

Regulatory impact analysis

**A single joint Australia and New Zealand
therapeutics goods agency**

Report to Working Group

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Preface

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- # and sometimes by external peer reviewers at the request of a client, although this usually entails additional cost.

Authorship

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We received important guidance and information from a range of officials in Australia and New Zealand, particularly from staff of the Therapeutics Goods Administration (TGA) and Medsafe. We are grateful for that, and for assistance and data provided by industry representatives in both countries.

EXECUTIVE SUMMARY

Conclusions

In July 2000, NZIER was commissioned to prepare a regulatory impact analysis of a move to a Single Joint Agency (SJA) to regulate therapeutic goods in Australia and New Zealand. Impacts were to be measured in three separable components.

- €# An analysis of the costs and benefits for Australia of setting up the proposed joint agency against the status quo.
- €# An analysis of the costs and benefits for New Zealand of setting up the proposed joint agency against the counterfactual of operation under proposed legislation to regulate medicines, medical devices and complementary medicines/healthcare products. (Option 1)
- €# An analysis of the costs and benefits for New Zealand of setting up the proposed joint agency against the counterfactual of operation under proposed legislation to regulate medicines, medical devices and complementary medicines/healthcare products, in a way which permits unilateral recognition by New Zealand of some other countries' certification. (Option 2)

Key conclusions are:

1. Use of therapeutic products involves risks to final consumers, the companies supplying these products, and the institutions and health professionals advising on their use.
2. Most countries have regulatory frameworks which support safe and effective use, and timely availability, of therapeutic products. These frameworks recognise the various risk dimensions facing both private and public sector stakeholders, including governments, as well as the economic costs of regulation.
3. Expansion of the range of therapeutic products, and their complexity, makes it increasingly difficult for small countries to maintain the necessary regulatory capacity.
4. New Zealand's current position in this regard is unsustainable. Medsafe rarely meets target times for pre-market approval of pharmaceuticals. It has limited regulatory oversight of medical devices and complementary medicines. The proposed new legislation in New Zealand would address some current difficulties.
5. Australia, through the Therapeutic Goods Administration, is currently in a much stronger position than New Zealand, in terms of regulatory capacity. But it faces similar problems in the next 5 to 10 years.
6. Relative to alternative regimes, there are potential net economic gains to government, industry, consumers and other stakeholders, in both countries, from a move to a SJA. But, these gains would, in themselves, be small.
7. More important support for the proposal, relative to the alternatives, comes from: its potential contribution to the collective regulatory capacity of the two countries in the medium and longer term; support for further convergence of regulatory arrangements under CER and the TTRMA; and possible benefits in terms of leveraging the regional standing of Australian regulatory arrangements and the Australian therapeutics industries.

General summary

The fundamental objective of regulatory agencies such as the TGA and Medsafe, and the proposed SJA, is to develop and implement frameworks for the quality, safety, efficacy, and timely availability of therapeutic products. The pace of change in international markets for these products means that it is increasingly difficult for small countries to maintain requisite regulatory capacity. Even such agencies as the US FDA will find this a challenge in coming years.

All regulation imposes economic costs, so important trade-offs have to be considered in the implementation of such regulations. For example, careful evaluation of a new product takes time – public health and safety comes at the cost of delayed access to final consumers, and reduced returns to suppliers.

These economic trade-offs and broader potential effects, such as on regional developments in therapeutics industries, are considered in this assessment of the SJA proposal. Although we have tried to provide quantities where possible, the assessment is largely qualitative. Important aspects to note are:

- ⌘ Our assessment of the SJA is not against the current regimes, but the regulatory options shown above. In New Zealand's case in particular, these represent major changes from the status quo.
- ⌘ Some difference in the starting positions of the two countries. Australia has greater regulatory capacity, relative to current demands, than New Zealand, as reflected in generally shorter turnaround times for approvals. Australia also has a substantial pharmaceutical manufacturing industry, whereas New Zealand's manufacturing industry is small.
- ⌘ In both countries, imports are the dominant source of therapeutic products. International manufacturers operate distribution activities in both countries, and there is a considerable degree of overlap between the two countries in terms of companies represented, and products supplied.

The overall conclusion from the assessment is that there are potential net economic gains to government, industry, consumers and other stakeholders, from a move to a SJA. But, these gains, relative to alternative regimes, would be small compared to the total size of the markets for therapeutics.

To the extent that the adoption of a SJA would enhance the collective regulatory capacity of the two countries, relative to alternative regimes, that represents a strong argument for its adoption. So, in this assessment, the non-quantifiable medium term public benefits from a move to a SJA would dominate the quantifiable economic gains.

Note: The pricing systems of both countries have been excluded from the scope of the Trans Tasman harmonisation project. Therefore, this study has not considered the PBS or Pharmac in assessing the costs or benefits of a SJA. As parallel importation would have a substantial impact on the integrity of pricing systems, the effects of this trade on the proposed model have also been excluded from this assessment.

Australia

Benefits:

Relative to the status quo the immediate economic benefits of this change would not be large. The new SJA might generate some scale economies from higher throughput of therapeutic approvals (Note that New Zealand does not currently

evaluate medical devices.), and this might be reflected in lower fees, than otherwise, in the longer term for Australian applicants. Further, the harmonisation envisaged represents some lowering of barriers to trade with New Zealand. This might lead to some additional gains to Australian based manufacturers or distributors, whose sales to New Zealand will be constrained by the separate regulatory options.

Medsafe operating separately from the TGA would probably process about 85% of the number of medicine approvals processed by the TGA. This overlap suggests some potential for operational economies with a SJA, which could be reflected in savings to Australian industry and reduced prices to consumers.

Under an SJA, Australian pharmaceutical companies which export to New Zealand would no longer have to submit applications for marketing approval in that country, hence there would be an immediate saving to them in regulatory costs. However, this same saving would not immediately apply to the complementary medicines or medical devices sectors. The proposed introduction of regulations in New Zealand will impose additional costs on Australian exporters of these products. So the SJA should offer them some savings in entering both markets, through a single application process.

The more important benefits to Australia would emerge in the medium term. The SJA would enhance Australia's regulatory capacity, and perhaps its global and regional standing as a centre of expertise. Such effects would be positive for consumers, government as the ultimate flagbearer, in safety and quality, and industry.

Costs:

Assuming the SJA adopts full cost recovery, the net fiscal costs of the SJA in a steady state, would be small. How this cost falls, in an ongoing sense, depends on industry and distribution structures in Australia and New Zealand and how they change in the lead up to and after establishment.

It is estimated that transitional costs equivalent to no more than 6% of annual combined expenditure of the TGA and Medsafe, would be incurred each year over about 3 years. This cost, i.e. about \$3 million per annum and \$10 million in total, could be met mainly by Australian and New Zealand governments, although there may be some partial cost recovery from industry.¹

New Zealand

Benefits:

The move to a SJA might represent a more substantial change for New Zealand than for Australia, depending on how long after implementation of proposed new legislation for regulation of medicines, medical devices and complementary medicines in New Zealand the move to a SJA occurred.

Relative to Option 1 (going it alone with new legislation) it offers benefits in the form of enhanced regulatory capacity, and possibly efficiency gains through faster processing times at the approval stage.

¹ All values in the report are in Australian dollars unless noted to the contrary.

Relative to Option 2 (new legislation plus unilateral recognition of some other countries' certification) the SJA would guarantee access to significantly greater regulatory capacity and information, and deliver greater confidence, to all stakeholders, in the management of public risk. From an external perspective, the SJA would imply higher regulatory standards and global standing for New Zealand products.

Adoption of Option 2 by New Zealand would put at risk all current regulatory co-operation with Australia, due to the potential impact on the level of public health protection provided by Australia, and the potential impact on Australia's reputation in the region.

Costs:

Charges to industry for approval of pharmaceuticals in New Zealand are currently below sustainable levels. At these levels, Medsafe's capacity to process approvals is severely constrained, as evidenced by approval periods. Further, Medsafe's costs have been held down to some extent by remuneration of outside experts at well-below market rates.

Hence, charges to industry for products that are only approved for, and sold in, the New Zealand market are likely to rise substantially, at least under Option 1, irrespective of any move to a SJA. The move to a SJA may involve further increases.

Responses by firms that distribute those products would vary, largely according to the size of additional imposts relative to turnover in the products affected. Likely economic effects include some degree of rationalisation of product lines and distribution structures, as between Australia and New Zealand. For the reasons already outlined, such rationalisation would only be attributable in part to the SJA; the new healthcare legislation in New Zealand would probably be a larger factor.

Caveats:

These conclusions are drawn on the basis of a largely qualitative decomposition of the possible effects of a move to an SJA, combined with various assumptions of how the markets for the various products operate. Given the range of products and distribution structures within the two markets, we cannot assume that the general assessments made will apply to all products and all parts of the therapeutics industry. The costs and benefits would depend not only on those factors, but also according to the operational details of the SJA, including evaluation standards and fees applied to products or product groups, relative to the various options for therapeutics regulation.²

The Terms of Reference for the Review seek analysis of several different aspects of the impact of a SJA. In the rest of this Executive Summary we provide an overview of our approach, and then brief reference to the various aspects.

² Industry responses to consultation about the SJA proposal are summarised in a separate report by officials: 'Report on Stakeholder Comment in response to the Consultation Paper: A Possible Framework for a Joint Trans-Tasman Agency to Regulate Therapeutic Goods (Including New Zealand Healthcare Products)' September 2000.

Overview

- €# This research considered options for regulation, in terms of safety, quality, and efficacy, of therapeutics goods used or being offered for use, in Australia and New Zealand. The product range is huge, but for these purposes has been condensed into three broad groups: pharmaceuticals, medical devices, and complementary medicines/healthcare products. Within each of these product sets is a wide spectrum of potential risks to consumers.
- €# Therapeutics goods regulation is complex and resource-intensive. Duplication of regulatory infrastructure in the two countries imposes costs on industry and the community. Australia and New Zealand are relatively small nations with a strong commitment to closer economic co-operation. The development of a single trans-Tasman therapeutics goods agency offers the opportunity for significant efficiencies in the medium to long-term.
- €# The proposal for a SJA is against the background of ongoing change in international industry structures and markets, including more complex products with potentially increased risks to public health and safety, growing consumer expectations, and thus more costly evaluation processes.
- €# Hence important underlying themes of this research are capacity to manage public health risk, the medium term options for small countries, and where the costs should fall.

Assessment of costs and benefits

- €# Therapeutics safety regulation is one of a number of ways in which governments influence the supply of and demand for therapeutic goods. Other important influences are government agencies as purchasers/subsidisers of medicines, intellectual property rules, and border controls.
- €# In assessing costs and benefits our aim has been to focus on the direct impacts of the proposed SJA, rather than indirect effects arising from interactions with other interventions. The direct effects of the SJA can be considered from the perspective of final consumers, industry groups, and governments – as purchasers and regulators.
- €# Some of the effects considered are theoretically quantifiable, but subject to major data constraints; others, such as possible effects on safety or international standing, are not amenable to measurement or valuation. And, importantly, we offer little numerically about price effects because of the difficulty of establishing price relativities, for products which are common to both markets. So the overall assessment is largely qualitative, with an attempt to identify the direction and relative scale of effects. As noted earlier, these effects are assessed relative to specific counterfactuals.
- €# Our understanding is that by volume or value, the products currently registered and supplied in New Zealand only would not be a large proportion of total markets for therapeutics in the two countries.
- €# The relative size of effects will differ as between Australia and New Zealand, and vary across product types, i.e. prescription medicines, OTC medicines, devices, and complementaries.

Impact on consumers, industry, and governments

We were asked, as part of the assessment, to consider the impact of a SJA on consumers, industry, professional groups, and the governments involved, including State and Territory Governments.

Summary findings are:

Australia

- €# The regulatory change, and its economic impacts on Australia, relative to the *status quo*, are fairly minor, because we assume that the functions of the SJA would be broadly equivalent to the combined functions of the TGA and Medsafe (as it will operate under new legislation). The main economic effects may be some lowering of entry barriers into the New Zealand market, some scale economies relative to the TGA, and hence potentially lower costs to industry than otherwise.
- €# For consumers in Australia, there seem unlikely to be significant changes in quality, for any of the product groups. Earlier availability of some products may result, particularly if the SJA enjoys enhanced global standing. Any price effects would be small, assuming cost imposts are minor and product markets remain competitive.
- €# For industry in Australia, which includes a substantial manufacturing base, the change offers increased market scale and scope, and some reduction in regulatory costs, relative to maintenance of the status quo.
- €# The net effect on the Australian government budget should be small, once a steady state is reached, assuming a continued policy of full cost recovery. However, the change will involve significant transitional costs, the larger part of which are assumed to be contributed by the Australian and New Zealand governments, and the remainder by industry.

New Zealand

Regulatory effects and economic impacts would be most marked on those products registered or marketed only in New Zealand at the time of transition to a SJA. To reiterate, Option 1 is new legislation in New Zealand with increased regulatory requirements; Option 2 is unilateral recognition of some other countries' certification.

- €# Relative to *Option 1*, the SJA might impose higher approval and monitoring costs than would apply under a New Zealand regime. This depends on the resources that would be required by Medsafe under Option 1, and the charging regime that would be adopted in New Zealand under this option. The effect of higher charges, on some product lines at least, would be to reduce the product range offered in New Zealand by some distributors. This would be an extension of effects likely to follow from the proposed new legislation in New Zealand, that is, would only be partially attributable to adoption of a SJA.
- €# Relative to *Option 2*, the additional resource costs resulting from the SJA would be greater than under the first counterfactual. The increment in fees to industry would consequently be slightly bigger than under Option 1.

Adoption of Option 2 could have adverse effects on international perceptions of New Zealand's standards in therapeutic products. Relative to this option, the SJA would result in benefits to New Zealand distributors and consumers in terms of early availability and product quality, and generally enhanced confidence in the

management of public risk. Effects on approval times would be highly variable, i.e. the SJA might increase them for some products, and reduce them for others.

- €# The net additional cost to the New Zealand government, relative to both Options, would depend on charging regimes, and the distribution of transitional costs, as between Australia and New Zealand, and government and industry.

Impacts on trade

- €# Relative to the *status quo*, the initial effects of the SJA on Australia's global trade in therapeutics seem likely to be minor. This is based on the assumption that the SJA will operate along similar lines to the TGA, and that factors, other than therapeutics regulation, are critical to determining the size and structure of trade. In the longer term, if the SJA helped establish Australia as a regional centre for therapeutics regulation, it might enhance the manufacturing base, and its potential for exporting.
- €# Effects of the SJA on bilateral trade flows might be more marked, especially from the New Zealand end, and particularly with respect to pharmaceuticals. We are assuming that the SJA will mean that most products previously registered in New Zealand only, or in both countries, will be distributed from Australia. So, assuming parallel imports from New Zealand to Australia are precluded, the balance, relative to either Option 1 or Option 2 in New Zealand, might swing towards increased exports from Australia to New Zealand, and reduced exports from New Zealand to Australia.³
- €# Against this, it would take only one or two of the larger Australian manufacturers to transfer part of their operation to New Zealand, to reverse the trade effects postulated above. For example, the shorter patent term in New Zealand for new products, means that an Australian manufacturer of generics could set up production in New Zealand five years before the patent expired in Australia. This is already possible in theory now, but under an SJA may be encouraged.

