

REGULATORY IMPACT STATEMENT

A proposal for a Trans Tasman Agency to Regulate Therapeutic products

1. PROBLEM DEFINITION

New Zealand's regulatory framework for therapeutic products is outdated, unsustainable and in need of reform. It does not adequately manage the public health risks associated with the use of medical devices and medicines. In addition, while the basic regulatory framework for pharmaceuticals is sound, its operation is unsustainable.

Pharmaceuticals

Pharmaceuticals (prescription and over-the-counter medicines) have significant health benefits, but can present serious risks, especially if used inappropriately. Before a pharmaceutical product can be offered for supply in New Zealand, the distributor must obtain the consent of the Minister of Health. Applications for consent are assessed by Medsafe to ensure that the benefits of use outweigh the risks if the product is used appropriately, and to identify any appropriate special requirements or restrictions on supply.

While the current regulatory approach is consistent with international best practice, the regime is unsustainable for New Zealand. As pharmaceuticals become increasingly complex and sophisticated, it is becoming increasingly difficult for New Zealand to maintain the expertise necessary to evaluate new products when such expertise is in short supply globally. Without adequate technical expertise, Medsafe will be unable to meet the regulatory objectives for pharmaceuticals within acceptable time frames.

Complementary medicines

Most complementary medicines contain ingredients with a very low inherent risk. Most of the risk arises from poor quality in manufacture, or from distributors making unsubstantiated and sometimes outrageous claims about the health benefits of products.

Risks arising from poor quality in manufacture can include:

- ⌘ Under or over potency, or complete absence of ingredients stated on the label;
- ⌘ Poor formulation leading to non-availability of active ingredients;
- ⌘ Adulteration with undeclared ingredients (including prescription medicines such as steroids), or substitution of a toxic herbal ingredient for the ingredient stated on the label;
- ⌘ Inaccurate or incomplete labelling, such as non-disclosure of ingredients, or inadequate dosage instructions and warning statements to enable the product to be used safely;
- ⌘ Contamination with heavy metals, microbes, radioactivity or other ingredients used by the manufacturer.

Unsubstantiated claims that a product can prevent or treat a serious disease result in a serious risk to the vulnerable consumer who believes the claim and either stops taking prescribed medication or fails to seek appropriate medical treatment.

In New Zealand, complementary medicines are currently marketed as foods under the Dietary Supplements Regulations 1985 (made under the Food Act 1981). The concerns with this regime are as follows:

- ⌘ Therapeutic claims on dietary supplements are prohibited. However, in practice only a low level of enforcement has been possible and many are marketed with therapeutic claims, some of which are inaccurate, misleading or potentially dangerous. There is currently widespread and constant distribution (in leaflets and magazines, and on websites) of advertisements for complementary medicines making unsubstantiated therapeutic claims including those for the prevention or treatment of serious diseases such as cancer, tuberculosis, diabetes, heart disease and obesity.
- ⌘ Manufacturing standards for food are not adequate for complementary medicines presented in pharmaceutical dose forms, where appropriate formulation, quality in the manufacturing process, and accuracy of labelling and dosage are essential to the safety, effectiveness and appropriate use of the product. It is estimated that up to 10% of the total retail sales value of dietary supplements in New Zealand comes from products manufactured in premises in New Zealand or overseas that do not meet Good Manufacturing Practice standards. Consumers purchasing products have no way of identifying which products are of high quality and therefore safe to use.
- ⌘ There is no requirement for new ingredients used in dietary supplements to undergo any pre-market safety assessment, or for products to be registered. There is therefore no safety check on ingredients being used, and no register of products or distributors to facilitate efficient investigation and product recall when a safety alert arises.
- ⌘ Because it is illegal to make therapeutic claims for dietary supplements, manufacturers and distributors are unable to lawfully provide consumers with the information they need to choose products wisely and use them safely. In many instances consumers are not provided with information about contraindications, adverse effects or interactions even when these are well recognised and may have a significant influence on whether they can safely use the product.

Medical devices

Medical devices include products ranging from very low risk (e.g. gauze dressings) to high-risk devices such as heart valves, which, if they fail, could lead to severe harm or death, with all the associated personal and social costs.

