand firms would find it easier to enter the Australian market, and thus we would expect to see a somewhat smaller degree of industry rationalisation.

## **Importers**

Our discussions with industry indicated that around 50% of New Zealand's imports of complementary healthcare products are sourced from Australia.<sup>28</sup> The impact on firms who import from Australia would depend on whether the product concerned was simply registered for export in Australia, or fully registered. The latter is most likely so that these firms would experience no cost increase compared to the status quo.

For the remainder of importers, the impact would be the same as under Option 2. We would expect substantial consolidation – small firms in particular would exit the market, and low value/low volume products would no longer be marketed from the New Zealand market (although consumers would be able to import those products directly).

### **b) Impact on consumers**

The impact on consumers would be similar to that under Option 2.

### **c) Impact on Government**

The option achieves CER objectives, although trans-Tasman trade is unlikely to increase substantially. However, firms remaining in the market would face lower incremental costs to trans-Tasman, compared to the *Status Quo* and other options.

The direct fiscal cost of this option to Government is low. There would be no additional administrative cost from extending pre-market regulation to complementary healthcare products, as these costs would be fully funded from fees. Pre-market registration of complementary healthcare products would reduce product recall costs where problems are discovered after a product has entered the market.

Removing the import duty on complementary healthcare products would have a fiscal cost, which we estimate to be in the order of \$3.5 million (see above). While this would be a fiscal cost to Government it is not a cost to the economy, as importers would receive an equivalent benefit.

## **7.4.4 Medical devices**

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<sup>28</sup> For example, discussion with Rob Shaw, Healtheries New Zealand Ltd, 17 January 2002.

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### **a) Impact on industry**

Firms holding national distributorships import most devices. An estimated 15% of this sector's turnover is in relation to trans-Tasman trade. If industry continued to be based on national distributorships they would be unlikely to benefit from the ability to market in both Australia and New Zealand with one licence. Instead, there would be a duplication of licenses. Some distributors would take advantage of the single test for both markets. The willingness to do so can be tested by behaviour of Australian-based import distributors of medical devices. Few have any presence in New Zealand, despite the lack of regulatory entry barriers to the New Zealand market. This suggests that regulatory barriers are a relatively minor issue compared to marketing considerations. As a result we believe the impact will be small.

Even if the nature of distributorship does change, the agency costs would not change much, as most of the costs pertain to post-market surveillance, the cost of which is more dependent on the number of different devices, rather than the number of licenses per medical device. But the distribution of the cost would then change, and be based more on the New Zealand's share of devices consumed compared to the combined Australian and New Zealand market (in other words, it would tend to 15%).

For the few New Zealand manufacturers of medical devices who also export to Australia, the impact should be neutral compared to the status quo, as they already pay TGA fees. JTA fees are likely to be in the same ball-park, although economies of scale and scope may reduce them over time.

As explained above (section 6.3), the issue is what share of the JTA's medical device budget would be faced by New Zealand. We estimate this to be around \$5.9 million.

Other industry compliance costs (staff time per application and delays to market) are lower under this option, compared to the other two new options– a midpoint estimate of \$2.4m per annum compared to \$3m. This is because an estimated 15% of products by value are exports to or imports from Australia, so that these do not face additional compliance activities. Total compliance costs to New Zealand industry would thus be about \$8.3m, or 1.25% of industry turnover.

If we assume that the nature of distributorships changes, so that distributorships are always for NZ *and* Australia, then New Zealand's share of agency costs would reduce to 15%. Assuming also that half of these distributors are based in NZ, then total compliance costs incurred in NZ would be \$3m, or 0.5% of industry turnover.

### **b) Impact on consumers**

The impacts on consumers will be similar as that described under option 2, but the compliance costs that may be passed on are somewhat lower.

### **c) Impact on Government**

The impacts on Government will be similar as that described under option 2, but the compliance costs that may be passed on through hospital budgets are somewhat lower.

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## 8. CONCLUSIONS

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Given the costs of compliance, whether any change from the Counterfactual is seen to be of net benefit to New Zealand or not depends on:

- €# a judgement of the additional benefits to consumer health and safety and the value of better information to consumers; and
- €# a judgement of the value to New Zealand of potential additional trade opportunities, and improved trans-Tasman and international relationships.

This trade-off is not that clear for medical devices and complementary healthcare products, and strongly depends on a judgement of the emerging risk profile, whether added regulation in New Zealand can influence this, and how much society values the risk reduction. No data is available to assess the magnitude of these factors.

Given the degree of uncertainty, the decision on whether the regulatory framework needs to be extended involves a qualitative assessment about how well consumers are equipped to deal with the risks, the ability to rectify harm (and the relevance of the precautionary principle), the perceived bias of producers to understate risks or regulators to over-regulate, how much risk reduction is valued, and different notions of liberty and responsibility.

With these caveats, the overall conclusion is that, relative to the other regimes considered in this paper, a move to a JTA has the potential to yield a small net benefit to government, industry, consumers and other stakeholders in both countries.

# APPENDIX A: INDUSTRY STATISTICS

**Table 11: Therapeutics sector New Zealand (NZ\$) 2001<sup>(1)</sup>**

Sector	Activity	Annual sales	Exports	Imports	Household Spending (3)
Medicines sector (2)	About 78 local distributors, supplying goods from 150 manufacturers to the local market. 30 licensed manufacturing sites, including 6 producers of blood products.	About \$900 million per annum – \$805m prescription and about \$100 million OTC medicines. Local manufacturing of medicinal and pharmaceutical products for human and veterinary consumption was about \$315m in 1999 (Stats NZ). Recent industry turnover data of the three key manufacturers indicate local pharmaceutical <i>manufacturing</i> is just over \$100m in 2001.	\$20m (4)	\$815m	\$249m
Medical devices	160 -170 distributors, and 10 local manufacturers, incl. F&P Healthcare sales of \$194 m in 00/01	Total annual sales around \$660 million, including \$475 million ex GST p.a. to public hospitals (incl. diagnostics, implants and prostheses, instruments, patient appliances, and disposables).	\$200m (5)	\$459m (1)	\$26m
Complementary healthcare products	Numbers unknown. 10 large to medium sized manufacturers 11 major importers/ distributors  In addition, possibly up to 100 small cottage-type manufacturers, and 100 smaller distributors and direct marketing firms (6)	Based on total annual sales of \$92m to households and export and import data, local production is imputed to be between \$85m and \$100 m. Industry sources suggested total sales of \$120 million (with local manufacturing of \$60million), suggesting local production of between \$113 and 135m. Overall, it is assumed that sales are worth an estimated \$100m, with local production slightly less. Differences likely to be due to different product classifications.	\$43m (1)	\$50 m (1)	\$92m
<b>Totals</b>		<b>\$1,660 million</b>	<b>\$263m</b>	<b>\$1,324m</b>	<b>\$367m</b>

Notes: (1) 1999 data.

(2) Trade figures estimated based on industry-supplied information. Due to differences in classification, official statistics on trade from either side of the Tasman cannot be reconciled.

(3) Household Expenditure Survey.

(4) Estimates only.

(5) Estimated. Fisher & Paykel HealthCare exports for 00/01 were about \$184 million alone.

(6) Estimated from industry sources, yellow pages and internet. Data sources conflict and are incomplete.

Sources: Medsafe, Statistics New Zealand, Ministry of Foreign Affairs and Trade, Researched Medicines Industry, Non-Prescriptions Medicines Association, Medical Industry Association, National Nutritional Foods Association.