Regulatory capacity

- €# A major consideration is the complex high level expertise required for approval and registration purposes for therapeutic goods. This expertise is in short supply globally and is in high demand domestically in both Australia and New Zealand.
- €# Given the increasing pressure of demand for such skills and international opportunities for employment across the field, a pooling of expertise in the regulation of therapeutic goods both in-house and for expert external advice may carry significant advantages in providing future sustained regulatory capacity.
- €# The SJA would need to be structured in ways that would encourage maintenance and enhancement of expertise in source countries, whether across-the-board or through agreed specialisations.
- €# Longer term outcomes with respect to capacity are to some extent dependent on the development of the therapeutic good sector and particularly the pharmaceutical industry in the region, as discussed in the following sub-sections.

³ Parallel importing is the importation of a product by a third party who is not the authorised agent of the patent holder.

Regional effects - therapeutic sector development and conformance

An SJA would help Australia, in collaboration with New Zealand, remain a force in global drug evaluation, along with the USA, EU and Japan. There is regional and global benefit from retention of some alternatives to the US FDA, since otherwise US industry imperatives can even more come to dominate the global market

A joint presence would help secure a continued membership of this group and underpin a key role as a voice determining or influencing outcomes in regional (and global) co-operation on standards and conformance matters – with reinforcing benefit flowing back to local regulatory capacity and industrial capacity.

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1. INTRODUCTION

1.1 Background

Australian and New Zealand Ministers have agreed to explore the viability of establishing a single joint agency (SJA) to regulate therapeutic goods.¹ The objective of proceeding to establish such an agency would be to deliver a net benefit for consumers, industry and governments in both countries.

Therapeutics goods regulation is complex and resource-intensive. Duplication of regulatory infrastructure in the two countries imposes costs on industry and the community. Australia and New Zealand are relatively small nations with a strong commitment to closer economic co-operation. The development of a single trans-Tasman therapeutics goods agency offers the opportunity for significant efficiencies in the medium to long-term.

The proposal for a SJA is against the background of ongoing change in international industry structures and markets, including for example:

- ## Increased ownership concentration in pharmaceuticals manufacture.
- ## More complex products and thus more costly evaluation processes.
- ## Changing technology and processes for evaluation.
- ## Raised public expectations as to the efficacy of goods, combined with greater risk aversion.

There are two key issues to be addressed through the establishment of a single joint Australia and New Zealand therapeutic goods regulatory agency:

(a) *Resolution of the special exemption for therapeutic goods*

Therapeutic goods (including New Zealand healthcare products) have been given a special exemption from the Trans Tasman Mutual Recognition Agreement (TTMRA). A condition of the special exemption for therapeutic goods is a trans-Tasman co-operation programme, where Australian and New Zealand regulators collaborate to resolve the exemption. Under the provisions of the TTMRA this can be achieved through mutual recognition, harmonisation or permanent exemption.

Australian and New Zealand Health Ministers have previously agreed that harmonisation of regulatory requirements is likely to be the best option.²

Harmonisation for the purposes of this project has been defined as ‘a process whereby standards and requirements in participating countries are aligned, including product and manufacturing standards and conformance assessment requirements.’³

¹ We consider these goods in three broad categories – health care products (also referred to as complementaries) pharmaceuticals and medical devices. The common link is some positive effect, or purported effect, on human health.

² 1999 Therapeutic Goods Co-operation Program Report to the Council of Australian Governments including New Zealand.

³ Therapeutic Goods Administration and Ministry of Health, 1998, Discussion Paper for the Liaison Group for Closer Trans Tasman Co-operation Discussion.

The therapeutic goods special exemption also captures the scheduling of medicines. Scheduling is a process used in Australia and New Zealand to control the level of access, availability and supply of medicines (and veterinary medicines and poisons in Australia). Different scheduling requirements (or other regulatory mechanisms) for a product in the two countries can result in additional compliance costs for industry (such as for different labelling) which could be avoided if the regulatory requirements were harmonised. A scheduling harmonisation project has been in progress since 1998 with around 70% of the schedules in the two countries harmonised.

b) Ensuring sustainable therapeutic good regulatory capacity

The future assurance of therapeutic goods regulatory capacity of both countries is an important factor in the development of future regulatory arrangements for both countries and in considering the resolution of the special exemption. The technology and expertise required for specialised scientific appraisal is becoming increasingly more sophisticated and expensive. In the short term, this has implications for New Zealand's capacity to maintain the critical mass required to undertake evaluations of emerging technologies (such as those derived from gene technology and nanotechnology). In the longer term, these issues are also likely to impact on the efficiency of the Australian regulatory system. A single agency offers the opportunity to share the available skilled resources. This in turn will facilitate timely evaluation of products developed through new and emerging technologies, thereby benefiting both industry and consumers. (Refer Tender document, 2000, pp.3,4)

1.2 Terms of reference

NZIER has been commissioned to prepare a regulatory impact analysis of the establishment of such an agency. The terms of reference for the study specify the following matters to be covered:

1. Assessment of costs and benefits arising from the project including but not restricted to direct financial impacts.
2. Exploration of the impact on consumers (members of the public), industry, professional groups, and the governments involved, including State and Territory Governments.
3. The impact on both countries' trade, including impact on control systems for imports and exports.
4. The longer term impact of a joint agency on future sustained regulatory capacity for the two countries.
5. An examination of the economic impact such a strong and credible agency might have on the development of the therapeutic goods sector and more particularly the pharmaceutical industry in Australia and New Zealand and the region. This should take into account potential influence on the investment and structuring of the sector.
6. Implications of the proposal for regional co-operation on standards and conformance matters.

1.3 Deliverables

The analysis and report is to deliver three separable components:

- €# An analysis of the costs and benefits for Australia of setting up the proposed joint agency against the status quo.

- €# An analysis of the costs and benefits for New Zealand of setting up the proposed joint agency against the counterfactual of operation under proposed legislation to regulate medicines, medical devices and complementary medicines/healthcare products, where local evaluation of products is required. **(Option 1)**.
- €# An analysis of the costs and benefits for New Zealand of setting up the proposed joint agency against the counterfactual of operation under proposed legislation to regulate medicines, medical devices and complementary medicines/healthcare products, in a way which permits unilateral recognition by New Zealand of some other countries' certification. **(Option 2)**.

The assessment includes establishment costs, operation in transition, and in a steady state. The time horizon is the first three to five years after establishment.

1.4 Report coverage & structure

The project only extends to regulatory decisions on the safety, quality, timely availability and efficacy of therapeutic goods, and to the implementation of these decisions in both countries.

It is noted that that national priorities and approaches have resulted in different health and industry policy outcomes in the two countries. Accordingly, consideration of a joint agency excludes New Zealand's Pharmac and the Australian Pharmaceuticals Benefit Scheme from the scope of the project. Impacts on the implementation of pharmaceutical pricing policies have not been taken into account in assessing fiscal impacts in both countries.

The rest of this report comprises the following main sections:

2. Approach
3. Regulatory principles
4. Therapeutics regulation in Australia and New Zealand
5. Administrative structures
6. Industries and markets
7. Economic effects of therapeutics regulation
8. Economic impact of SJA
9. Cost benefit assessment – Australia
10. Cost benefit assessment – New Zealand
11. Flow-on effects of SJA

2. APPROACH

2.1 Principles adopted

In preparing this report we needed to cover a wide range of potentially relevant issues within a fairly tight timeframe. Given that exhaustive treatment was not possible, this called for adoption of some general principles to help prioritise, and put a boundary around, the topics researched and analysed.

Taking into account, *inter alia*, the terms of reference, ongoing changes in global markets for therapeutics, and the likely timeframe for moving to a SJA, we have given our main attention to:

1. Distinguishing between a) regulatory interventions, which are significant but not directly affected by the SJA proposal, and b) other regulatory interventions which could become mutually inconsistent and thus would have to change with adoption of a SJA.
2. The range of activities and performance standards likely to be adopted by a SJA, relative to the other regulatory options.
3. Other policies adopted - for example standards of evidence with respect to new medicines, influence of decisions in overseas markets, local industry development consideration - which may change decision-making rules, processes, and outcomes, relative to the options.
4. 'In-house' capacity and processing, relative to reliance on evaluations by offshore agencies.
5. Articulating what we understand to be the case now and what could apply in the future, for example, given global pressures such as industry concentration, evolving complexity of therapeutics, changing legislation in New Zealand, and activities of States and Territories relative to the Commonwealth Government in Australia.

With respect to item 1 in particular, we note that in the markets for pharmaceuticals, the government agencies Pharmaceutical Benefits System (PBS) in Australia and Pharmac in New Zealand have a major influence. While this may not be affected by the move to a SJA, there is potential for changes in the way these organisations operate, e.g. increased collaboration between them, which might be attributed to the move to the SJA. It is therefore important that we make clear the boundary around our analysis.

2.2 Conceptual structure

In evaluating whether it is worthwhile for society to pursue a particular policy or project, the predominant approach is via cost-benefit analysis (CBA). This compares costs and benefits beyond those captured in market transactions, and approves measures only where the benefits exceed the costs.

The focus is on net public benefit, taking into account possible trade-offs between the interests of consumers, producers, and other stakeholders including government.

CBA involves assigning a value to the stream of these costs and benefits over time. CBA recognises that social appraisals need not coincide with private appraisals. This is because of the existence of so-called 'externalities' - effects external to the private decision-maker - or benefits outside the observable market transactions.

Conducting a CBA involves:

- # identifying all relevant effects of a policy;
- # where possible, quantifying and valuing these effects, and classifying these as costs or benefits;
- # reducing effects which occur at different periods into commensurable monetary units, through a process such as discounting to present values;
- # testing the sensitivity of the results to changes in key values or assumptions made.

However, a full and rigorous application of the cost-benefit approach may not always be feasible. As in this case, the necessary data for many important dimensions of such an analysis may be lacking.

In such circumstances a cost-benefit assessment is required. This incorporates those factors reasonably capable of quantification along with systematic identification and qualitative review of other factors. This essentially gives a planning balance sheet for evaluation purposes and is, in practice, the most common way of proceeding other than for narrow and limited projects, e.g. dam or road construction.

In this paper both quantitative and qualitative assessment is used as necessary, within a general cost-benefit assessment framework.

2.3 Assessing regulatory impacts

In making an assessment of regulatory impact, two options are under consideration:

1. The establishment of a single joint trans-Tasman therapeutics goods agency based on harmonised regulatory arrangements.
2. The maintenance, under the TTRMA, of the separate regulatory arrangements in each country through the adoption of a permanent exemption that:
 - a) For Australia would involve the continuation of current regulatory arrangements;
 - b) For New Zealand would involve the adoption of a system based on a new therapeutics and healthcare legislation which either requires local evaluation of products (Option 1) or introduces unilateral recognition of products approved by other regulatory authorities in place of local evaluation (Option 2).

Our approach for this assessment divides the research and analysis into three broad topic areas, based on assumed direct effects of a move to a SJA:

1. **Administrative efficiency of service provision.** Here we consider, for example, potential for cost reductions and improved service delivery. Based on these, we consider fiscal implications for governments in Australia (Commonwealth, States, and Territories) and for New Zealand. This also refers to the effectiveness of the various regimes - to what extent do they provide government with confidence in their efficacy as in managing safety and other risks such as litigation associated with approval and use of therapeutic products.

2. **Impacts on industries and markets.** For example, what would be the implications for competition in the trans-Tasman market for therapeutic goods and of possible economies of scale in the trans-Tasman industry? The latter is pertinent to prospects for the industry in a wider Asia/Pacific context. In the context of international fora, such as the WTO, what are the implications in terms of export certification?
3. **Community welfare.** What would be the effects felt by consumers, and other stakeholders such as medical professionals, in terms of prices, safety, quality, timely availability and efficacy of therapeutic goods in both countries? What are the effects on public and professional confidence in the regulatory system, for example of reliance on 'second-hand' information, as implied by Option 2 in New Zealand.

As in most studies of this type, a limited degree of quantification is feasible. Our main aim is to point out the likely direction of change in the various components of net public benefit, and provide guidance as to how their likely relative size might be judged.

3. REGULATORY PRINCIPLES

This section provides general background to the consideration of therapeutics regulation in the next section, and the broader assessment of regulatory impacts in later sections.

The term regulation usually refers to partial or complete intervention in economic decision-making by the government or one of its agencies. The usual justification for this departure from free market principles is market failure. However, the potential for government failure is recognised i.e. market failure is a necessary but not sufficient condition for regulatory intervention in all cases. Hence, doing nothing can be an option.

The standard reasons given for regulation are to control the effects of monopoly power and of externalities. But the other main reason is the high cost to individuals of obtaining and interpreting information relating to product safety and design. This is one of the key justifications for organisations such as those which regulate supply of therapeutic products - the Therapeutics Goods Administration (TGA) in Australia, and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) in New Zealand.

By contrast, the monopsony purchasers of pharmaceuticals, such as the PBS and Pharmac, offer economies of scale and scope, information gathering ability, and countervailing power in the face of large and complex purchasing arrangements. They have different 'terms of reference' but both have major impacts on the returns to suppliers, prices to consumer, and choice. The major forms of government intervention, include:

- €# Using taxes and subsidies to alter incentives;
- €# Establishing rules;
- €# Supplying goods or services through non-market mechanisms;
- €# Creation of public enterprises to run activities that are natural monopolies;
- €# Price controls.

Each intervention aims to produce a social benefit but involves costs to achieve the desired outcome. The marginal social costs include all the additional costs incurred as a result of the intervention and include:

- €# Development, enforcement and administrative costs.
- €# Compliance costs, initially borne by the targets of the intervention.⁴
- €# Allocative (efficiency) costs, where allocative efficiency is the production of the 'best' or optimal combination of outputs by means of the most efficient combination of inputs.⁵

⁴ The terms 'compliance costs' refers to the costs to affected parties of interacting with government in meeting an obligation or obtaining a services. However, there are various views on what costs should be captured. Compliance costs include the costs to affected parties of understanding their obligations, and the processing and providing of information. They may also include the direct costs of an obligation e.g. on investment/employment decisions of the affected firm; the purchase of equipment to meet a safety standard; the costs of training to meet an occupational requirement; or fees associated with the obligation. (NZIER, 1998, p.17)

€# Dynamic efficiency costs, i.e. on innovation/investment.