In contrast to most developed countries, New Zealand does not require medical devices to be approved before being marketed.¹ Medsafe's role is limited to market surveillance and dealing with safety issues as they emerge. Because there is no register of medical devices, this is inefficient and costly.

The vast majority of medical devices are imported, mainly from the US, Europe, Japan, and Australia, where devices are required to be registered. Most medical devices in use in New Zealand would therefore meet adequate safety standards, particularly as world standards converge around the Global Harmonisation Task Force (GHTF)

¹ A small subset of devices (condoms, pregnancy test kits and devices containing medicinal substances) does need approval from Medsafe before they are sold in New Zealand, to ensure they meet appropriate standards.

requirements. However, without similar standards applying in New Zealand, there is a risk that poor quality product that cannot be sold overseas will be dumped on the New Zealand market, with potentially serious health risks. Anecdotal evidence also suggests that the overall risk to consumers from medical devices is increasing.

Magnitude of risk

Risk cannot be eliminated. From society's point of view, the objective is to achieve an appropriate risk reduction at reasonable cost. While lack of data makes it difficult to quantify the risk for complementary medicines and medical devices, the risk can be significant, resulting in serious injury and death.

In most developed countries, regulatory arrangements for therapeutic products are predicated on the assumption that the costs of harm are likely to be far greater than the costs of policies aimed at reducing risk. For medical devices and complementary medicines, New Zealand's regulatory regime is out of step with international practice and World Health Organisation recommendations. Given the rising risk profile as products become more widely used and more sophisticated, and the existing evidence of problems and their consequences (discussed above), there is a prima facie case for policy intervention.

Trans-Tasman Mutual Recognition Arrangement (TTMRA)

In the context of Closer Economic Relations (CER), the Australian Commonwealth, the States and Territories and New Zealand committed to the Trans-Tasman Mutual Recognition Arrangement (TTMRA) in 1998. One of its objectives is to allow goods and services legally traded in Australia to be also traded without regulatory impediment in New Zealand, and vice versa.

Therapeutic products are one of six areas where mutual recognition has not yet been achieved. Australian and New Zealand Health Ministers concluded that:²

“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.”

2. PUBLIC POLICY OBJECTIVES

Health objectives

The primary policy objective is to manage the risks to public health and safety from avoidable harm associated with the use of therapeutic products. In particular, to regulate therapeutic products for safety, quality and efficacy to ensure that the benefits of use will outweigh the risks if the product is used appropriately; to regulate products in accordance with international best practice, adopting a globally harmonised approach where possible; and to ensure that health and safety objectives are met while minimising costs to business and Government, and without imposing unnecessary trade barriers.

² 1999 Therapeutic Goods Co-operation Program Report to the Council of Australian Governments including New Zealand. Page 28.

Wider objectives

Policy options can have different impacts on the Government's objectives for trade and industry development. In the context of therapeutic products, secondary policy objectives are:

- ⌘ Progression of Closer Economic Relations;
- ⌘ Facilitation of trans-Tasman trade in therapeutic products;
- ⌘ Facilitation of exports of therapeutic products beyond Australia;
- ⌘ Development of the therapeutic products industry in New Zealand, including research and development.

3. FEASIBLE OPTIONS

Non-regulatory options

There are no non-regulatory options that would adequately achieve the health and safety objectives.

In an unregulated but highly competitive market, there would be a lack of incentive for suppliers of therapeutic products to provide balanced information about the benefits and risks of their products. Consumers would find it extremely difficult or impossible to identify quality product from substandard and potentially harmful product, or to take a case under consumer protection legislation because of the high burden of proof required.

Public education programmes (designed to enable consumers to evaluate the benefits and risks of products, make informed choices and use products safely), would not be effective, since most consumers do not have the knowledge or skills required to assess the accuracy or completeness of the available information or to interpret that information appropriately.

Regulatory options

Four regulatory options have been identified.

Continuation of the Status Quo

Under this option the main focus would be on evaluating and approving pharmaceuticals and on post-market monitoring functions. There would be no pre-market requirements for medical devices. Dietary supplements would remain under food legislation with therapeutic claims prohibited. The current Medsafe budget is \$6.7 million, of which \$2.9 million is Crown funding and the remainder comes from fees paid by industry.

