

# REGULATORY IMPACT STATEMENT

## BACKGROUND

In November 2002 Cabinet [CAB Min (02) 31/9 refers] agreed that complementary medicines should be regulated as therapeutic products under a risk-based regulatory scheme, and agreed in principle that they should be regulated by the joint therapeutic products agency (JTPA). Officials were directed to report back to Cabinet on the outcome of further work to refine the details of the regulatory scheme and investigate options for distributing regulatory costs across the sector in a way that is equitable, and which reduces the potential cost burden on smaller distributors of complementary medicines.

The term “complementary medicine” in this statement is a collective term that includes products referred to as complementary or alternative medicines (e.g. herbal medicines, homoeopathic medicines), traditional medicines (e.g. Chinese and Ayurvedic medicines) and therapeutic-type dietary supplements (e.g. vitamins, minerals and amino acids).

## STATEMENT OF THE NATURE OF THE PROBLEM AND THE NEED FOR GOVERNMENT ACTION

The introduction of risk-based regulation of complementary medicines, with full cost recovery through fees paid by industry, will result in new regulatory fees and compliance costs for New Zealand distributors of complementary medicines. New costs will apply regardless of whether complementary medicines are regulated under a joint scheme with Australia or under a New Zealand-only regulatory scheme, although costs will be lower under a joint regulatory scheme. Regulatory fees, with respect to the complementary medicines sector, have been estimated at \$3.2M per annum. However, the incremental costs arising from implementation of a joint regulatory scheme have been estimated at \$2M or 0.9% of current sales per annum (see Net Benefit section below).

The industry has expressed concern about the impact of regulatory and compliance costs, particularly on the large but unknown number of small businesses. The greatest impact would fall on small to medium-sized businesses, particularly those importing and distributing large ranges of products. In order to minimise the negative impact on these businesses, compliance costs incurred through regulation must be minimised and distributed equitably across the complementary medicines sector.

Australian Ministers have indicated that their final decision to enter into a joint regulatory arrangement with New Zealand is contingent on complementary medicines being included within the joint scheme. The recent experience with the company Pan Pharmaceuticals, whose actions sparked a massive recall of pharmaceuticals and complementary medicines in Australia and New Zealand recently, has reinforced their view that all medicines should be regulated under a single regulatory framework. The practices of Pan Pharmaceuticals, which included falsifying documentation and failure to meet basic quality standards in the production of their products, indicates that effective regulation is required to both set and enforce standards for the production of all therapeutic products.

## STATEMENT OF THE 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 (including to the complementary medicines sector) and Government, and without imposing unnecessary trade barriers.

### **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.

## **STATEMENT OF FEASIBLE OPTIONS (REGULATORY AND/OR NON-REGULATORY) THAT MAY CONSTITUTE VIABLE MEANS FOR ACHIEVING THE DESIRED OBJECTIVES**

The following options for achieving equitable distribution of regulatory costs across the complementary medicines sector have been assessed:

### **Option 1: Status quo**

Currently, most complementary medicines are regulated under the Dietary Supplements Regulations 1985 (made under the Food Act 1981). They avoid risk-based regulation by being sold as "dietary supplements". The decision made by Cabinet in November 2002 was that complementary medicines be regulated under risk-based regulation and Cabinet agreed in principle that complementary medicines be included in the joint Trans-Tasman therapeutic products regulatory agency (JTPA). The Dietary Supplements Regulations prohibit therapeutic claims, although such claims are still made. This option does not meet the government's decision to apply risk-based regulation to all therapeutic products, and is therefore not supported.

### **Option 2: Flat rate levy based on turnover**

Note: Under Options 2 and 3, complementary medicines would be subject to a risk-based approach to regulation. There would be an up to three year (depending on risk profile of the products) transition period to allow companies to achieve compliance with new requirements and companies would be able to continue marketing their products in New Zealand during the transition period. Regulation would include:

- €# Applying limited regulatory controls on market entry for low-risk products (estimated as comprising 95% of the market), including safety assessments of ingredients, and self-certification for the limited therapeutic claims permitted. 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;
- €# Applying more extensive regulatory controls for medium and high risk products (estimated as comprising 5% of the market), involving pre-market evaluation before a product licence is issued;

- €# Requiring all manufacturers to meet appropriate standards of Good Manufacturing Practice (GMP) relating to premises, equipment, staff and procedures. Manufacturers would be audited and licensed by the regulatory agency;
- €# Post-market monitoring and controls, including adverse reactions monitoring, testing, complaints investigation, recall procedures and controls on labelling and advertising.

Under Option 2, a flat rate levy based on turnover would shift costs from smaller to larger business. Under a joint regulatory scheme, it would also reduce the regulatory fees paid by New Zealand companies and shift costs to Australian companies with larger turnovers.

Such a levy would not be consistent with cost recovery guidelines (Treasury guidelines for setting charges in the public sector and equivalent Australian guidelines) and is not considered efficient, since it does not appropriately approximate where the true cost of the regulation lies.