⁵ Optimal output might be determined in various ways but in analysis of net public benefits, of a regulatory change for example, is generally held to be that output combination which would be chosen by individual consumers responding in perfect markets to prices which reflect true costs of production. The efficient combination of inputs is that which produces outputs at the least opportunity cost. The use of inputs in this manner is sometimes referred to as technical efficiency.

4. THERAPEUTICS REGULATION IN AUSTRALIA & NEW ZEALAND

4.1 Overview

The economics of the healthcare and therapeutics goods industries in Australia and New Zealand can be seen as being shaped by regulation, and by a whole set of non-regulatory influences. The logic of the analysis is to focus on the effects of administrative and regulatory change implicit in the proposed SJA.

The range of regulated products is medicines, medical devices and complementary medicines/healthcare products (such as vitamins). This includes specialised medicinal products such as gene technology products and blood and blood products. While New Zealand does not currently regulate medical devices and complementary medicines/healthcare products to the same extent as in Australia, it plans to introduce legislation to do so in future. This is taken as given for this study.

Australia is considering further enhanced regulation of medical devices, particularly in the light of a Mutual Recognition Agreement between Australia and the EU and the work of the medical device Global Harmonisation TaskForce.

The Australian Therapeutic Goods Act 1989 and its associated regulations cover not only medicines but also medical devices and complementary medicines/healthcare products. The TGA regulates the supply of therapeutic goods through five main processes:

- €# Pre-market evaluation and approval of registered products intended for supply in Australia;
- €# Licensing of manufacturers;
- €# Post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries;
- €# Development, maintenance and monitoring of the systems for listing of medicines; and
- €# Assessment of medicines for export.

‘The regulatory framework for medicines in New Zealand remains based on three ageing and disparate pieces of legislation: the Medicines Act 1981, which deals with pharmaceuticals, the Food Act, which deals with dietary supplements, and the Misuse of Drugs Act 1975. The current legislation does not adequately regulate complementary medicines or medical devices.’ (1999 Co-operation Report, p.8.)

In New Zealand, Medsafe undertakes substantially the same regulatory functions for medicines as the TGA undertakes in Australia, with the following specific exceptions:

- €# Medsafe undertakes some activities performed by the States and Territories in Australia. For example, Medsafe is responsible for monitoring aberrant prescribers, auditing and licensing medicine wholesalers and for quality audits of pharmacies. These are activities performed by the States and Territories in Australia.

≠ The TGA also performs activities that are not undertaken by Medsafe, such as chemical assessments. An example of functions performed by the TGA but not Medsafe, is assessing and advising on agricultural and veterinary chemicals. In New Zealand, this assessment is the responsibility of the Ministry of Agriculture in conjunction with the Environmental Risk Management Authority.

Australia and New Zealand use a very similar framework for the regulation of medicines, which is consistent with global harmonisation initiatives. Current differences of approach are mostly at the operational level.⁶

4.2 Australian regulation

The Australian community has an expectation that therapeutic goods are safe and of a high quality, to a standard equal to that of comparable countries.

The objective of the Therapeutic Goods Act 1989 is to provide a national framework for the regulation of medicinal products and medical devices in Australia so as to ensure their quality, safety, and timely availability, while keeping the regulatory impact on business to a minimum. This is achieved through a risk management approach which includes pre-market evaluation and approval of therapeutic products, licensing of manufacturers and post-market surveillance. In addition, the TGA aims to minimise potential public health risks posed by chemicals used in the community. This is achieved by providing advice to other regulatory authorities on toxicology, pre-market assessment and public health issues relating to agricultural, veterinary and industrial chemicals.

4.2.1 Listing and registration of medicinal products

The Therapeutic Goods Act 1989 prescribes the requirements for inclusion in the Australian Register of Therapeutic Goods (ARTG), and, together with its associated regulations, set out the steps, time frames and fees for the evaluation processes.

Essentially, any product for which therapeutic claims are made must be either *listed* or *registered* in the ARTG before it can be supplied in Australia. While devices are included in this regulatory regime, the processes by which they are listed or registered are different from those for medicines, which are described below.

Listed medicines are considered to be of lower risk than *registered medicines*. The majority of listed medicines are self-selected by consumers and used for self-treatment. Listed medicines contain well known established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. These products are assessed by the TGA for quality and safety but not efficacy. It is a requirement under the Act that sponsors hold information to substantiate all of their product claims.

Medicines assessed as having a higher level of risk must be registered (not listed). The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data. In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical

⁶ There remain some distinctions between the two countries in terms of governance rules. These are potential entry barriers, or at least influences on the way distribution is organised. Under Australian company law, if a company has one director, then that director must be ordinarily resident in Australia. If the company has two or more directors, then one director must be ordinarily resident in Australia. There is no such residency requirement in the New Zealand legislation. However, the Medicines Act requires that the sponsor of a product be resident in New Zealand.

condition for which the product is intended to be used, is taken into account. Medicines are evaluated as either 'high risk' (prescription medicines) or 'low risk' (non-prescription) medicines. Those medicines which are for export only are listed (not registered) in the ARTG.

4.2.2 Complementary medicines

Complementary medicines, including vitamin, herbal, aromatherapy and homeopathic products, may be either registered or listed, depending on their ingredients and the claims made. Most complementary medicines are listed in the ARTG and some are registered.

4.2.3 Registration and listing of medical devices

Medical devices are currently regulated under a similar risk-based regime to medicines and complementary medicines. High risk medical devices are required to be evaluated for safety, quality and efficacy prior to marketing approval being granted, while lower risk products are listed subject to meeting safety and quality standards.

Australia proposes to introduce amendments to the Therapeutic Goods Act and Regulations that will establish new regulatory requirements for medical devices. The changes will be based on the principles set by the Global Harmonisation Taskforce and the EU Medical Devices Directives and are expected to be in place by mid 2001.

Good manufacturing practice

Australian manufacturers of therapeutic goods must be licensed under the Act and their manufacturing processes must comply with principles of Good Manufacturing Practice (GMP), unless exempt. The aim of these regulations is to protect public health by ensuring that therapeutic goods meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants.

4.2.4 Drugs and poisons

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) lists drugs and poisons according to the recommended restrictions on their availability to the public. The reasons for such restriction include toxicity, safety, and the risks and benefits associated with the use of the product. The categories which are most relevant to medicines on the ARTG are: controlled drugs (Schedule 8), prescription only medicines (Schedule 4), non-prescription medicines for supply by pharmacist only (Schedule 3) and non-prescription pharmacy medicines (Schedule 2). Medicines which are not scheduled in the SUSDP can be sold through any distribution outlet such as a supermarket or health food store. The SUSDP also encompasses restrictions on related matters such as labelling, packaging and advertising.

The National Drugs and Poisons Schedule Committee (NDPSC) makes scheduling decisions in relation to new substances, new presentations of substances already in the Schedules, and rescheduling of substances already in the SUSDP. The NDPSC includes representatives from all Australian jurisdictions and New Zealand, as well as industry, consumers and professionals. The wholesale and retail supply of therapeutic goods is regulated under the relevant State and Territory legislation. Generally, NDPSC decisions are adopted by all the States and Territories either by reference or by orders published in the gazette of the relevant jurisdiction.

It should be noted that the scheduling committees in both Australia and New Zealand are discussing proposals for aligning their processes.

4.2.5 Advertising and labelling

The Act and its associated regulations also govern the appearance and content of labels and advertising, for which there is a specific *Therapeutic Goods Advertising Code*. But implementation in law of most packaging, labelling, storage and handling requirements for these products, operates under State and Territory legislation. This latter is currently the subject of review under a National Competition Policy national inquiry.

4.2.6 TGA budget and activity data

TGA's global budget estimates for 2000-01 have been allocated between the categories of goods as follows:

£#	Prescription medicines (pre and post market)	\$27.4m
£#	OTC (pre and post market)	\$3.7m
£#	Listable medicines (pre and post market)	\$4.8m
£#	Medical devices (pre and post market)	\$6.9m
£#	Good Manufacturing Practice	\$2.5m

Overall, TGA has steadily increased the number of applications it processes each year, as can be seen in the table below. Since 1995-96, there has been proportionally greater growth in some types than others, e.g. applications for registrable therapeutic devices have doubled, and those for listable medicines and listable therapeutic devices by almost 40%. By contrast, the annual number of applications for export only medicines has remained fairly constant over the same period.

Table 1: TGA applications by type

Type of application	1995-96	1996-97	1997-98	1998-99	%change over period
Prescription medicines	806	993	1,006	1,133	28.8
Note: The TGA does not record any notifications (including minor changes) in their prescription medicines reporting whereas Medsafe does.					
Non-prescription medicines	420	420	556	540	22.2
Low risk non-prescription medicines (listable medicines)	2,173	2,176	3,052	3,564	39.0
Export only medicines	518	506	451	517	0.0
Therapeutic devices subject to evaluation (registrable devices)	72	140	187	144	100.0
Therapeutic devices not subject to evaluation (listable devices)	1,830	2,143	2,525	2,334	21.6
Certificate of Pharmaceutical Product	2,263	3,027	2,643	3,748	39.6
Source: TGA Annual Report 1998-99					

4.3 New Zealand regulation

4.3.1 Medsafe's role

Medsafe is responsible for administering the Medicines Act 1981 and Regulations 1984 and parts of the Misuse of Drugs Act and Regulations 1977.

The pre-market approval system for medicines is managed by Medsafe. The subsidisation of medicines is managed by Pharmac on behalf of the Health Funding Authority. Medsafe and Pharmac work independently and Medsafe is not involved in funding issues.

Post-market surveillance monitors the safety of medicines and medical devices in use. Products shown to be unsafe are removed from use, and prescribers are advised about new safety information for products.

Medsafe is responsible for applying a framework of controls designed to ensure that the therapeutic products available in New Zealand can be expected to have greater benefits than risks if used appropriately. This approach to regulating therapeutic products is applied by regulatory agencies internationally, and is consistent with guidelines for drug regulatory authorities published by the World Health Organisation.

The products used for therapeutic purposes which Medsafe regulates to varying extents includes:

- €# Medicines
- €# Related products
- €# Medical devices (generally relates to recall of products)
- €# Controlled drugs used as medicines.

At present Medsafe's testing and pre-approval function is mainly concentrated in medicines. Under the current regime in New Zealand, for example, complementary medicines are covered by food safety legislation. Under proposed new legislation, such products will be brought under the umbrella of therapeutics regulation. Any efficacy claims for such products will have to be substantiated to standards comparable to those applied in Australia for similar products.

Risk-based controls on medical devices would also be introduced under the new proposed New Zealand legislation. They are planned to broadly harmonise with the proposed new Australian EU principles-based regulatory requirements for these products.

4.3.2 Proposed legislation

In November 1994, following an extensive period of policy development and public consultation, proposals were developed for new legislation – a Healthcare and Therapeutics Products Bill.

New Zealand’s proposed healthcare and therapeutic products legislation will introduce new controls on medical devices and complementary medicines/healthcare products. Controls on medical devices will be consistent with those adopted by Australia and based on globally harmonised standards. The legislation will also align the food/therapeutics interface with Australia by regulating healthcare products as therapeutics. This will close, but not eliminate, the legislative and functional differences between the two countries.

It is intended that this change will proceed irrespective of the adoption of a SJA.

4.3.3 Medsafe activity and performance data

The volume and mix of applications received in the year to June 2000 remain similar to those received in the previous year.

Table 2: Medsafe applications by type

Category	July 1998-June 1999				July 1999 – June 2000			
	Change	New	Self-assessable	Total	Change	New	Self-assessable	Total
Prescription Medicines	1534	279	295	2108	1829	271	11	2111
Non-prescription	523	126	146	795	526	91	6	623
Not yet classified	0	0	0	0	8	4	0	12
Total	2057	405	441	2903	2363	366	17	2746

Note: May not be comparable with TGA data. See note to Table 1.
Source: Medsafe

Evaluation statistics show that in the year to June 2000, Medsafe met target times for between 30% and 40% of applications in generics, or new high-risk medicines, and about 66% of OTC product applications.

Medsafe currently provides priority assessment of some generic medicines when requested by Pharmac, in support of cost-savings in government pharmaceutical expenditure. In effect, such medicines are allowed to ‘queue jump’.

5. ADMINISTRATIVE STRUCTURES

5.1 Australia

The TGA's operations are fully funded by cost recovery from industry, through charges and fees for services. The cost recovery applies to all activities within the scope of the Act, including industry regulation and the TGA's responsibilities both in public health and as part of a Commonwealth agency, such as providing Ministerial advice.

Table 3: TGA Budget Figures

Operating Expenses		2000/01 (estimate)
Employees		26,780,089
Suppliers		16,411,456
Depreciation and amortisation		.2,248,080
Net loss from sale of assets		
Total Operating Expenses		45,439,625

Revenues from independent sources		2000/01 (estimate)
Revenue for services		45,795,795
Interest		369,510
Other Revenue		475,272
Total revenue from independent sources		46,640,577

The Departmental services provided to the TGA 2000/2001 are estimated at \$4.6 million for a range of corporate services including payroll, training and development, financial and human resource management information systems and information technology systems.

The TGA's non-financial assets of infrastructure, plant and equipment net value in 2000/2001 is estimated at \$6.8 million⁴⁴. These assets include, for example, laboratory and office equipment, furniture and fittings and leasehold improvements.

In 2000/2000/ the TGA has budgeted to employ an average of 375 FTE staff.

5.1.1 Medsafe's budget

Budget figures for the latest financial year are summarised in the following table. These are based on a current staff complement of 52. This is about 10% of the TGA's staff complement.

Table 4: Medsafe budget 1999/2000

	\$000
Crown funding(1)	2595
Third party revenue	3962
Total revenue	6557
Personnel costs	2908
Operating costs	2956
Depreciation	308
Corporate overheads and capital	385
Total expenses (2)	6557

Notes: (1) Part of Crown funding is for activities which in Australia are conducted by State governments, and thus might not be transferred over to a SJA.

(2) Expenses held down to some extent by the arrangement under which Medsafe receives free from TGA, evaluation reports for prescription medicines.

Source: Medsafe

Medsafe's business income is dependent on a mix of Crown funding and industry fees. The Medicines Act 1981 does not permit fees to be collected for many activities, which could be paid for by industry. The funding mix in 1999/2000 comprised about 40% Crown revenue, 47% evaluation revenue and 13% other third party revenue. (Medsafe, February 2000, p.22).

The Crown contribution is intended to cover activities not linked to the evaluation of medicines. The major component of other revenue is derived from fees paid by pharmaceutical companies for the evaluation of new and changed medicines and related products. Other sources of third party revenue include fees paid by industry for licences and special audits, and payment for audits of hospital and retail pharmacies conducted on behalf of the Pharmaceutical Society and the Health Funding Authority.