Enhancing the regulatory framework, with local evaluation to international standards

Under this option, the regulatory framework would be extended to incorporate pre- and post-market controls for the full range of therapeutic products – prescriptions and over-the-counter medicines, complementary medicines and medical devices. There would be local evaluation to international standards, and mutual recognition arrangements with other reputable regulators for some aspects (such as evaluation of medical devices and assessment of good manufacturing practice).

A global shortage of expertise in evaluating increasingly specialised high-tech products makes it unlikely Medsafe could recruit the additional staff required under this option.

The estimated budget for Medsafe regulating the full range of therapeutic products to international standards is \$43 million per annum.

Enhancing the regulatory framework, but adopting a unilateral recognition scheme

Under this option, the regulatory framework would be extended to incorporate pre- and post-market controls for the full range of therapeutic products. Local evaluation would not occur. Instead, evaluations carried out by competent overseas regulatory authorities would be recognised by Medsafe. Products intended only for the New Zealand market and not approved by any of the recognised overseas authorities would be evaluated under contracts with other regulators that would be managed by Medsafe. New Zealand would maintain a list of overseas regulatory authorities in whom it had confidence, and only evaluations carried out by those authorities would be recognised for the purposes of approving products for the New Zealand market. New Zealand would have no input into the standards or procedures adopted by those overseas authorities, and no direct access to their medical and scientific expertise. The scheme would be backed up by enhanced local post-market surveillance in recognition of the increased potential for New Zealand to receive product that did not match the safety, quality and efficacy standards of that originally evaluated.

The estimated annual budget for Medsafe operating a unilateral recognition scheme covering all therapeutic products is \$29.4 million.

Establishing a joint Australia/New Zealand therapeutic products agency

Under this option, New Zealand and Australia would adopt a single comprehensive regulatory scheme for all therapeutic products marketed in either country. The scheme would be administered by a single trans-Tasman regulatory agency, applying international best practice.

The agency would operate on the basis of full cost recovery with an estimated annual budget of \$68 million. The New Zealand industry's share of these costs is estimated at \$20 million per annum, based on the assumption that 30% of product licence holders will be based in New Zealand.

Ministers agreed in principle to the establishment of a joint trans-Tasman agency to regulate therapeutic products supplied in Australia and New Zealand markets in December 2000, subject to the development of governance arrangements satisfactory to New Zealand (CAB (00) M 41/2D refers).

The proposed governance arrangements would ensure an equal voice for each country through a Ministerial Council consisting of the Australian Commonwealth and New Zealand Ministers of Health. A Board, appointed by the Ministerial Council, would be accountable to the Ministerial Council for the strategic and financial direction of the agency. The Managing Director would be accountable to the Board for financial and administrative matters, and would be the statutory decision maker accountable to stakeholders through an internal appeal process as well as external judicial review and merits review mechanisms.

Options for resolving the existing special exemption under the Trans-Tasman Mutual Recognition Arrangement

The current Special Exemption for therapeutic products will expire on 30 April 2003 and a further 12-month extension will be sought. The longer-term options are permanent exemption, harmonisation of regulatory requirements, or mutual recognition.

Mutual recognition is not a feasible option because New Zealand does not have a sustainable regulatory capacity, the regulatory frameworks are not matched, and there is not an acceptable level of confidence that equivalent regulatory outcomes are achievable under the existing separate schemes. Creation of a joint regulatory scheme is a specialised form of harmonisation that would achieve the trade objectives of the TTMRA, whereas permanent exemption would maintain current trade barriers.

4. NET BENEFIT OF THE PROPOSAL

A lack of accurate data about some sectors of the therapeutic products industry, the products they market, and the risks arising from use of those products means that any analysis of the costs and benefits is reliant on a qualitative assessment of whether or not any change from the Status Quo would be of net benefit to New Zealand society. This assessment involves making a judgement about the:

- ≠ Additional benefits to consumer health and safety and the value of better information for consumers; and
- ≠ Value to New Zealand of potential additional trade opportunities, and improved trans-Tasman and international relationships.

Enhancing the regulatory framework with local evaluation to international standards would fail to meet public health and safety objectives, as it would not be viable in light of the global shortage of appropriate expertise. It is already very difficult to get the expertise needed to evaluate pharmaceutical products to international standards in a timely fashion, and the situation is expected to get worse over time. The same problem would occur with high risk medical devices. Compliance costs would be high, and existing trade barriers would be maintained.