### **Option 3: A cost recovery schedule based on fees and charges (preferred option)**

Under this option, the same key features would apply as per Option 2, but the costs of regulation would be fully recovered through a range of fees and charges paid by industry. This approach is currently used by the Therapeutic Goods Administration (TGA) in Australia and approximates the approach suggested by official cost recovery guidelines.

The TGA currently operates a system under which substantially reduced annual charges are paid for low revenue products. Almost 50% of Australian complementary medicines qualify and it is anticipated that a greater or equal percentage of New Zealand complementary medicine products would also qualify. The annual product licence fee for low revenue products is likely to be less than \$100 and the total amount paid by a distributor would be capped.

## **STATEMENT OF THE NET BENEFITS OF THE PROPOSAL, INCLUDING THE TOTAL REGULATORY COSTS (ASMINISTRATIVE, COMPLIANCE AND ECONOMIC COSTS) AND BENEFITS (INCLUDING NON-QUANTIFIABLE BENEFITS) OF THE PROPOSAL, AND OTHER FEASIBLE OPTIONS**

### **Government**

The benefits to Government include New Zealand meeting its objectives for the regulation of complementary medicines in a way that fully recovers costs from industry in an equitable way. The Government may lose some duty income from those products that would no longer be classified as dietary supplements and subject to duties in respect of some countries, but it is not possible to quantify this loss due to a lack of clarity over international tariff classifications and how the complementary medicines industry has to date been classifying imported products. The New Zealand Government's previously agreed financial contribution to the establishment of the joint agency will cover the cost of expanding the approved list of substances used in existing complementary medicines to incorporate New Zealand-specific substances during the transition period.

### **Complementary medicines industry**

Under a full cost recovery regime, it has been estimated that annual fees and charges paid by New Zealand businesses would be in the region of \$3.2M or 1.5% (+/- 0.2 percentage points) of total domestic and export sales (estimated at \$218M per annum).

There are no reliable data on the number of products on the market or the number of businesses distributing them, the nature of those products or businesses, or the extent of overlap between the New Zealand and Australian markets. For this reason, any estimate

of impacts on the industry must be based on assumptions that it is not possible to validate. However, since it has been assessed that more than one third of the estimated \$3.2M is already being paid by New Zealand companies that export to Australia (and consequently must meet regulatory controls in Australia, which are similar to what is proposed under a joint regulatory scheme), the incremental regulatory costs for a cost-recovered regulatory scheme of the type proposed, administered by the JTPA, would be of the order of \$2M or 0.9% of current sales.

For manufacturers, in relation to products already sold in both countries, the extent to which regulatory 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 product licensing costs, and no additional costs associated with upgrading and licensing manufacturing premises.

For importers, the greatest cost impact would fall on businesses with large product ranges sourced from many different manufacturers. Those importing from countries such as the USA, where some manufacturers do not comply with GMP standards because this is not required for supply to their domestic market, may need to find alternative sources of product. Such manufacturers are unlikely to be prepared to undertake the necessary steps of upgrading facilities and being audited to meet the requirements of the relatively small Australia/New Zealand market.

There will be no delay in getting new products to market for the estimated 95% of complementary medicines that fall into the low risk category, since applications to licence these products will be made online and processed in real time.

Some dietary supplements are currently subject to import duty of up to 7%, depending on the country of origin and whether a concession has been granted. The actual amount of duty paid on dietary supplements imported into New Zealand is unknown. However, it is possible that their classification as medicines in the new legislation may result in the removal of the 7% import duty and help offset the new fees. The (re)classification of dietary supplements will be the subject of further discussion with Customs.

A fees and charges regime gives a fairer distribution of costs across the complementary medicines sector than would occur if a levy based on turnover were applied. Lower annual product licensing fees for low revenue products will reduce the impact on smaller businesses and those distributing large ranges of products in low volumes.

The following company scenarios have been used to demonstrate the impact of annual product licensing fees on a number of different types of companies.

**Company A** is a large manufacturer. It manufactures and distributes 300 products in New Zealand and exports 100 products to Australia. It has an annual turnover of \$20 million and has no low revenue products. Under a joint agency, the company gains access to the Australian market for the remaining two thirds of its product range. The factory is already GMP licensed and will continue to pay manufacturing licence fees, but there is no additional cost involved in upgrading the manufacturing facilities.

**Company B** is a medium-sized manufacturer. It manufactures and distributes 50 products in New Zealand and exports 10 products to Australia. It has an annual turnover of \$2 million, and 20 of its products are low revenue products. Under a joint agency, the company gains access to the Australian market for the remainder of its products and since it is already GMP licensed, there will be no additional cost involved in upgrading the manufacturing facilities.

**Company C** is a small manufacturer. It manufactures and distributes 10 products and does not export to Australia. It has an annual turnover of \$200,000 and half of its products

are low revenue. The company is not GMP licensed and would be required to either upgrade its manufacturing facilities to GMP standard, or cease manufacturing and contract with an already-licensed manufacturer. It could, however, continue marketing its products in New Zealand during the transition period.

**Company D** is a large importer. It imports and distributes 500 products from a variety of sources. It has an annual turnover of \$5M, and 300 of its products are low revenue.