The TGA's operations are fully funded by cost recovery from industry, through charges and fees for services. The cost recovery applies to all activities within the scope of the Act, including industry regulation and the TGA's responsibilities both in public health and as part of a Commonwealth agency, such as providing Ministerial advice.

d the Health Funding Authority.

5.2 Harmonisation and CER

Australian and New Zealand Health Ministers have previously agreed that harmonisation of regulatory requirements is likely to be the best option for resolving

the special exemption for therapeutic goods under the TTRMA.⁷ Harmonisation for the purposes of this project has been defined as a 'process whereby standards and requirements in participating countries are aligned, including product and manufacturing standards and conformance assessment requirements.'⁸

CER originally just 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 in Trade in Services to the ANZCERTA. Elimination of tariffs was achieved five years ahead of schedule in 1990. Initially, this Agreement was subject to a list of exceptions, but this has now been whittled down to eight.

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 agreement has now been in force for a couple of years, and encompasses amongst other things, occupational entry, and joint food standards. The Joint Foods Standards Treaty (1995) establishes the joint foods standard system.

In relation to this report, it is important to record that Australian and New Zealand Health Ministers concluded in the 1998 Therapeutic Goods Co-operation Report under the Trans Tasman Mutual Recognition Arrangement, that:

"Mutual recognition in any area of the program is not acceptable at this time, or in the future, unless there are significant changes in the legislative framework that lead to a greater convergence in regulatory arrangements in the two countries." (p.28)

This was re-affirmed in the 1999 Therapeutic Goods Co-operation Report also – and so is taken as a given for the purposes of this current report. Hence mutual recognition is not one of the options for further consideration here.

5.3 International treaties and agreements

TGA participates in international harmonisation initiatives which enable Australia to be exposed to current trends and new technologies, and to further the harmonisation of Australian regulation of therapeutic goods with comparable countries. For example, Australia has representatives on the Global Harmonisation Task Force and associated Study Groups, which include the European Union, United States, Canada, and Japan, dealing with the development of standards for international medical device harmonisation.

Bilateral agreements covering the exchange of evaluation reports and information on drugs under evaluation exist between Australia, Canada, and New Zealand. Australia and New Zealand are members of the Pharmaceutical Evaluation Reports (PER) Scheme for the supply of evaluation reports on pharmaceuticals. PER was established by the European Free Trade Association countries in 1980, and over time has become less useful to Australia with the advent of the European Medicines Evaluation Agency (EMA).

The TGA's capability to assess medical devices to European standards has been specified in the Mutual Recognition Agreement (MRA) with the European Union in

⁷ Therapeutics Goods Cooperation Programme (1999) 'Report to Council of Australian Governments including New Zealand.'

⁸ Therapeutics Goods Administration and Ministry of Health (1998) 'Discussion paper for the Liaison Group for Closer Trans Tasman Cooperation.'

relation to medical devices, which took effect from the beginning of 1999. New Zealand has a similar MRA with the EU with respect to medical devices.

Australia and New Zealand have signed an international convention covering border control of narcotics.

5.4 Pharmaceutical Benefits Scheme

The Australian Pharmaceutical Benefits Scheme has been in operation for 50 years. It provides subsidy for a wide range of medicines for all consumers, whilst targeting extra assistance to those most in need via concessional co-payment and safety net provisions.

It provides one of the four elements of a so-called National Medicines Policy Framework, the other elements being : supply of medicines of acceptable quality, safety and efficacy; quality use of medicines by providers and consumers; and maintenance of a viable pharmaceutical industry in Australia. Its own objective is to provide equity of access to necessary medicines, in a timely, reliable and affordable manner.

The Scheme covers 559 drug substances available as 1354 items and marketed as 1992 brands. In 1998-99 the PBS dealt with 128.9 million benefit prescriptions at a cost to government of \$3069.7 million. Patient co-payments added \$601.3 million. Average dispensed price of PBS medicines was \$26.35, and average cost to government was \$21.68. Government expenditure on concessional benefits represented 80% of total government cost.

Under the structure of the Scheme, the supplier receives 90% of the Government agreed price to the pharmacist, the wholesaler gets 10% of that price and the pharmacist receives a mark-up of 10%, except for prices above \$360 where the mark-up falls to 5%. There are also certain fees and allowances paid to pharmacists.

Admission of drugs to the PBS, given TGA market approval, is through the Pharmaceutical Benefits Pricing Authority and the Pharmaceutical Benefits Advisory Committee for Minister's approval and subsequent admission to the Pharmaceutical Benefits Schedule.

Under the PBS, the government exerts considerable market power over the supply of drugs affecting both the price it pays, the companies' willingness to supply pharmaceuticals on government terms, and hence on their availability to the wider community.

5.5 Medsafe

In New Zealand, as in most other countries, the government has a major role in the market for therapeutics. This is through two principal organisations - Medsafe and Pharmaceutical Management Agency Ltd (Pharmac).

Medsafe depends on a mixture of industry and crown funding, and on medical and other scientific expertise drawn from around New Zealand to advise on therapeutics. Given the complexity of new pharmaceuticals, it is becoming increasingly difficult for a small country like New Zealand to sustain an adequate independent approval and monitoring capability.

Medsafe is part of the Public Health Directorate of the Ministry of Health and is directly responsible to the Deputy Director-General of this Directorate. Medsafe operates out of four sites nation-wide, with centralised administrative functions and standards setting based at the head office in Wellington.

The **Evaluation** team focus is on providing advice to the Minister and the Director-General of Health on the safety, efficacy and quality of medicines and related products proposed for distribution in New Zealand.

The **Compliance** team focus is on ensuring that therapeutic products and persons involved in their manufacture, distribution, and prescription, comply with legislative requirements and Codes of Practice to maintain the integrity of the distribution chain.

The **Business Development and Support** team focus is on developing Medsafe's operational and strategic policy, and managing pharmacovigilance, medicine classification, communication and information services. The team also has a role in supporting the work and management of the Evaluation and Compliance teams.

The statutory role of Medical Officer of Health is shared by the Chief Advisor, Safety and Regulation who is based at the Ministry of Health in Wellington, and by the Medical Officer of Health based in the Northern Medicines Control Office in Auckland.

To assist Medsafe fulfil its regulatory responsibilities and obligations, certain services are undertaken via contracts. These services include:

- €# expert technical advice
- €# scientific analysis and advice
- €# adverse reactions monitoring
- €# prosecutions
- €# computer software development and IT services in relation to specialised business needs.

5.6 Pharmac

The Pharmaceutical Management Agency Limited (Pharmac) manages the New Zealand Pharmaceutical Schedule on behalf of its owner - the Health Funding Authority (HFA). The Pharmaceutical Schedule is the list of all subsidised medicines, along with any restrictions on eligibility for subsidy. The Government subsidy means patients pay, on average, only a small proportion of the full cost of their medicine.

Pharmac aims to get the best value (in terms of health gain) from the Government's expenditure on Pharmaceuticals when deciding which drugs should be subsidised, and at what levels. In addition, Pharmac seeks to balance the needs of patients for equitable access to health care with the needs of taxpayers for responsible management of the costs they ultimately bear.

The Pharmac Board makes the decisions on listing, subsidy levels, and prescribing guidelines and conditions, with input from independent medical experts on the Pharmacology and Therapeutic Advisory Committee (PTAC) and its specialist sub-committees, and Pharmac's managers and analysts. Pharmac's decisions are made with regard to Pharmac's Decision Criteria.

Suppliers may apply to Pharmac to have a medicine listed on the Pharmaceutical Schedule for subsidy, conditional upon Ministry of Health (Medsafe) marketing approval of the product.

Pharmac's core activity is the review and publication of regular updates of the Pharmaceutical Schedule. This involves continual assessment of drug effectiveness and cost, and transacting with pharmaceutical companies.

Priorities for Pharmac activities are set by taking into account: known patient needs, feedback from PTAC and other medical groups, commercial opportunities and reports of the National Health Committee.

6. INDUSTRIES AND MARKETS

6.1 Global trends

The global therapeutic goods industry is large and fast-growing. Global pharmaceutical sales alone are about \$A400 billion.⁹ As scientific knowledge increases and as populations age, the growth trend of past decades is expected to continue to be sustained.

In developed countries, four key features commonly characterise the sector:

- ⌘ Importance of R&D and patent protection
- ⌘ Operations can involve both high risks and high returns
- ⌘ Presence of major international companies
- ⌘ Heavy government regulation and involvement.

Recent predictions by major innovators in pharmaceuticals indicate a rapidly growing workload for regulators over the next few years. This in turn calls for international collaboration by regulators to make effective use of agency resources, and to enable adaptation to changing demands and regulatory processes. (Gannaway, 1999).

6.2 Australia

For the community the use of medications and related goods is the most common health-related action taken by people. The 1990 and 1995 National Health Surveys found as follows:

Table 5: Australia - persons taking health-related actions

Action	1990 (%)	1995(%)
Medications	64.1	59.1
Vitamins/minerals	23.3	25.8
Herbal/natural	n.a.	9.4
Professional consultations	29.9	33.4

Source: ABS 4377.0

The key findings are the extensive use of therapeutic goods for health and the growing use of vitamins, minerals, herbal and natural preparations vis-à-vis conventional medications.¹⁰

⁹ IMS Health *Quarterly Indicator* Volume 1, Issue 1, 2000.

¹⁰ G.M. Shenfield et al "Alternative Medicine: an Expanding Health Industry", *Medical Journal of Australia*, v.166, 1997, pp. 516-517.

In economic terms, over the same period, the sector represented the following average weekly expenditure per household:

Table 6: Australia – annual household expenditure on therapeutic products

	1989 (\$m)	1994 (\$m)	1999 (\$m)
Prescriptions	372	747	1089
Proprietary pain relievers	104	169	185
Proprietary ointments and lotions	175	193	267
Proprietary medicines n.e.c. (including vitamins)	330	575	937
Creams, tablets	130	285	311
Surgical dressings	62	69	78
Therapeutic appliances	79	100	130
Total medicines, pharmaceutical products, therapeutic appliances and equipment	1252	2138	2997
Source: ABS 6535.0			

Of course, household expenditure is not the whole market. In addition to private household consumption, there are major purchases by governments and professionals, e.g. pharmaceutical subsidies to pharmacists, supply of hospitals and medical surgeries.

6.2.1 Pharmaceuticals

On the production side a strong local industry provided the major part of supply for this consumption. The Australian Bureau of Statistics records medicinal and pharmaceutical product manufacturing as follows for the latest data available (June 1998):

- €# Employment: 12,500 persons
- €# Wages and salaries: \$578.8m
- €# Turnover: \$4.594b

For the period 1985-95, the pharmaceutical industry's production grew at a rate of 7.5% compared to 2.5% for total Australian manufacturing. From 1990-1995, average annual pharmaceutical production growth more than doubled over 1985-90, while the growth rate for other manufacturing industries decreased.¹¹

Pharmaceutical exports have grown significantly in recent times. For example, the decade to 1999 saw an increase from \$203 million in 1989 to \$1.26 billion in 1999. Australia continues to import more pharmaceuticals than it exports, but the gap has been narrowed in general as the following table illustrates:

¹¹ R. Bewley and C. Morrison, "Economic Contribution of the Pharmaceutical Industry in Australia: 1985-1995", CAER Working Paper No. 1998/1, Sydney: UNSW

Table 7: Australia - pharmaceutical exports to imports ratio (%)

Year	Ratio
1988-89	32.3
1989-90	32.7
1990-91	33.3
1991-92	42.2
1992-93	38.7
1993-94	46.4
1994-95	47.2
1995-96	48.6
1996-97	46.7
1997-98	42.8
1998-99	41.9

Source: APMA, 2000

The Australian pharmaceutical industry comprises over 120 companies involved in the supply of prescriptions and over-the-counter medicines. Within the Australian industry:

- €# In the prescription and pharmacist-only sector, the top four firms account for 28% of sales ex-manufacturer and the top ten represent 50% of sales (APMA 2000).
- €# The dominant firms are multi-nationals such as Astra, Merck Sharp & Dohme, Glaxo Wellcome and Alphapharm, but there is a small number of significant local companies such as Faulding, Sigma, CSL and AMRAD.
- €# R&D expenditure has risen sixfold in the decade to 1996 and represented 5.5% of production income compared to 1.1% for general manufacturing.¹²
- €# Prescription pharmaceutical average prices at the end of the decade to 1998 have not increased over 1988 levels, as opposed to a 30% increase in the consumer price index.
- €# In the mid-1990s, Australian pharmaceutical prices were 54-83% of average OECD prices (Productivity Commission 1996).

In relation to government involvement in the Australian industry, regulation issues are discussed elsewhere. But direct expenditure by government is also important. In 1998-99 the total cost of government payments for pharmaceutical benefits was \$3.07 billion. Patient contributions were \$601 million or 19% of the cost of these medicines.

Overall, the pharmaceutical industry body APMA estimates total 1998-99 turnover as \$6.44 billion for human-use pharmaceuticals.

¹² *Australian Economic Analysis*, "Pharmaceuticals and Australia's Knowledge Economy: A Report on Australia's Pharmaceutical Industry", Sydney, 1998.

Relative to other countries, 1996 OECD health data show:

- €# Australian government expenditure on prescription medicines per person is seventh lowest of OECD countries (New Zealand is twelfth)
- €# Australian total per capita (public and private) outlays on pharmaceuticals is fifth lowest in the OECD (New Zealand is seventh).

Further government outlays are provided to the industry via direct industry development initiatives. The so-called Factor (f) Scheme was the primary source of Commonwealth industry assistance. Operating over 11 years to June 1999 the Scheme provided funding of \$1.15 billion over that whole period for 17 companies, of which \$958.2 million was paid as direct entitlements. From July 1999 the Factor (f) Scheme was replaced by a new Pharmaceutical Industry Investment Program.

6.2.2 Complementary medicines

Complementary medicines or healthcare products are a significant and rapidly growing area of Australia's medicinal products industry. It is not a homogenous or even closely linked group of substances or treatments. It includes herbal remedies of Western or Eastern origin, homeopathic remedies, vitamins, minerals and other nutrient substances. Many substances and products are manufactured in Australia, and sold through a large and varied network of retail networks including pharmacies, specialist health food stores and supermarkets, as well as directly by alternative practitioners.

Unlike the much more concentrated, subsidised and tightly regulated pharmaceutical industry, there is not available a comprehensive and consistent set of data for this industry. However the industry body, the Complementary Healthcare Council (personal communication, August 2000) estimates wholesale turnover at \$600 million and retail turnover at \$1 billion p.a. currently.

6.2.3 Medical devices

Finally, in relation to medical devices, which range from condoms to wheel-chairs and heart pace-makers, the 1996 Industries Commission report into the medical and scientific equipment industry estimated that in 1995, total turnover was \$1.1 billion, with imports of \$225 million and exports of \$525 million. Local production was \$670 million.