Enhancing the regulatory framework, but adopting a unilateral recognition scheme could meet public health and safety objectives and be sustainable over time. It would, however, result in a loss of New Zealand's ability to reach independent decisions about therapeutic products supplied in New Zealand or to have any voice in deciding the standards applied in evaluating products. Because of the need for enhanced post-market activities, compliance costs would be high. Existing trade barriers would be maintained and could increase if New Zealand was seen to be adopting a third-World approach to therapeutic product regulation.

Establishing a joint Australia/New Zealand therapeutic products agency would meet public health and safety objectives, and be sustainable over time. While there would be a risk that the joint scheme may not always result in decisions that were the best fit for New Zealand, this risk would be managed by ensuring New Zealand had an equal voice and there was no lesser accountability to Government, stakeholders and the public than at present. An opt-out mechanism would ensure that New Zealand would not be forced to adopt a position to which it had a fundamental objection.

The economies of scale and removal of duplication that would result from regulating jointly with Australia would lower overall administrative and compliance costs. The actual impact on New Zealand would depend on how the costs were shared between the two countries in the longer term, but the overall compliance costs for New Zealand industry would be lower in a joint scheme.

The joint agency option would also meet CER objectives. The immediate impact on trade is likely to be small, given New Zealand's significant reliance on imports from across the globe. An approval from a trans-Tasman regulator with international credibility may make it easier for local manufacturers to break into export markets. However,

compared with the Status Quo, the added compliance costs for medical devices and complementary medicines would reduce export competitiveness and local profitability, which could result in some beneficial products not being marketed locally, and some businesses in those sectors closing.

The following table provides a summary assessment of the benefits and costs of unilateral recognition and a joint agency, options, compared with continuation of the Status Quo.

	Consumers	Industry	Government	Additional compliance cost
Unilateral Recognition				
Benefits	<p>Meets health objectives through</p> <ul style="list-style-type: none"> • higher standards • better post-market surveillance • better consumer information for complementary medicines and medical devices. 	<p>Reduced business compliance costs for pharmaceuticals to partly offset higher fees from full cost recovery.</p> <p>Reduced trans-Tasman import duties if Tariff amended to exclude complementary medicines.</p>	<p>Reduced cost and increased efficiency of managing product alert/recalls.</p> <p>Reliance on other regulators resolves sustainability concerns.</p>	
Costs	<p>Small price increases likely for pharmaceuticals.</p> <p>Larger price increases for medical devices and complementary medicines.</p> <p>Reduced choice likely.</p> <p>A precautionary stance may further reduce choice.</p> <p>Overseas regulatory decisions may not always “fit” NZ circumstances.</p>	<p>Higher regulatory fees for all product groups will reduce profitability and be passed on to consumers.</p> <p>Higher costs for local manufacturers would reduce international competitiveness.</p>	<p>Some impact on ACC and health budgets.</p> <p>Does not contribute to CER objectives.</p> <p>Loss of import duties of approx. \$3.5m (a transfer to industry and possibly consumers).</p>	\$24.5 million

	Consumers	Industry	Government	Additional compliance cost
Joint Agency				
Benefits	<p>Meets health objectives through</p> <ul style="list-style-type: none"> • higher standards • better post-market surveillance • better consumer information <p>for complementary medicines and medical devices.</p> <p>A possible reduction in pharmaceutical prices.</p>	<p>Overall compliance costs will reduce, particularly for importing pharmaceutical companies.</p> <p>Single regime facilitates trans-Tasman trade.</p> <p>Import duties reduce if Tariff is amended to exclude complementary medicines.</p>	<p>As above. Improves wider CER relationship.</p> <p>Lower pharmaceutical costs may increase Health and ACC purchasing power.</p> <p>Combined regulatory resources addresses sustainability concerns.</p> <p>Stronger trans-Tasman agency may improve international reputation.</p>	
Costs:	<p>Price increases for medical devices and complementary medicines (but lower than Unilateral Recognition option), and some reduction in choice.</p>	<p>Increased compliance costs and reduced competitiveness for complementary medicines and medical devices, but less so than for Unilateral Recognition option.</p>	<p>Higher cost of medical devices will have some impact on ACC and health budgets, but smaller than Unilateral Recognition option.</p> <p>Foregone tax revenues from duty removal and firms relocating regulatory affairs to Australia.</p>	\$8.3 million

Given the costs of compliance, whether any change from the status quo is seen to be of net benefit to New Zealand depends on judgements as to the additional benefits to consumer health and safety, and the value to New Zealand of potential additional trade opportunities and improved trans-Tasman and international relationships.