**Company E** is a medium-sized importer. It imports 100 products from several sources. The company has an annual turnover of \$1 million, and 70 of its products are low revenue.

**Company F** is a small importer. It imports 20 products, all of which are low revenue, and has an annual turnover of \$100,000.

A table summarising the regulatory costs for these companies follows on page six.

Although companies D, E and F may import some products from Australia, they are not the distributors of the product in Australia. It has therefore been assumed that they would have to pay product licence fees for these products. These companies are also likely to have some products that are manufactured in GMP-licensed facilities, so the importers could expand into the Australian market with these products. Products not manufactured in GMP-licensed premises could continue to be marketed in New Zealand throughout the transition period, during which time the importer would need to arrange GMP-licensing of the manufacturer or look for alternative sources of product.

### **Consumers**

Consumers will benefit from having increased confidence in the safety and quality of products on the market, and better access to reliable information about products. Regulatory costs for some products may be passed on to consumers in increased prices. Some product brands will be taken off the market, leading to decreased consumer brand choice. However, it is unlikely that any low-risk substances currently available in complementary medicines will be lost.

### **Wider economy**

Benefits to the wider economy include the effective regulation of the complementary medicines industry in a way that imposes costs in an equitable manner, thus limiting loss of product lines and costs for small to medium businesses. A trans-Tasman regulatory scheme will also facilitate trade in complementary medicines between the two countries by rationalising regulatory controls and reducing the need for dual approvals for products.

## **STATEMENT OF CONSULTATION UNDERTAKEN**

The Treasury, State Services Commission, Parliamentary Counsel Office, Te Puni Kokiri, the Ministries of Foreign Affairs and Trade, Justice, Social Development, and Economic Development, the New Zealand Food Safety Authority, the New Zealand Customs Service and the Departments of Courts, Prime Minister and Cabinet, and Inland Revenue have been consulted on this paper.

There has been no direct consultation with industry on the issue of distribution of the costs of regulation. Work undertaken was based on the clear views articulated by industry during previous consultation exercises that fees should be as low as possible, and on government guidelines in New Zealand (the Treasury guidelines) and Australia relating to equitable recovery of regulatory costs from industry.

***Incremental impact of annual product licence fees on different types of companies in the complementary medicines industry***

Company Type of company	A	B	C	D	E	F
	Large manufacturer	Medium manufacturer	Small manufacturer	Large importer	Medium importer	Small importer
<b>No. of products manufactured</b>	300	50	10	0	0	0
<b>No. of products imported</b>	0	0	0	500	100	20
<b>No. of products also sold in Australia (no new fee applies)</b>	100	10	0	0	0	0
<b>No. of products subject to full fees (at \$500 per product)</b>	200 (\$ 100 K)	30 (\$ 15 K)	5 (\$ 2.5 K)	200 (\$ 100 K)	30 (\$ 15 K)	0
<b>No. of low revenue products (at \$100 per product to a maximum of \$10 K)</b>	0	10 (\$1 K)	5 (\$ 500)	300 (\$ 10 K)	70 (\$ 7 K)	20 (\$ 2 K)
<b>Total new annual PL fees under joint agency scheme</b>	\$ 100 K	\$ 16 K	\$ 3 K	\$ 110 K	\$ 22 K	\$ 2 K
<b>Annual turnover</b>	\$20 M	\$2 M	\$ 200 K	\$ 5 M	\$1 M	\$ 100 K
<b>New annual PL fees as percentage of turnover</b>	0.5%	0.8%	1.5%	2.2%	2.2%	2%

## BUSINESS COMPLIANCE COST STATEMENT

For the complementary medicines industry, compliance costs would arise from:

- # preparing and submitting applications to the regulator;
- # gaining an understanding of the new requirements;
- # introducing new labels;
- # preparing documentation and training staff to meet GMP requirements (for those manufacturers that do not currently meet GMP requirements and wish to continue manufacturing).

The compliance costs will fall directly on:

- # manufacturers (about 10 large to medium companies, half of whom are believed to be exporting to Australia, plus up to 100 small manufacturers); and
- # importers (estimated to be 11 major companies and up to 100 small businesses)

with estimated total sales of \$218M per annum (\$144 million in local sales and \$74M in exports). The larger local manufacturers are thought to account for at least three quarters of the total industry turnover.

Business compliance costs (excluding the cost of upgrading manufacturing facilities and any implementation costs) have been estimated at \$0.9M (NZIER, 2002). However, it should be noted that this estimate was based on information provided by the industry, which was often incomplete and inconsistent.

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. Due to the lack of reliable information on the makeup of the industry, estimates of compliance costs must be based on assumptions that it is not possible to validate.

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 manufacturing facilities and procedures in order to obtain a manufacturing licence. It is expected that many will choose to cease manufacturing and contract with one of several companies that is already licensed.

There will be a transition period of up to three years, during which firms will be able to learn about the requirements, compile the required information, and adjust their production, labelling and distribution processes. For low risk products, the full three year period will apply. Companies will be able to continue marketing their products in New Zealand during the transition period.

Prior to commencement of the new scheme, there would be an extensive education and training programme to allow those in the industry to become familiar with the new requirements and procedures.