If the above data are brought together for each of the major industry sectors, and if the 1995 medical devices data are projected to grow by 36% uniformly to give an estimated \$1.5 billion turnover, as calculated for 1998-99 by the Medical Industry Association of Australia, then the broad configurations of the therapeutic products sector for Australia in 1998-99 are as follows:

Table 9: The pharmaceutical products industry in Australia (\$bn 1998-99)

Sector	Annual Sales	Local Production	Exports	Imports	Household Expenditure	Activity
Pharmaceutical	\$6.44	\$4.69	\$1.26	\$3.01	\$1.930	120 companies
Complementary	\$1.0	n.a.	n.a.	n.a.	\$0.937	n.a.
Devices	\$1.5	\$0.882	\$0.691	\$1.309	\$0.130	n.a.

NB: Due caution is needed with these data as they are not fully consistent nor thoroughly attested in all cases. Sources are as given in the preceding text.

6.3 New Zealand

6.3.1 Therapeutics overview

There is no well-defined 'therapeutics' industry. For the purposes of this study, data for three broad product categories – medicines, medical devices, and complementaries - is grouped to represent levels and trends in distribution and consumption. The three product groups are not easily separable or fully captured in official statistics, so data presented here on production, consumption, and external trade, is based on a mixture of official data and estimates provided by industry bodies.

Table 8: Therapeutics sector New Zealand (NZ\$)⁽¹⁾					
Sector	Activity	Annual sales	Exports	Imports	Household Spend ⁽³⁾
Medicines sector (2)	78 local distributors, supplying goods from 150 manufacturers to the local market. Local manufacture limited to generic medicines	About \$900 million annually, including about \$230 million for OTC medicines.	\$120m	\$627m	\$83m
Medical devices	170 distributors supplying goods – limited local manufacture	Total annual sales about \$700 million	\$135m	\$459m	\$27m
Complementary medicines	11 importers/ distributors 10 manufacturers	Dietary supplement sales est. at \$145 million. Total sector sales about \$200 million.	\$43m	\$50m	\$72m
Totals			\$298m	\$1136	\$182m
<p>Notes: (1) Data for 1999 – there are a few major manufacturers in each of these categories. Most businesses are distributors only.</p> <p>(2) Trade figures include ‘miscellaneous’</p> <p>(3) Only part of household ‘consumption’ as many of these goods are purchased by institutions, or in the case of prescription drugs, subsidised by Pharmac.</p>					
<p>Sources: Medsafe, Statistics New Zealand, Ministry of Foreign Affairs and Trade, IMS New Zealand, Researched Medicines Industry, Non-Prescriptions Medicines Association of New Zealand, Medical Industry Association of New Zealand, National Nutritional Foods Association of New Zealand.</p>					

Data on the three categories of therapeutics as captured in the Household Economic Survey (HES) is set out below. Note that this only includes purchases by households, so excludes expenditure on drugs by Pharmac, hospitals etc., and on devices by hospitals and other institutions. Hence, only for complementary medicines/healthcare products are these amounts anything like a full representation of the value of products consumed.

Table 9 Aggregate annual household expenditure on therapeutic products

NZ\$ million	1988	1996	1997	1998
Pharmaceuticals	43.146	77.242	81.379	83.342
Complementaries	16.575	51.505	53.888	72.236
Devices	17.381	22.641	21.755	27.017

Notes: (1) Coverage in each category may be incomplete. For pharmaceuticals and devices these figures represent a small proportion of final consumption of such goods.

Source: Statistics New Zealand *Household Economic Survey*

For all such products available in the major international markets, there can be a number of permutations in terms of local availability, i.e. some are marketed in both countries, some only in Australia, some only in New Zealand, and others in neither of these two countries.

Approval processes and costs in each country will be one of a number of possible factors affecting where a particular product sits in this list of possibilities. In turn, the impact on products of a regulatory change such as the move to a SJA will depend on their status in this regard. A general proposition would be that products approved only for the New Zealand market, at the time of the move to an SJA, would be those subject to most marked changes in distribution structures and availability, as a result of the change.

More than half the international companies distributing pharmaceutical products in New Zealand have their regulatory affairs divisions in Australia. (Source: Medsafe)

6.3.2 Pharmaceutical distribution in New Zealand

This section provides a broad overview of trends in the New Zealand industry structure. This is intended to illustrate trends that have occurred largely in the absence of any significant regulatory change in the period.

'Other than late stage clinical testing, very little research and development is undertaken in New Zealand. The vast majority of participants are distributors of pharmaceuticals developed overseas – in most cases by their related entities. Existing participants in New Zealand do face the threat of new entry in the form of imports. Barriers to entry at the distribution level are low, in that the cost of establishing a viable distribution network in New Zealand for pharmaceutical products is modest, and it is relatively inexpensive to obtain the required regulatory approvals... particularly for a generic product.' (Clearance application to Commerce Commission, July 2000)

The table provides data on sales of pharmaceuticals by broad classification and trends over the last two years.

Table 10: Pharmaceutical sales New Zealand

NZ\$ million

	Year to June 1999	Change %	Year to June 2000
SELECTED TOTAL	811.8	8.7	882.3
NZ Pharmacy Index	663.6	12.7	748.0
ETHICAL	579.7	12.7	653.2
POPULAR	83.9	13.0	94.8
NZ Hospital Index	148.1	-9.4	134.2
ETHICAL	145.7	-9.4	132.0
POPULAR	2.5	-8.9	2.2

Notes: (1) Ex-manufacturer
(2) Excludes GST, but includes bonuses, and internet sales

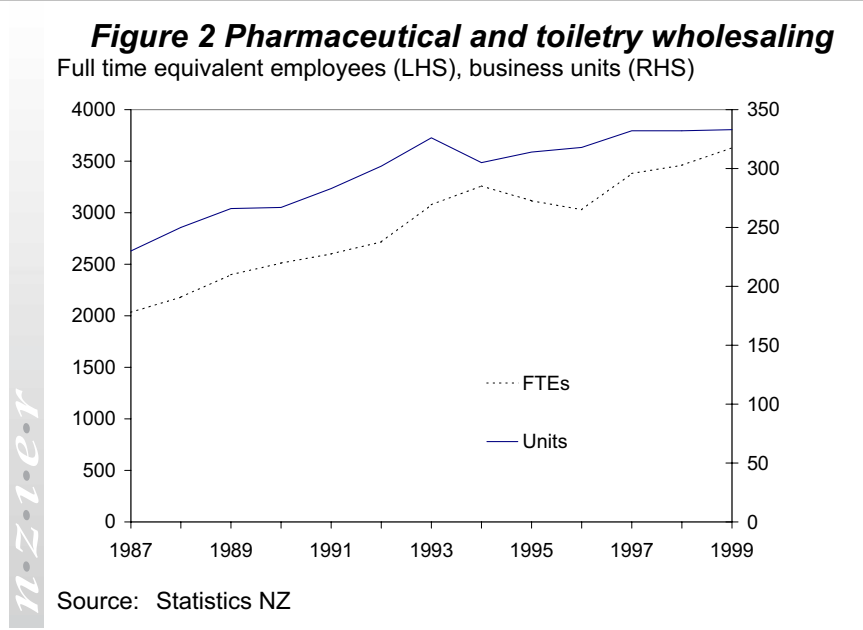
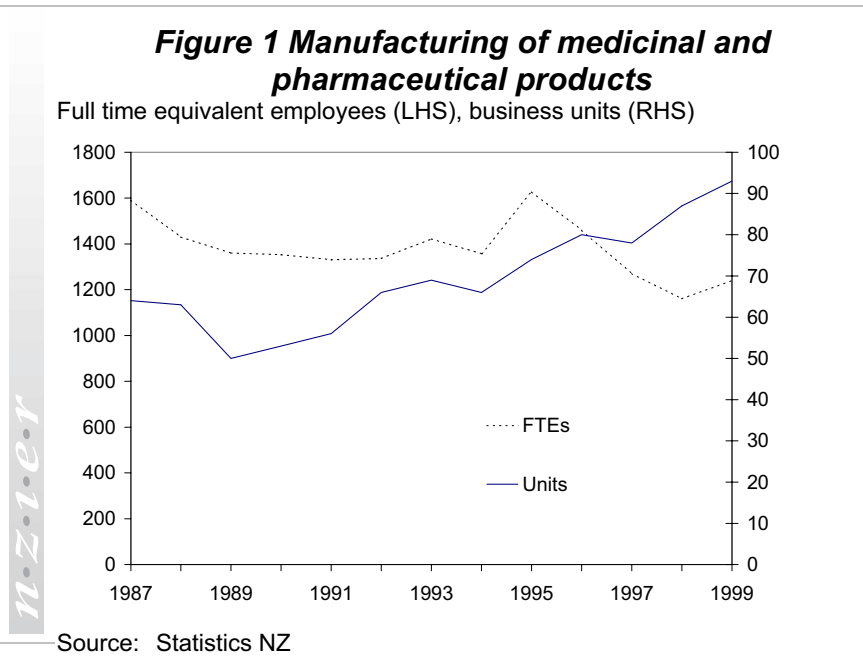
Source: IMS (New Zealand) Limited

The following data comes from the Business Activity Survey (and the earlier Business Patterns Survey).¹³

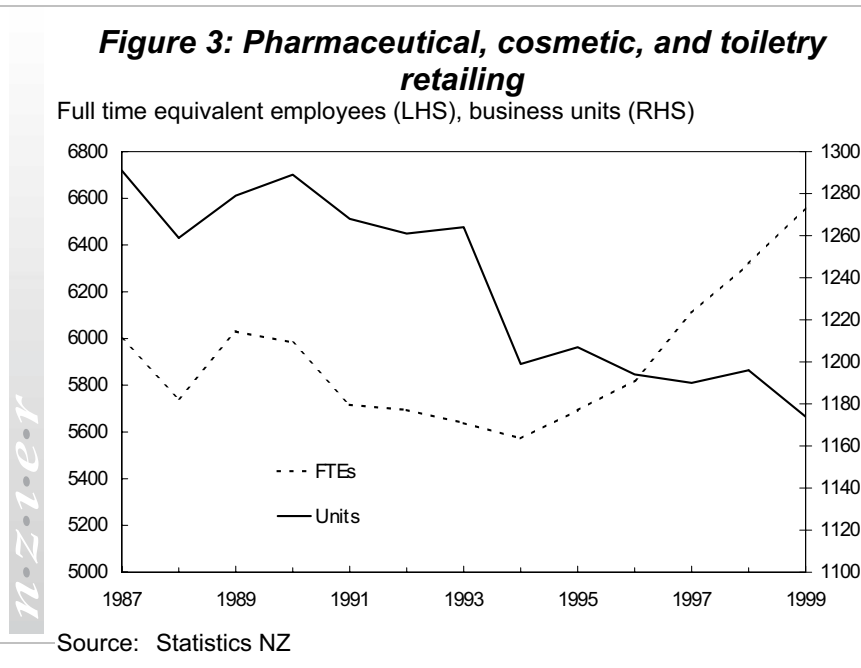
¹³ These surveys include only businesses with an annual turnover of \$30,000 or more that are registered for GST, or are GST exempt.

Full time equivalent employees are defined as the sum of full time employees and working proprietors, i.e. those working 30 hours or more each week, and half the part time working proprietors and employees.

A business unit is described as a "single operating unit engaged in New Zealand in one or predominantly one kind of economic activity from a single physical location or base from which work is carried out." The types of economic activity are based on the NZSIC or ANZSIC (Australia New Zealand Standard Industry Classification) codes.



The graph below describes the trend since 1987 in pharmaceutical retailing in New Zealand. It is based on official statistics gathered on companies whose only or primary activity is pharmaceutical, cosmetic and toiletry retailing.



Following are some comments on regulatory barriers and market conditions in each of the categories under review:

6.3.3 High risk medicines

New Zealand has no manufacturers of new chemical entities.

Prescription only medicines go through standards testing in the country of origin (which may be the US, EU, Japan, Australia) but also on entering Australia or New Zealand for the first time.

Availability and price (to the consumer) depends on numerous factors which can be considered in several broad categories:

1. Global distribution strategies of multinational manufacturers, taking into account for example, market size and income levels.
2. Macroeconomic factors such as exchange rates and inflation.
3. Strategies of local manufacturers, including for example, export orientation.
4. Regulatory barriers to market entry.
5. Rules as to intellectual property and parallel importing.
6. Strategies of purchasing agencies, e.g. PBS, Pharmac, hospitals.

Arguably item 4 is a subset of item 3, but for this discussion we keep them separate.

In an absolute sense, item 3 (TGA, Medsafe) intervention effects are dominated by interventions as per item 5 (PBS, Pharmac). Such interventions have major direct influence on prices to suppliers, prices to consumers, availability, and fiscal costs. Item 3 does influence the costs of getting a product on to the market (application costs, delays) the significance of which depends on the size of the market for that product and how long it will be on the market.

So the question is, how would a move to a SJA change the regulatory barrier in each country, how would suppliers respond, and are there other knock-on effects which we need to take into account?

Table 11: Expenditure on prescription drugs in New Zealand

\$ million

The Top 15 Expenditure Groups [^]					
By British National Formulary (BNF) group by claim date					
(\$ in millions, GST exclusive, June years)					
BNF Group	1994	1995	1996	1997	1998
Cardiovascular system	140	148	146	169	167
Central nervous system*	63	72	78	96	107
Respiratory system	98	100	90	89	92
Infections	44	47	51	53	58
Gastro-intestinal system	54	53	54	53	57
Endocrine system	34	36	37	42	45
Skin	27	30	31	30	30
Musculoskeletal & joint diseases	25	25	22	21	20
Obstetrics, gyn & UTI disorders	18	18	17	18	18
Nutrition & blood	12	15	16	17	18
Malignant disease & immunosupp	16	16	17	17	17
Monitoring & diagnostic agents	10	10	12	13	15
Ear, nose and oropharynx	12	12	11	11	9
Drugs acting on the eye	6	6	7	8	8
Galenicals	1	1	1	1	2
Totals	560	589	590	638	663

[^] Some figures differ slightly from last year due to the inclusion of North Health ProNet data in this year's figures.

* In 1998 – unadjusted for a \$2 million Prozac rebate.

Source: Pharmac

6.3.4 Intermediate and low risk medicines

Douglas Pharmaceuticals Limited and Pacific Pharmaceuticals Co Limited manufacture generics in New Zealand. Generics are off-patent medicines, the effect of which is to increase supply of medicines and force down prices rapidly, relative to prices of the innovator/branded products. They are described as intermediate risk because in most cases they contain the same active ingredients as products that have been on the market for years. So most evaluation focus is on quality of formulation.