For medical devices and complementary medicines, this trade-off depends on a judgement of the emerging risk profile, whether added regulation in New Zealand can influence this, and how much society values the risk reduction. No data are available to assess the magnitude of these factors.

Given the degree of uncertainty, the decision on whether the regulatory framework needs to be extended involves a qualitative assessment about:

- ⊘ how well consumers are equipped to deal with the risks;
- ⊘ the ability to rectify harm (and the relevance of the precautionary principle);
- ⊘ the perceived bias of producers to understate risks or regulators to over-regulate;
- ⊘ how much risk reduction is valued; and
- ⊘ different notions of liberty and responsibility.

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

5. CONSULTATION UNDERTAKEN

Medsafe has consulted widely in developing these proposals. In 2000, Medsafe published a discussion document seeking comment on the proposed form of a joint therapeutic products agency. This informed decisions by Ministers in December 2000. In further developing its proposals Medsafe has held regular meetings with consultative groups comprising representatives of the key stakeholder groups affected by the proposal, primarily therapeutic products suppliers. In December 2001 and June 2002, Medsafe distributed further discussion documents, seeking feedback on the design and role of the proposed agency.

Response to the discussion paper released in June 2002

While a large number of responses was received, fewer than 15% were commenting on the proposals set out in the discussion paper. Government departments, representative bodies, consumer groups and those in the pharmaceutical and medical device industries broadly supported the proposals.

The bulk of the responses came from consumers, health practitioners and industry players from the complementary medicines sector who did not appear to have seen the proposals in the discussion paper but were reacting to some of the misinformation being circulated during the consultation period. They claimed there was no risk and therefore no need to regulate complementary medicines. They were fearful of increasing prices and decreasing product choice, and objected to decisions about which products they could access being made by an Australian bureaucrat.

Opinion expressed in submissions on the proposals contained in the discussion paper ranged from strong support for the proposals, to support for some aspects and concern about others, to outright rejection of any proposal to enter into a joint agency arrangement with Australia. All sectors of industry rejected the concept of 100% cost recovery, and there was considerable concern about Australian domination and loss of voice for New Zealand, although much of this concern was based on a misunderstanding of both the current system and the proposed governance and accountability arrangements.

Pharmaceutical sector

The pharmaceutical industry generally supported the proposals, although there was some concern about loss of expertise within New Zealand. Most of the comments

related to more detailed aspects that would be the subject of further consultation with stakeholders as subordinate legislation is developed.

Medical device sector

The medical device industry strongly supported the adoption of the Global Harmonisation Taskforce (GHTF) approach to device regulation and was broadly supportive of the joint agency proposals, provided certain aspects of the detail of the regulatory scheme for medical devices can be satisfactorily resolved.

Complementary medicines sector

Opinion amongst those with an interest in the complementary medicines sector was divided. Some rejected any proposal to regulate the sector at all, although much of the industry supported regulation of product quality and claims, recognising that while the ingredients were generally very safe, there were risks from poor quality products and outrageous claims, and these were damaging to the industry.

Much of the negative comment centred on the current Australian regulatory scheme, which was seen as draconian, bureaucratic and expensive. There was considerable concern about the impact of compliance costs on small businesses, with claims that hundreds of small distributors would go out of business if the proposed scheme were introduced.

The larger manufacturing companies (about 10 companies that account for around 80% of the total market value) are broadly supportive of the joint agency concept and the overall approach to regulation. Most of their concerns relate to the detail of how the scheme would be administered and how the agency's accountability to the fee-paying industry would be ensured.

There is no accurate record of the number of small manufacturers and importers who account for the remaining 20% of the market, although it is estimated there could be more than 200 small businesses involved. It was claimed that many of the products they distribute would be low value/low volume products that would not be viable in a regulated market. It is therefore likely that rationalisation of large product ranges or multiple distributors of the same or very similar products would result in some job losses for this group. The impact on importers and small manufacturers would depend on the size and distribution of fees, and on some aspects of the detail of the regulatory scheme, such as labelling requirements and interpretation of the Code of Good Manufacturing Practice.

There was support for the concept of a joint regulatory scheme for aspects such as advertising controls, adverse reactions monitoring and scheduling of medicines, but mandatory licensing of export-only products was considered inappropriate as it would not facilitate export or add any value for exporters.

6. BUSINESS COMPLIANCE COST STATEMENT

Sources of compliance costs

Compliance costs under the Joint Agency proposal would arise from the following:

€# For pharmaceutical companies:

4# increases in regulatory fees for product licences and variations, manufacturing licences, and the introduction of annual product licence fees for all products due

to a shift to full cost-recovery (offset by a reduction in the total number of licensed products as most products now need only one licence for both New Zealand and Australia); and

• For complementary medicine and medical device companies:

4# the introduction of regulatory fees for: product licensing (upfront and annual fees), licence variations, approval of new substances for use in complementary medicine, and licensing of manufacturing sites;

4# (for some manufacturers) the cost of upgrading manufacturing facilities and procedures;

4# time required to submit applications to the regulator, and gain an understanding of the new requirements;

4# costs of introducing new labels;

4# delay in getting new product to market (where an ingredient is not on the permitted list of substances in low risk products).

The parties likely to be affected

The compliance costs of this proposal will fall directly on:

• About 78 pharmaceutical companies and 24 pharmaceutical manufacturing sites with total industry turnover of around \$900 million per annum. Two large manufacturing companies are New Zealand based, and are exporting to Australia. Almost all of the remainder are multinational companies marketing in both New Zealand and Australia. Only a small percentage would be expected to maintain separate products licences in the two countries, so that rationalisation of products and regulatory activities will result in reduced compliance costs. Compliance costs will increase for the few companies whose products are only available in New Zealand.

• About 10 local manufacturers and about 170 importers of medical devices. It is believed that at least one third of these companies distribute products in both Australia and New Zealand. Compliance costs will, therefore, fall mainly on those importers sourcing product from countries other than Australia. There would be little impact on compliance costs for those manufacturing locally and exporting.

• Manufacturers (about 10 large to medium companies, half of whom are believed to be exporting to Australia, plus an unknown number of small manufacturers) and importers of complementary medicines (estimated to be 11 major companies and 200 or more small businesses) with local sales of over \$100 million per annum. The larger local manufacturers account for at least three quarters of the total industry turnover.

The complementary medicines industry comprises a broad range of businesses, from large companies with multi-million dollar turnovers that manufacture, distribute and export a range of products, to one-person businesses importing and distributing one or two products. Because the industry is so diverse and is not currently regulated in New Zealand, it has not been possible to obtain complete and accurate information about the numbers and types of businesses involved. During research for the cost benefit analysis, NZIER found there were no official statistics and no comprehensive and reliable data available from industry organisations. Information provided by industry members was inconsistent and sometimes contradictory.

Compliance cost spread for the complementary medicines sector

Without accurate information about the makeup of the industry it is difficult to estimate the impact of compliance costs on different types of businesses with any accuracy.

For companies trading in both countries, the extent to which compliance costs will increase will depend on the degree of overlap in product ranges between the two markets, which is currently unknown. For these companies, there would be no additional costs associated with licensing manufacturing premises.

For the unknown number of local manufacturers who do not currently meet GMP requirements, costs will vary depending on the extent to which they need to upgrade their premises in order to obtain a manufacturing licence. The greatest impact will be on smaller businesses requiring significant upgrading.

Compliance costs should not change significantly for those companies importing product from Australia (estimated to account for 50% of the total value of imports). For companies importing products from countries other than Australia, the greatest compliance cost impact would fall on businesses with a large product range.

The proposed annual product licence fee is intended to cover the costs of post-market activities – adverse reactions monitoring, product testing and handling complaints and recalls. If there were a standard fee per product, the impact would be greatest for those companies with large product ranges, and particularly for those that also had a small annual turnover. Possible mechanisms for managing the impact of compliance costs on small businesses include a fee waiver for low value/low volume products, or charging each company a fee based on a percentage of turn over. The latter is based on the premise that the costs of post-market activities relating to a company's products will be proportional to the level of risk exposure and therefore to the volume of product the company has in the marketplace.