Over-the-counter (OTC) or non-prescription medicines may fall into each of the three risk categories, but generally are towards the lower risk end. They are usually manufactured by companies who also produce prescription drugs. However, local distribution channels may differ as a significant proportion by value are sold through general retailers.

There is overlap between OTC medicines sold in New Zealand and those sold in Australia, although some OTC products in New Zealand are classified as prescription

medicines in Australia. Distributors in New Zealand may be reporting to a regional manager in Australia, but in some cases distribution in New Zealand is managed from elsewhere.

In New Zealand, OTC medicines have to go through similar pre-approval (consent to market) processes as prescription medicines. The fees for OTC medicines are about \$8,000, or about half the fees for prescription medicines. The reason for the difference is that they are lower risk than new substances, and have been in use in other markets, and thus require less extensive testing than new substances.

6.3.5 Medical devices

Almost all businesses in this sector, thought to be about 170, are importers and distributors. About 30% of these would be agencies of international companies, the balance being New Zealand businesses serving the local market.

Sales, estimated at about NZ\$700 million per annum currently, are mainly to hospitals, clinics, and resthomes.

Because of lower regulatory standards here, New Zealand may use some products at the simpler end of the device range, e.g. disposables like gloves and dressings, which Australia does not accept. However, for higher end products such as heartvalves, there is likely to be much more overlap between the two markets.

Devices are considered in three risk levels, depending on where and how they are used in or on the body. They can involve numerous mechanical and chemical technologies, which will make it hard for a small agency such as Medsafe to develop and sustain the evaluation capacity that will be required under the new legislation.

Overall there is probably an 80-90% overlap between the medical device product ranges in Australia and New Zealand.

6.3.6 Complementary medicines/healthcare products

Because this is such a broad term it is difficult to establish clear boundaries around the products that should be included. For example, there is some overlap with foodstuffs (for which no therapeutic claims are made) and cosmetics. HES data above suggests that the New Zealand market as a whole might be of the order of \$70-80 million. Total turnover of New Zealand-based businesses has been estimated to be about \$120 million per annum, including about \$20-\$30 million of exports, and \$20 million of imports.¹⁴

Ministry of Health (1999, p.79) reports that:

- €# One half of the New Zealand population consumed a vitamin and/or mineral supplement over the previous year; 23 percent less than once a week and 28 percent at least once a week.
- €# Multi vitamins and/or mineral were the most frequently chosen supplement over the previous year (19 percent).
- €# Almost one-third of the New Zealand population consumed dietary supplements over the previous year; 12 percent less than once a week and 17 percent at least once a week.

¹⁴ In the summary table and Appendix B we assume that the figures cited in this sections are understated, due to incomplete coverage, and use a figure of NZ\$200 million for turnover.

New Zealand has several manufacturers who have gone through the Australian approval process and are selling product in that market. In general the products, packaging, and labelling are common to both markets, so that scale economies can be realised.

Manufacturers tend to concentrate on a relatively small number of product lines with substantial markets in each. Pure importers, by contrast, tend to deal in many product lines, but each of these tends to be fairly low volume. The economic viability of this group is vulnerable to increased cost imposts at the product approval stage.

6.4 External trade and relationships

Trans-Tasman trade figures for therapeutics are heavily influenced by distribution structures adopted by multilateral companies, rather than the location of manufacture. Regulatory considerations have an important influence on these structures, so that a change in regulation, such as proposed with the SJA, could have an important bearing on numbers employed in distribution in each country, and trade flows.

Despite detailed joint research on trade in therapeutics using tariff codes, it has not been possible to reconcile Australian and New Zealand data on trans-Tasman trade flows. This work by the Australian Department of Foreign Affairs and Trade, and New Zealand's Ministry of Foreign Affairs and Trade, and other officials, identified various obstacles to reconciliation. (Refer Appendix 6, Tender document).

The following tables set out the data that has been generated, which as noted in the Tender document, are subject to some classification problems and major inconsistencies.

Table 12: Australia – trade flows in therapeutics

\$A million, 1999

Imports from:	New Zealand	Global
Complementary medicines	22.0	
Medical devices	18.4	
OTC medicines	16.3	
Prescription totals	17.2	
Total therapeutics imports	73.8	5552.9
Exports to:	Australia	Global
Complementary medicines	194.4	1063.4
Medical devices	164.4	727.3
OTC medicines	5.0	23.4
Prescription totals	61.7	399.2
Total therapeutics exports	425.5	2213.4

Source: Department of Foreign Affairs and Trade/ Ministry of Foreign Affairs and Trade

Table 13: New Zealand – trade flows in therapeutics

NZ\$million, 1999

Imports from:	Australia	Global
Complementary medicines	5.7	49.6
Medical devices	55.7	459.3
Miscellaneous	129.0	406.3
OTC medicines	23.7	54.0
Prescription totals	45.9	166.6
Total therapeutics imports	260.1	1135.8
Exports to:	Australia	Global
Complementary medicines	6.6	42.9
Medical devices	37.3	134.9
Miscellaneous	11.6	36.6
OTC medicines	21.3	25.6
Prescription totals	16.6	58.2
Total therapeutics exports	93.3	298.5

Source: Department of Foreign Affairs and Trade/ Ministry of Foreign Affairs and Trade

7. ECONOMIC EFFECTS OF THERAPEUTICS REGULATION

The aim of this section is to set out for the **current** regulatory regimes in Australia and New Zealand:

- €# The types of regulatory intervention affecting therapeutic products.
- €# The regulations managed by the TGA and Medsafe, inferring actual or potential economic impacts, and the products and stakeholders affected, in Australia and New Zealand.

Note that this is against a hypothetical counterfactual of no regulation.

In Section 8 we analyse the economic impact of the proposed SJA against the various regulatory options.

The next figure provides an overview of the set of relevant regulatory interventions, and their impact *vis-à-vis* a free market. This review is directly concerned only with the therapeutic pre-marketing approval function and also post-market surveillance. The other regulatory functions are nevertheless listed so that their respective roles and impacts can be clearly differentiated and any flow-on effects from SJA approvals (and surveillance) to these functions can be considered and allowed for.

In the following we try to disentangle the various objectives (benefits, or costs avoided) and impacts of current therapeutic regulation, relative to a hypothetical counterfactual of **no intervention**, with a view to quantifying, or at least identifying the direction of the impacts. The analysis is based mainly on pharmaceuticals but is intended as a general framework for application to therapeutics regulation in general.

Figure 4: Regulatory objectives and impacts in therapeutics – general framework

Form of regulation	Consumer Impacts			Industry	Government
	Safety, efficacy, quality	Access and diversity	Prices to consumers		
Therapeutic – pre marketing approval, including GMP; prescriber and consumer information	<p>Object: To ensure products: Have a positive benefit risk profile; and are true to label and not contaminated. Provide for accurate product information to ensure appropriate use.</p> <p>Outcome: Improves</p>	<p>Object: Allow different levels of access according to risk. Ensure products available are those which have greater benefits than risks if used appropriately.</p> <p>Outcome: Some restrictions and delays</p>	<p>Outcome: Minor increase for many products, critical for some, due to pass through by industry</p>	<p>Object: Provide a transparent regulatory framework in which both local and offshore professionals and industry can have confidence.</p> <p>Outcome: Extra costs - fees, time to market, 'sponsor' costs, labelling</p>	<p>Object: Provide a regulatory framework in which domestic government can have confidence, and which is in keeping with international obligations.</p> <p>Outcome: Cost varies according to industry contribution and cost of service provision</p>
Post- market surveillance	Supports enhancement	Reduces diversity	Minor increase	Major effects on range of products sustainable	Varies according to industry contribution and cost of service provision
Scheduling of pharmaceuticals	Important gain in prescription and pharmacy medicines	Reduces access and diversity	Reduces prices by competition reduction e.g. supermarket restricted	Major effects on market size and competition Enhances role of professions	Varies according to industry contribution and cost of service provision
Monopsony purchasing	Neutral	Neutral	Reduces substantially	Major price reductions to manufacturers. Turnover gains to retailers, especially pharmacists	Increases tax cost substantially; plus agency costs.
Intellectual property/patent life rules	Neutral	Enhances invention but restriction on diffusion	Some impacts through reduced access to generics or need to pay royalties	Important issue for industry	Some impact on drug purchasing bill
Parallel importing policy	Neutral	Some influence	Potentially significant	Potentially significant	

Note: Relative to hypothetical counterfactual of no regulation.

This figure is constructed in a general form. The applicability and magnitude of the impact, as opposed to its general nature and direction, will then depend upon the

precise form of the regulatory function, its implementation in a particular jurisdiction, and upon the particular area of therapeutic products to which the function is applied.

The form of regulatory function differs at present between Australia and New Zealand, and the product and effects will differ between medicines, medical devices and complementary medicines/healthcare products.

The following tables apply a more detailed approach for the economic impacts of existing regulations in each of Australia and New Zealand for the core regulatory functions of concern under the SJA proposal.

NB The underlying regulatory objectives are assumed to be the same as in the preceding general framework, and are not reiterated here.

Figure 5: Regulatory impacts in therapeutics vis-à-vis free markets – Australian approvals for product groups

Product group	Consumer impacts			Industry Impacts	Government Impacts
	Safety, efficacy	Access and Diversity	Prices		
Medicines	Substantial improvement	Some important delay and restriction	Some minor increase in consumer prices due to pass through of costs by industry	Significant increase in complexity and cost of industry operations – fees, time to market, documentation and registration	Major government policy and regulatory implementation costs with potential for cost recovery from industry
Medical Devices	Significant improvement	Some important delay and restriction	Some minor increase in consumer prices due to pass through of costs by industry	Significant increase in industry costs	Major policy and implementation costs with potential cost recovery from industry
Complementary medicines/health care products	Minor improvement	Minor delay and restriction	Some minor increase in consumer prices due to pass through of costs by industry	Major increase in industry costs	Minor policy and implementation costs with potential cost recovery from industry

Note: Economic impacts inferred relative to hypothetical counterfactual of no therapeutics regulation

The equivalent figure for New Zealand is as follows.

Figure 6: Regulatory impacts in therapeutics vis-à-vis free markets – New Zealand approvals for product groups

Product group	Consumer impacts			Industry Impacts	Government Impacts
	Safety, efficacy	Access and Diversity	Prices		
Medicines	Substantial improvement	Some important delay and restriction	Some minor increase in consumer prices due to pass through of costs by industry	Significant increase in complexity and cost of industry operations – fees, time to market, documentation and registration	Major government policy and regulatory implementation costs with potential for cost recovery from industry
Medical Devices	Minor improvement – limited to post-market surveillance outcomes	Minor effects	Minimal	Minor increase in industry costs	Minor resource costs to government
Complementary medicines/health care products	Minor improvement limited to post-market surveillance outcomes	Minor effects	Minimal	Minor increase in industry costs	Minor resource costs to government

Note: Economic impacts inferred relative to hypothetical counterfactual of no therapeutics regulation

These lay the basis for the difference between the impact of the present regulations (vis-à-vis the free market) to be contrasted with the impact of the SJA proposal (vis-à-vis the regulatory options) to see if it enhances or diminishes the various impacts of current structures. Refer Section 8.

In addition we must factor in ‘other’ economic and social impacts which may not be quantifiable but are significant in this context:

- ⌘ Harmonisation objectives under CER
- ⌘ Regulatory capacity
- ⌘ Regional influence
- ⌘ Impact on control systems for imports and exports.

These are discussed in Section 11.

8. ECONOMIC IMPACTS OF A SJA

8.1 Objective

Officials have agreed that the SJA model is the preferred one of the four canvassed. This is based on assessment against criteria of regulatory approach, regulatory outcome, global positioning, and cost.

Appendix A sets out typical regulatory decisions expected to be made by the SJA. These include, for example, market authorisation of new prescription and non-prescription medicines, high risk devices; approving major changes to existing medicines/high risk devices. Our assumption – which may be an oversimplification – is that the range of interventions made by the SJA, and the rules and procedures applied, will not differ greatly from the TGA regime as at present.

This section discusses the probable economic impacts of the move to a SJA relative to the three other options specified in the terms of reference.

To reiterate, we are required to analyse the economic costs and benefits, relative to three options:

- €# For Australia, the *status quo*.
- €# For New Zealand, firstly, local evaluation under proposed legislation to regulate medicines, medical devices and complementary medicines/healthcare products. Secondly, under the proposed legislation, unilateral recognition by New Zealand of some other countries' certification.

In all three cases, products and markets are evolving quite rapidly, as are demands on regulatory agencies. So, even in the Australian base case of the *status quo* we have to think what this might mean by the time the SJA would be operational, i.e. perhaps several years on from this study.

8.2 Broad analysis

Examination of the regulatory impact and costs and benefits of the creation of a SJA for approval and registration of pharmaceuticals, medical devices and complementary medicines is complicated by interlocking effects of several regulatory processes and objectives.

We can think in terms of three stages at which the effects might be observed:

- €# Direct, i.e. specific to the institutional change – how does the new SJA differ from the other options in terms, for example, of real resource costs, allocation and recovery of those costs, therapeutic standards, recognition of international information, decision speed?
- €# Indirect, i.e. mainly industry responses to the direct effects. Examples could be changes in where new products are registered, reorganisation of distribution structures as they affect Australia and New Zealand, changes in pricing behaviour at the manufacturing/import, wholesale, and retail stages.
- €# Longer-term effects, i.e. those affecting consumers especially the lags between products being launched in innovator countries and becoming available in Australia and New Zealand; range of therapeutic products available; responses by major purchasing groups, e.g. pharmacies, other retailers, PBS, Pharmac, hospitals.

The further along we follow these possible response chains, the more speculative the assessment becomes and, perhaps, the less important the effects become when discounted back to present day public benefit terms.

8.2.1 Direct effects

If the assessment is confined to the direct effects of the creation of the SJA , conceptually the analysis is quite straightforward. The direct implications of the SJA for various categories of supplier or product can be summarised as follows. The parties that will gain the benefit or face the costs are indicated in italics.

Figure 7: Direct effects of the SJA – relative to alternatives

Category	Likely benefits			Likely costs		
	Status quo Australia	Option 1: New Zealand	Option 2: New Zealand	Status quo Australia	Option 1: New Zealand	Option 2: New Zealand
Products supplied in Australia and New Zealand	Only one registration process necessary <i>Applicants</i>	Only one registration process necessary <i>Applicants</i>	Only one registration process necessary <i>Applicants</i>		S	
Products registered/supplied in New Zealand only		Faster approval processes <i>Applicants</i>	Improved quality of assessment processes and information <i>Consumers, governments</i>		Additional fees with full cost recovery by SJA <i>NZ Applicant</i>	Additional fees with full cost recovery by SJA <i>NZ Applicants</i>
Products registered/supplied in Australia only	Some cost reduction from economies of scale/scope achieved by SJA <i>Applicants</i>					
Note: Parties mainly affected are indicated in italics. Assumes that SJA processes, rules etc. will be broadly equivalent to those of the TGA. 'NZ applicants' includes applicants from outside New Zealand registering products in New Zealand only.						

The balance of direct costs and benefits then depends on the values assigned to the various cells in the table and the relative proportions of products falling into the three categories.

One important consideration is the fee allocation and funding structure for a SJA. It is possible that a staged approach could be adopted by a SJA, with the first stage being confirmation by the SJA that a product is 'approvable'. The second stage might be granting a licence for the sponsor to market the product in Australia, or New Zealand, or both. Fees for each of these stages could be set to ensure adequate funding for the SJA.

8.2.2 Indirect effects

It is probable that a move to a SJA would have a range of indirect effects but only some of these are appropriately included in an assessment of the costs and benefits of its creation. The cost changes noted above may lead to relocation of business activities.

For example, if a manufacturer or distributor maintained a New Zealand office largely to process applications to Medsafe, those functions are likely to be made redundant under the SJA. The operation of the SJA could cause suppliers to consider Australia and New Zealand as a single market. Over time this would lead to greater integration of business operations and strategies. This is of course consistent with the aims of CER.

The SJA could also lead to the elimination of subtle or artificial differences in products, labelling and the like. In the absence of regulatory mechanisms to prevent parallel importation of pharmaceutical products, the formation of a SJA would reduce barriers to this trade. However, we understand that mechanisms to prevent parallel importation will be implemented in the transition to the new agency.

To the extent that separate registration processes allowed private interests to block trade which did not contravene accepted intellectual property rights, or parallel trade restrictions, it might be argued that the elimination of such practices was a benefit from the SJA rather than a cost.

It is also important to separate issues of price from the registration process. Except to the extent that a change in cost of registration may flow through to drug or device prices, or such costs may be such a proportion of overall returns to a supplier that availability of a drug or device is restricted, prices should be largely unaffected by a move to a SJA. Pharmac and the PBS largely determine prices for prescription drugs. Prices for other drugs are set by demand and supply conditions in wholesale and retail market. A move to the SJA is unlikely to have a significant effect on overall prices.

9. COST BENEFIT ASSESSMENT - AUSTRALIA

9.1 Australia

Impacts of a SJA for Australian interests are deduced by comparing the outcomes of the existing regulatory arrangements as defined in Section 7 above, with those which would be likely to apply in the event of SJA adoption by the two countries.

Assuming that the nature and operation of SJA would conform to the general approach of the TGA, allows us to deduce an array of impacts as specified in the figure.

Figure 8: Impacts of SJA for Australia – relative to status quo

Product Group	Consumer Impacts			Industry Impacts	Govt Impacts
	Quality	Availability	Price		
Prescription					
New	No change in standards	Increase	Same or small decrease (see industry impacts)	Enhanced market due to reduced compliance costs and fees for registration in both countries allowing more economies of scale and scope – assuming no increase in parallel imports	Same, due to full cost recovery policy
Old	No change in standards	Same or small increase	Same or small decrease (see industry impacts)	Enhanced market due to reduced compliance costs and fees for registration in both countries allowing more economies of scale and scope – assuming no increase in parallel imports	Same, due to full cost recovery policy
OTC Medicines					
New	No change in standards	Same or small increase	Same or small decrease (see industry impacts)	Enhanced market due to reduced compliance costs and fees for registration in both countries allowing more economies of scale and scope – assuming no increase in parallel imports	Same, due to full cost recovery policy
Old	No change in standards	Same or small increase	Same or small decrease (see industry impacts)	Enhanced market due to reduced compliance costs and fees for registration in both countries allowing more economies of scale and scope – assuming no increase in parallel imports	Same, due to full cost recovery policy

Product Group	Consumer Impacts			Industry Impacts	Govt. Impacts
	Quality	Availability	Price		
Medical devices	No change in standards	Same or small increase	Same or small decrease (see industry impacts)	Enhanced market due to reduced compliance costs and fees allowing more economies of scale and scope – assuming no increase in parallel imports	Same, due to full cost recovery policy
Complementary Medicines	No change in standards	Same or small increase	Same or small decrease (see industry impacts)	Enhanced market due to reduced compliance costs and fees allowing more economies of scale and scope – assuming no increase in parallel imports	Same, due to full cost recovery policy

Note: Relative to the *status quo* in Australia

As the proposed SJA is essentially the same as the current TGA, the specified effects for Australia derive from:

- a) administrative changes including possible relocation of the administrative base for some activities to Australia e.g. OTC medicines approvals; post-market surveillance;
- b) reduced compliance costs for industry due to single applications instead of dual and enhanced by any “knock-on” effects to associated regulation not otherwise harmonised, e.g. uniformity in packaging, labelling, storage and handling regulations;
- c) economies of scale and scope in a single market for manufacturers, wholesalers and retailers, opened up by reduced administration and compliance costs, “knock-on” effects, and so-called “announcement effects” that can come from greater awareness of business opportunities when policy change is announced.

These changes have the likely consequence of:

- €# no change in product safety and efficacy, as approval and registration processes do not change;
- €# small decreases in consumer prices to the extent of reduced costs where these occur and can be passed on – though prescription pricing arrangements may divert gain to wholesalers and retailers in that area;
- €# improved early availability and range of products as the standing of the Joint Agency helps reassure global pharmaceutical and related companies of the symbolic and market importance of early, not delayed, release of products. Reduced administration costs and compliance costs within the market will have a small effect on enhancing diversity, by making some releases and trades more economical.

The effects are greater for those product groups where global innovation is most prominent and where application and compliance costs loom larger. This is to say,

advanced pharmaceuticals will experience bigger impacts than other elements of the sector.

However a key unknown in judging these effects is SJA cost-sharing arrangements between the two countries.

The above analysis assumes that there is some administrative saving to Australia through cost-sharing and it is assumed that regulatory and patent policies in each country continue to inhibit any change in parallel importation.

Transitional issues in forming a SJA and longer-term effects in terms of sustainable regulatory capacity, industry development and regional positioning have been discussed above and are considered in Section 11.

10. COST BENEFIT ASSESSMENT – NEW ZEALAND

10.1 The status quo, other regulatory options, the SJA

In New Zealand's case, we adopt a two stage approach in identifying the regulatory changes and associated real resources impacts associated with a move to a SJA. First, we set out what we are assuming about the distinctions between the *status quo* (the same Act and regulations as at present) and Options 1 and 2. Second, we set out what we are assuming about the distinction between the economic effects of other regulatory options and the SJA.

10.1.1 Regulatory conditions - status quo versus options

Regulatory conditions under the New Zealand options are assumed to differ from the New Zealand *status quo* in the following ways:

a) Option 1 - New legislation:

- ⌘ Medical devices will require pre-market approval, funded by fees charged to distributors (as at present in Australia).
- ⌘ Complementary medicines/healthcare products – will be separated from food legislation, and require listing.

b) Option 2 - Unilateral recognition (and new legislation):

Both the above plus the following:

- ⌘ Principal effect would be to reduce the amount of pre-approval activity in New Zealand relative to the status quo, and possibly alter regulatory standards for each of the broad product categories.

10.1.2 Economic impacts in New Zealand

Option 1 - We assume that the proposed new legislation would impose higher resource costs than the status quo, mainly through expanding the scope of regulation under the Act - i.e. to encompass New Zealand pre-approval of devices and complementary medicines/healthcare products. We further assume that there will be no change, arising from the new Act, in the regulatory standards applied to pre-approval or post-market surveillance of medicines.

The principal aim of this legislation is assumed to be to enhance safety, efficacy, quality over the full range of therapeutic products available in New Zealand, although effects in medicines will be minor. The impact of the new legislation on the range of products marketed here, and early availability, is unclear.

Option 2 (new legislation combined with unilateral recognition) compared with the status quo, is assumed to have the objective of enhancing safety, efficacy, quality over the full range of therapeutic products, including medicines, because unilateral recognition will draw on standards at or above those applying in New Zealand. For example, we would look to approval outcomes from the US, UK, EU, Canada, and Australia.

There may be some risks attached to this option which would not apply under the first option. For example, under Option 2 there may be higher risk of counterfeit imports,

requiring increased post-market surveillance effort. There might also be a tendency for pressure to lower regulatory standards, i.e. accepting products approved in countries with standards lower than New Zealand would try to maintain under Option 1. Pressure would come both from major purchasers of therapeutics in New Zealand, interested in reducing their outlays, and from product traders looking for short-term opportunities.

Overall the effect of Option 2 might be to expand the range of products that would be available under Option 1, but with a tendency for price considerations to dominate quality standards.

We assume that the other object of unilateral recognition is to reduce resource costs, relative to maintaining the full regulatory capacity required by the new legislation. In other words, New Zealand would rely on overseas agencies for much of the pre-approval work, while attempting to maintain capacity necessary to assess information received from overseas therapeutic agencies. This would involve a difficult trade-off between achieving cost savings, and maintaining sufficient critical mass to provide an effective monitoring role. The ongoing costs would thus be higher than under the status quo but lower than under Option 1. (Refer Medsafe budget data in Section 10.2.1)

10.1.3 SJA versus other regulatory options

Regulatory effects and economic impacts would be most marked on those products which, at the time of transition, are registered or marketed in New Zealand only.

€# Relative to *Option 1*, the SJA would impose higher resource costs on New Zealand, and generate greater safety benefits, because New Zealand would be aligning with a more intensive and higher unit cost regime, across all therapeutics, than would apply under a New Zealand regime.¹⁵ Turnaround times are assumed to be shorter than the counterfactual. To the extent that all products (or homogenous product lines) would be subject to approval, the effect might be to reduce the number of small importers operating in New Zealand, and to reduce the product range. This would be an extension of an effect likely to follow from the proposed new legislation in New Zealand.

€# Relative to *Option 2*, the additional resource costs resulting from the SJA would be greater than under the Option 1. We are less certain about the effects of the SJA on other key parameters, i.e. standards, turnaround times, early availability, and product range.

Our assumption is that in general, Option 2 would represent a lower regulatory hurdle than Option 1 and the SJA. Hence the impact of the SJA, relative to Option 2, would be to achieve higher standards, and preclude some of the pressures to lower standards discussed in Section 10.1.2. But it would involve greater costs to industry, slower approval times, and perhaps result in narrower product ranges than under Option 2.

¹⁵ Charges to industry for approval of pharmaceuticals in New Zealand are currently below sustainable levels. At these levels, Medsafe's capacity to process approvals is severely constrained, as evidenced by approval periods. Further, Medsafe's costs have been held down to some extent by rates of remuneration to outside experts which are well-below market.

10.2 Cost benefit assessment of SJA in New Zealand

We indicate below some broad categories in which we can examine the possible economic effects of an SJA on New Zealand’s consumers, therapeutics industry, and government.

Figure 9: Impacts of SJA for New Zealand – relative to Options 1 and 2

Consumer Impacts						Industry Impacts		Govt impact in New Zealand	
Quality		Availability		Price					
Option 1	Option 2	Option 1	Option 2	Option 1	Option 2	Option 1	Option 2	Option 1	Option 2
Minor Difference	Higher standards	Small increase	Small reduction	Same prices, minimal change in product range	Slightly higher prices, some reduction in product range	Higher costs; lower approval times on average	Higher costs; lower approval times on average	Access to greater regulatory capacity Some transitional cost imposts, no net ongoing costs assuming full cost recovery from industry	Access to greater regulatory capacity Some transitional cost imposts, no net ongoing costs assuming full cost recovery from industry

We note that ‘consumers’ of therapeutics in New Zealand fall into two main groups:

- €# Institutions: Pharmac, hospitals, clinics, rest homes, which purchase the major proportion of prescription medicines, and medical devices, by value.
- €# Households/individuals: Which purchase OTC medicines and complementaries, and make some copayments towards prescription medicines.

The first group tends to have greater market power than the second, in the face of any tendency for prices to rise as a result of the SJA, e.g. because some New Zealand distributors want to pass on increased registration costs. Because of this, and the fact that they account for the bulk of purchases, any price effects are likely to be minimal in aggregate.

10.2.1 Budgets for option 1 and option 2

Budget estimates for the two options show aggregate costs more than double current levels, with Option 1 more costly than Option 2. Salary costs are the main contributing factor in this difference.

Table 14: Medsafe budget – current and options

NZ\$000

1999-2000 Budget	Option 1	Option 2
2752 Personnel - Salaries	7530	5480
156 Personnel - Other	414	310
2908 Personnel Costs	7944	5790
Operating Costs		
1462 Professional Specialist Fees	3160	4247
343 Travel	445	445
324 Contractors	324	324
253 Rental	683	503
248 Printing & stationery	669	493
326 Other	880	648
308 Depreciation	308	308
Transitional Costs	200	150
3264 Total Operating	6669	7118
6172 Total Direct Costs	14613	12908
386 Corporate Overhead & Capital Charge	1042	768
6558 Total Expenses	15655	13676

Source: Medsafe projections August 30, 2000

Option 1: Assumptions

increase in professional fees	\$160,000 for two additional committees \$500,000 increase to adverse reaction contract to monitor devices and healthcare goods plus increase in current contract \$600,000 increase to pay for specialist evaluation reports (10@60K)
other costs	\$240,000 increase to testing. Double current budget Rental - increase proportional to salary cost increase. Travel - 30% increase to cover additional committees. Other costs increase proportional to salary increase. Printing and stationery proportional to salary increase. Corporate overheads increase proportional to salary cost increase.

Option 2: Assumptions

increase in professional fees

\$658,000 increase to adverse reactions contract

\$1,000,000 to purchase evaluations

\$1,260,000 increase to testing programme

decrease in professional fees

decrease \$160,000 for committees

other costs

Rental - increase proportional to salary cost increase.

Other costs increase proportional to salary increase.

Printing and stationery proportional to salary increase.

Corporate overheads increase proportional to salary cost increase.

11. FLOW-ON EFFECTS OF SJA

11.1 Transitional issues in forming SJA

Any regulatory change and reorganisation such as this involves significant costs and elapsed time, even if groundwork prior to decisions by governments is excluded from the assessment. Post-agreement in principle by the two governments, transition and implementation would involve the following major components:

1. Implementation of legislative mechanisms for establishing the joint agency;
2. Prior to the establishment of the agency, the development of an agreed single set of guidelines and administrative arrangements for the full range of functions that would be jointly performed from day one of the agency;
3. The development of a set of administrative procedures and guidelines to facilitate the phasing-in of products already approved in one or both markets; and
4. The development, over an agreed timeframe of 3 -5 years, of processes for the substantive integration of products on the two markets into the operations of the joint agency.

(Refer Tender document p. 6, and Appendix 4, p.28, for further detail).