The following tables indicate the likely impact of annual product licensing fees under the proposed joint agency scheme under different fee application scenarios. The company descriptors are as follows:

- €# Company A manufactures and distributes 100 products and has an annual turnover of \$5 million. (Note that if the company already exports to Australia, the additional compliance costs will be reduced or eliminated, depending on the degree of overlap of product ranges in the two countries.)
- €# Company B imports 500 products and has a turnover of \$1 million. Products are imported from countries other than Australia.
- €# Company C manufactures and distributes 5 products in New Zealand and does not export. Annual turnover is \$250,000
- €# Company D imports 5 products from countries other than Australia and has an annual turnover of \$100,000.

The tables show that while the total amount collected in annual product licence fees remains at 2.5% of the total turnover under both scenarios, the impact on individual companies varies considerably. Company B would pay 10% of total turn over in annual product licence fees if a flat fee of \$500 per product were applied. This does not include the costs of completing product licence applications. By contrast, Companies A and C would each pay only 1% of turn over. (Note that this does not take into account the cost of Company C obtaining a licence to manufacture.)

Setting the annual product licence fee at 2.5% of turn over would increase the amount paid by Company A by 250%. Company D would pay the same amount under either scenario.

Scenario 1: Annual product licence fee of \$500 per product. No fee waiver for low volume/low value products or for companies with large product ranges.				
	Company A	Company B	Company C	Company D
Total annual turnover	\$5 million	\$1 million	\$250,000	\$100,000
Number of products	100	200	5	5
Estimated annual product licence fees	\$50,000	\$100,000	\$2,500	\$2,500
Fees as % of turnover	1%	10%	1%	2.5%

Scenario 2: Annual post-market fee set at 2.5% of turnover				
	Company A	Company B	Company C	Company D
Total annual turnover	\$5 million	\$1 million	\$250,000	\$100,000
Number of products	100	200	5	5
Estimated annual product licence fees	\$125,000	\$25,000	\$6.250	\$2,500
Fees as % of turnover	2.5%	2.5%	2.5%	2.5%

The proposed fee structure for the joint agency is yet to be determined. Work will continue, in consultation with the industry, on options for distributing regulatory costs in a way that is equitable, and which reduces the potential cost burden on distributors of complementary medicines. The outcome of this work will be the subject of a future paper.

Incremental compliance costs

Estimates of annual and transitional compliance costs are summarised in the table below. This table assumes full cost-recovery from industry through regulatory fees. Other cost-sharing options are possible, which would shift some or all the regulatory costs from industry (and consumers) to taxpayers.

The table also assumes that Joint Agency costs are shared, based on an estimate that about 30% of all product licences will be held by New Zealanders. The incremental estimates are indicative only and do not include the changes in fiscal costs to Government or transition costs. Actual compliance costs for pharmaceuticals and complementary medicines would be higher as the above estimates do not include the (potentially substantial) costs of manufacturing licences and audits.

Table 1: Incremental Compliance Costs			
Annual costs, Midpoint estimates			
	Unilateral Recognition	JTA (NZ's share)	
Pharmaceuticals (+/- 11%)			
Regulatory fees		\$10.9M	\$3.0M
Other business compliance		(\$3.9M)	(\$4.4M)
Total		\$7.0M	(\$1.4M)
% of industry turnover		0.8%	(0.2%)
Complementary Healthcare products (+/- 30%)			
Regulatory fees		\$6.0M	\$1.7M
Other business compliance		\$1.2M	\$0.9M
Total		\$7.2M	\$2.6M
% of industry turnover		7.2%	2.6%
Medical devices (+/- 30%)			
Regulatory fees		\$8.4M	\$5.8M
Other business compliance		\$1.9M	\$1.2M
Total		\$10.3M	\$7.0M
% of industry turnover		1.6%	1.1%
Total Sector			
Total		\$24.5M	\$8.3M
% of sector turnover		1.5%	0.5%
Source: NZIER			

Risks associated with estimates

The estimates of incremental compliance costs are sensitive to assumptions made about the risk profile of therapeutic products and agency and industry costs. The table above indicates the uncertainty of +/- 11% for pharmaceuticals, and +/- 30% for the other therapeutic products.