Given that regulatory capacity would need to be maintained by both countries right through this period, transition costs should properly be measured as those over and above the ongoing costs of providing regulatory functions during the transition period. Main categories of transitional costs that could be incurred by TGA, Medsafe, and respective governments would include the following. Indicative annual costs allocations which reconcile with estimated total annual transition costs of \$3 million are:

- €# Legislative processes (\$250k)
- €# Costs of staff appointments, training, travel (\$300 k)
- €# Premises in Canberra and Wellington – some reconfiguration (\$400k)
- €# Information systems reorganisation and telecommunication links (\$750k)
- €# Internal administrative reorganisation – human resources, legal, accounting, records (\$500k)
- €# External corporate communication – branding, publications, representation (\$500k)
- €# Other (\$250k).

11.2 Trade and control systems

We were asked to examine the impact on both countries' trade, including impact on control systems for imports and exports.

We can consider impacts of trade from two main perspectives – global and bilateral. As set out in the tables in Section 6, and summarised here, both countries are substantial net importers of therapeutics products from the rest of the world, although Australia has an exports to imports ratio in pharmaceuticals of over 40%.

Table 15: Trade in therapeutics – summary data (\$A million)

Australia		New Zealand	
Exports to New Zealand	208	Exports to Australia	75
Exports to rest of world	2213	Exports to rest of world	239
Imports from New Zealand	75	Imports from Australia	208
Imports from rest of world	5552	Imports from rest of world	909

Note: Despite extensive efforts, DFAT and MFAT are faced with fundamental inability to reconcile the New Zealand and Australian Statistics for trans-Tasman trade in therapeutic goods.

Source: DFAT/MFAT (NZ figures converted at NZ\$1 = \$A0.8)

Relative to the counterfactual of the *status quo*, the initial effects of the SJA on Australia's global trade in therapeutics do not seem likely to be major. This is based on the assumption that the SJA will be responsible for a similar range of functions as the TGA and Medsafe, and that factors, other than therapeutics regulation, are critical to determining the size and structure of trade. In the longer term, if the SJA helped establish Australia as a regional centre for therapeutics regulation (see below), it might enhance the manufacturing base, and Australia's potential for exporting.

Effects of the SJA on bilateral trade flows might be more marked, particularly from the New Zealand end, and particularly with respect to pharmaceuticals. We are assuming that the SJA will mean that most products previously registered in New Zealand only, or in both countries, will be distributed from Australia. So, assuming parallel imports from New Zealand to Australia are precluded, the balance, relative to either Option 1 or Option 2 in New Zealand, would swing towards increased exports from Australia to New Zealand, and reduced exports from New Zealand to Australia.

We would note, though, that the balance of effects is sensitive to quite small changes in location of production and distribution. The move to a SJA could be seen as removing any regulatory disadvantage, in terms of access to the Australian market, of locating production in New Zealand. Under current intellectual property laws there is potential for an Australian manufacturer of generics to set up in New Zealand, take advantage of the five year lead time allowed there, and be ready to export across the Tasman once the product goes off-patent in Australia.

Also it must be recognised that fewer and fewer pharmaceuticals companies have offices in New Zealand under the status quo, despite exceptions such as Glaxo New Zealand which reports direct to a UK Head Office.

On the OTC and medical devices front, many Australian companies have given New Zealand agencies the right to New Zealand marketing and those licensing agreements may be adversely affected by a joint agency. In many cases distribution agreements would substitute and in some cases New Zealand operators may take advantage of a more uniform market. But it is likely that overall there will be a loss of New Zealand separate rights and the Australian companies will enhance further their dominance over New Zealand counterparts. The key decisions will therefore be made more in Australia even if the level of new Zealand distribution activity is not damaged dramatically.

11.3 Regulatory capacity

What might be the longer term impact of a joint agency on future sustained regulatory capacity for the two countries?

Longer term effects increasingly become more imprecise and vague as a requirement to project further out in time is imposed, and as the extent of adjustments and repercussions spreads. But such effects can be very important and so must still be considered.

Three effects in particular are singled out for consideration:

- ⌘ Future sustained regulatory capacity
- ⌘ Development of the therapeutic goods sector
- ⌘ Regional co-operation on standards and conformance matters.

The Tender document (p.4) notes that:

‘ The future assurance of regulatory goods capacity of both countries is an important factor in the development of future regulatory arrangements for both countries and in considering the resolution of the special exemption. The technology and expertise required for specialised scientific appraisal is becoming increasingly more sophisticated and expensive. In the short term, this has implications for New Zealand’s capacity to maintain the critical mass required to undertake evaluations of emerging technologies (such as those derived from gene technology and nanotechnology). In the longer term, these issues are also likely to impact on the efficiency of the Australian regulatory system. A single agency offers the opportunity to share the available skilled resources. This in turn will facilitate timely evaluation of products developed through new and emerging technologies, thereby benefiting both industry and consumers.’

Capacity, in this context, implies principally access to expertise and the ability to fund application of this expertise to the various approval processes. So the longer term questions surround the ability of staff employed in Australian and New Zealand to keep pace with changing technologies, and given the assumption of full industry funding, the ability and willingness of industry to provide the necessary financial resources.

In terms of regulatory capacity, a major consideration is the complex high level expertise required for approval and registration purposes for therapeutic goods. This expertise is in short supply globally and is in high demand domestically in both Australia and New Zealand. These countries are fortunate in having long-standing infrastructure which has supported training and experience in the biological sciences and the emerging associated fields.

But given the increasing pressure of demand for such skills and international opportunities for employment across the field, a pooling of expertise in the regulation of therapeutic goods, both in-house and for expert external advice, may carry significant advantages in providing future sustained regulatory capacity. The SJA would need to be structured in ways that would encourage maintenance and enhancement of expertise in both source countries, whether across-the-board or through agreed specialisations.

The same pool of talent that can support a sustained regulatory capacity is part of a knowledge profile that also helps meet a necessary condition for a substantial therapeutic goods sector providing high value added production in the global economy, particularly in the pharmaceutical industry. The area is highly intensive in

research and development and in requirements for professional staffing. And as its products grow more complex with time, these requirements will increase. In addition any reduction in trade barriers within the trans-Tasman market that lowers regulatory charges or improves regulatory efficacy, reduces compliance costs and allows greater economies of scale and scope enhances the prospects of a growing Australasian industry *vis-à-vis* other international suppliers.

So longer-term outcomes with respect to capacity are to some extent dependent on the development of the therapeutic goods sector and particularly the pharmaceutical industry in the region, as discussed in the following sub-sections.

11.4 Regional effects: therapeutic sector development & conformance

Australia has about 1% of the world market for drugs. It has been argued that Australia's population, and therefore market for therapeutic goods, is too small to justify the cost to both government and industry of having a sovereign drug regulatory system. The alternative view, which is under consideration here, is that there is scope to expand the market base against which regulation occurs, to the benefit of Australian industry, taxpayers and consumers. Acceptance of drugs in Australia already influences decisions in a number of other countries, especially the SE Asia region, so that the effect of Australian drug regulation is much greater than the 1% of world market would suggest.

At present there is global industry talk of Australia falling into "second wave" country status with a danger for New Zealand of "third wave" categorisation. This refers to timing of product availability and release. Such categorisation is determined by global drug companies in terms of: Evaluation processes and capacity; company presence and activity; and government purchasing/pricing policies for subsidised drugs. An SJA would assist New Zealand in particular to retain second wave access to timely release and availability of drugs.

An SJA would help TGA remain a force in global drug evaluation, along with the USA, EU and Japan. There is regional and global benefit from retention of some alternatives to the US FDA, since otherwise US industry imperatives can even more come to dominate the global market

A joint presence would help secure a continued membership of this group and underpin a key role as a voice determining or influencing outcomes in regional (and global) co-operation on standards and conformance matters – with reinforcing benefit flowing back to local regulatory capacity and industrial capacity.

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TGA Information Kit (www.health.go.au/tga)

APPENDIX A: SJA – TYPICAL REGULATORY DECISIONS

Regulatory decisions in relation to the inclusions of therapeutic products in the joint register

Grant marketing authorisation (new prescription and non-prescription medicines, high risk devices)

Approve major changes to existing medicines, high risk devices

Revoke/modify marketing consent for therapeutic products

Maintain list of active ingredients acceptable for (listable) complementary medicines

Grant market authorisation for listable complementary medicines

Set standards for therapeutic products & their packaging and labelling

Set standards for the manufacture and distribution of therapeutic products

Set access restrictions (where appropriate) for medicines through the scheduling system

Issue/Revoke/Modify Licences to manufacture therapeutic goods

Issue export certification

Grant approval to export/import unapproved products

Authorise access to unapproved products

Grant approval to cultivate/import/export/possess/distribute medicines (e.g. narcotics/psychotropics)

Authorise Clinical trials of new products

Take enforcement action (e.g. detention, seizure, search premises)

Prosecute for breaches of the Act

Accreditation of people with technical expertise for the purposes of the Act (criteria for members of expert committees)

Monitoring the safety of products when used in the community

Monitoring compliance with the requirements of the Act

APPENDIX B: MEASUREMENT PROBLEMS

Any assessment of a proposed regulatory change tends to be largely qualitative in nature. But it is helpful to policymakers if some guidance can be provided on relative magnitudes of effects resulting from a proposed change.

In the context of this report, we are trying to provide a basis for likely effects on industry and consumers, for each of the broad product groups affected, namely medicines, medical devices, and complementaries. Ideally, we would like to know:

1. The aggregate value of final consumption for each product group in Australia and New Zealand. Given the extent and direction of the impacts inferred for each product group, as a result of regulatory change, this data could provide weightings in terms of overall effects on consumers.
2. Main effects of interest here are on quality, early availability, and price. The latter is theoretically a measurable effect. But because of the vast range of products covered in each category, particularly in medical devices and complementaries, there is no obvious way of making meaningful comparisons between aggregate price levels in the two countries, or how they might change, as a result of moving to a SJA.

For pharmaceuticals it may be possible to identify a list of specific products which are common to both countries and account for a significant proportion of pharmaceutical expenditure in each. Ideally these comparisons should exclude any effects of subsidies, and be based on 'free market' data only.

3. We are also interested in how industry might respond to changes in therapeutic arrangements. We have speculated in the body of the report that the most marked changes might relate to products currently registered only in New Zealand.¹⁶ Under a SJA, given a new higher level of approval charges and a common approval framework the possibilities are:

€# Supply of such products ceases because it is no longer profitable.

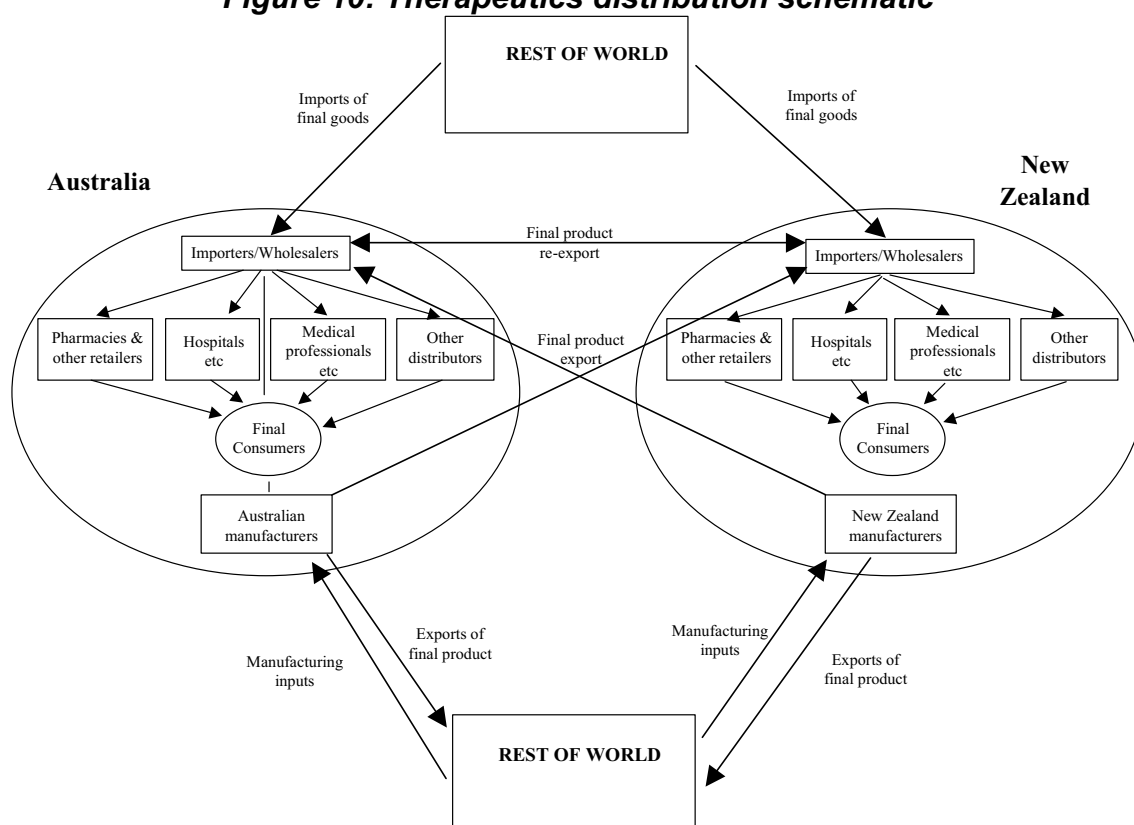
€# Distributors focus on the larger (Australian) market, and reorganise distribution bases and chains accordingly. (This rationalisation is assumed to further shrink New Zealand's industry, but this may not be the only possible outcome).

The response to regulatory change would be at the product or product group level, depending on the mechanisms and fee structures used in the approval process. These would then flow to individual firms depending on product ranges offered and the extent to which they are common to both countries or distinct.

Following is a simplified schematic of distribution flows in therapeutics.

¹⁶ There is a question here about what market/regulatory factors would have led to this outcome.

Figure 10: Therapeutics distribution schematic



Source: NZIER

Some of the information we would like to have is simply not feasible to collect. So our aim is limited to present data, for market size and trade flows, which broadly appears to reconcile.

Sales data is summarised in the following table. Given that New Zealand’s population is about 20% of Australia’s, but per capital incomes are lower, we would expect consumption ‘volumes’ in New Zealand to be in the range 15-20% of Australia’s. Based on this rule of thumb, the ratio for devices looks like an outlier.

Table 16: Annual sales data (\$A million)

	Australia (1)	New Zealand (2)	Ratio of (2) to (1)
Pharmaceuticals	6440	800	13%
Devices	1500	560	34%
Complementaries	1000	160	16%
Totals	8939	1518	17%

Notes: New Zealand figures converted at NZ\$1 = \$A0.8

Possible explanations for apparent disparities include:

1. Inconsistent statistical coding, product definitions and coverage between the two countries.
2. Incomplete coverage of therapeutics.
3. Differing stages at which prices and values are being measured, e.g. ex manufacturer, wholesale, retail.