The estimates are indicative only, as the details of the proposal, including how costs will be recovered, are still being developed. Final compliance costs may vary from the estimates here, e.g. if assumptions underlying the agency costs or the sharing of costs between countries change from those assumed for this assessment, or if estimates of industry costs are inaccurate because uncertainties about the detail of the regulatory scheme.

Key issues identified in consultation

Complementary medicines/dietary supplements are viewed by the industry as very low risk. A number of stakeholders questioned the need for additional regulation, particularly if the Dietary Supplement Regulations were updated. Industry members are concerned that a number of small suppliers in New Zealand, particularly importers, would be likely to exit the market as a result of the additional costs from the proposed regulation. This would be primarily a distributional issue, as most ingredients in imported products are likely to be available in locally manufactured products, and where this is not the case, larger firms would introduce substitutes for affected product lines where sufficient profits could be made. However, some low value/low volume products would be likely to be removed from the market.

The major source of concern for the other sectors is the magnitude of fees. The Medical Industry Association of NZ (representing the medical device industry) raised concerns that fees may force many small importers out of business and reduce the range of product available in New Zealand. The Association is also concerned that the proposed harmonisation with Australia would cause many international device manufacturers to cancel contracts with New Zealand based distributors, and rely on their distributors in Australia to supply product in both countries. The latter appears unlikely, however, as there is nothing to prevent this happening now.

Overlapping compliance requirements with other agencies

Some dietary supplement manufacturers are also covered by regulations administered by MAF covering meat and dairy based products. However, those controls would not be duplicated by the proposed joint agency controls.

The Environmental Risk Management Authority regulates products incorporating genetically modified organisms. Medicines and medical devices using genetically modified organisms must gain approval from ERMA and from the regulator of therapeutic products before being marketed in New Zealand, as each agency is regulating different aspects of product safety.

Steps to minimise compliance costs.

All options employ a risk-based approach, with pre-market entry requirements based on the level of risk. Under the proposed product licensing scheme, suppliers of low risk therapeutic products would be able to self-certify that the product met specified requirements, and subject to electronic validation of key requirements such as the licence status of the manufacturer, a product licence would be issued immediately. In this way, pre-market evaluation of individual products and delays in getting the product to market would be avoided for an estimated 95% of complementary medicines and a significant proportion of medical devices.

Mutual recognition agreements can continue under each of the options to reduce duplication. Under each of the options, the regulator recognises manufacturing licences and audits conducted by overseas regulators in which it has confidence.

Under the joint agency proposal, product or ingredient approvals need to occur only once to cover both the Australian and New Zealand market. This reduces duplication, and so reduces the sum of regulatory fees for all (benefiting particularly manufacturers of products that are traded across the Tasman).

Transition arrangements

There will be a period of transition during which firms will be able to learn about the requirements, compile the required information, and adjust their production, labelling and distribution processes. There would be no application fee for existing complementary medicines and medical devices to get onto an interim product licence register. They could continue to be sold in New Zealand during the transition period. Once full compliance with the joint agency's requirements was achieved, a joint agency product licence would be issued and the product could then be sold in both countries. Annual licence fees would apply from commencement of the new scheme, but there would be no initial licensing fee for products that are not currently required to be registered.

Substances used in existing complementary medicines but not currently permitted in low risk products in Australia would undergo a safety assessment for inclusion in a new

joint agency list. This work would be completed as part of the implementation process for the joint agency, at no cost to industry.

Much of the impact of the new scheme could be managed by:

- €# Allowing distributors to place products on the product licence register free of charge (i.e. no application fee, although annual licence fees would apply); and
- €# Adopting appropriate transition times to allow licence holders to achieve compliance with any new requirements.

Distributors of complementary medicines would be required to place their products on an interim register (at no charge), but could continue selling existing products in New Zealand for a transition period of up to five years while full compliance with the new requirements was achieved (such as manufacturers upgrading premises to meet GMP requirements). Similarly, a suitable transition period can be selected to permit label stock to be substantially exhausted before new labels are required.

Establishment of an interim register of medical devices

It is proposed to amend the Medicines Regulations to enable establishment of a register of medical devices as an interim step towards GHTF-style device regulation. There would be no fee for placing devices on the register. This would facilitate transition to the proposed joint agency regulatory scheme, and is well supported by the medical device industry. Many medical devices have a relatively short life span and will have been superseded by newer products before the transition period expires.