Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products

Report of the Health Committee

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Contents

Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products

Summary of recommendations to the Government

Following its inquiry, the Health Committee makes the following recommendations to the Government:

- that it strengthen domestic regulation as the most appropriate method of governing complementary healthcare products in New Zealand (Page 48)
- that it pursue a mutual recognition regulatory option rather than pursue a joint agency with Australia (Page 48)

Assessment of regulatory system

- that it consider and assess all options for regulating complementary healthcare products in light of these best practice guidelines:

    a) the Council of Australian Governments' *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (as well as *A Guide to Regulation* of the Office of Regulation Review of the Australian Productivity Commission) and

    b) international regulatory best practice, including the work of the Organisation for Economic Co-operation and Development, the United Kingdom Better Regulation Task Force on principles of good regulation, United Kingdom Cabinet Office and the United Kingdom National Audit Office on regulatory impact assessment (Page 43)

- that it maintain ongoing consultation with the Ministerial Panel on Business Compliance Costs on the regulation of complementary healthcare products and ensure that the panel is satisfied with proposals relating to such regulation (Page 43)
- that compliance with New Zealand regulatory requirements be independently verified (Page 43)
- that it ensure the decision-making process of any regulatory regime for complementary healthcare products reflects its Treaty of Waitangi obligations and the interests of Māori (Page 38)
- that, if it proceeds with a trans-Tasman agency to regulate therapeutic products, it ensure that both the treaty establishing such a regime and any implementing legislation in both countries reflects its Treaty of Waitangi obligations and the interests of Māori (Page 38)
- that it commission an independent risk assessment of complementary healthcare products (Page 24)

Regulation of complementary healthcare products

- that it ensure any system for regulating complementary healthcare products:
    - is risk-based (Page 24)
    - establishes a separate category for low-risk complementary healthcare products that do not make therapeutic claims distinct from categories for food and medicine (Page 15)
    - requires all products and their ingredients to be listed by the supplier on a central register (Page 24)
    - includes a simple electronic lodgement and notification system (Page 30)
    - is based on a negative list that records which ingredients are not permitted to be used because a safety issue has been identified (Page 29)
    - takes full account of the voluntary nature of risks accepted by consumers in this area and places an appropriate emphasis on disclosure of adequate and accurate relevant information to consumers (Page 23)
    - has labelling requirements that govern the adequate and accurate disclosure of information (Page 23)
    - requires compliance with good manufacturing principles (Page 24)
    - includes monitoring, enforcement, and review of quality assurance, with ongoing random sampling and auditing to ensure maximum compliance (Page 24)
    - allows for innovation in products and processes and new product entry (Page 29)
- takes into account the impact of the cost of complying with any regulatory regime on the New Zealand complementary healthcare products industry (Page 29)

Compliance of joint agency proposal with regulatory guidelines

- that before it takes any decisions on the proposed trans-Tasman agency to regulate therapeutic products, it ensure that it demonstrates that all of its requirements with respect to best regulatory practice have been fully complied with, including:
    a) the five principles and guidelines (efficiency, effectiveness, transparency, clarity, and equity) set out in the 1997 *Code of Good Regulatory Practice* administered by the Ministry of Economic Development and

    b) the Cabinet Office and Ministry of Economic Development requirements relating to regulatory impact statements and business compliance cost statements (Page 43)
- that it satisfy itself that the joint agency proposal has been subject to all appropriate regulatory impact and business compliance cost assessments in Australia with respect to complementary healthcare products (Page 43)

- that it consider the implications of the section on the Treaty of Waitangi and Māori policy contained in the Ministry of Economic Development guidelines for preparing regulatory impact statements when assessing the impact of any joint agency on Māori (Page 32)
- that it assess the joint agency proposal with reference to the small firms' impact test and the competition assessment (including the competition filter test) contained in the United Kingdom Cabinet Office guide to regulatory impact assessment (Page 43)

Controls on the proposed joint agency

- that if the joint agency proposal proceeds, it ensure that questions of parliamentary accountability in accordance with New Zealand requirements be resolved in detail in the proposed treaty and implemented appropriately in the legislation of both countries (Page 35)
- that, if it proceeds with a trans-Tasman agency to regulate therapeutic products, it ensure there is a complaints system that gives equal recourse to New Zealanders and Australians (Page 37)
- that, in the event that it were to decide to proceed with the proposed joint agency, it ensure that the regulatory powers allocated to the Ministerial Council and the managing director are consistent with the principles and controls relating to delegated legislation in New Zealand (Page 40)
- that the powers of the managing director of any trans-Tasman agency not exceed the powers of other New Zealand public service chief executives (Page 37)
- that the Official Information Act 1982, the Privacy Act 1993, and the Protected Disclosures Act 2000 apply to any agency that regulates complementary healthcare products in New Zealand (Page 37)
- that it ensure that any agency with responsibility for the regulation of therapeutic products in New Zealand be covered by the Sixth Schedule to the Public Finance Act 1989 and be subject to the same reporting and accountability requirements as any other Crown entity (Page 35)
- that it consider how the application of the Auditor-General's powers would be preserved under any joint agency (Page 35)

Effects of joint agency proposal

- that it consider carefully the impact that the joint agency proposal would have on the relative positions in domestic and external markets of the New Zealand and Australian complementary healthcare products industries (Page 45)
- that, in the event that it were to decide to proceed with the proposed joint agency and to include complementary healthcare products in the agency's coverage, it consider a more appropriate merging of the regulatory systems that would involve not only a raising of New Zealand's regulatory standards but also a reduction of the regulatory burden in Australia (Page 46)

Summary of recommendations to the House

The Health Committee makes the following recommendations to the House:

- that the Foreign Affairs, Defence and Trade Committee refer any treaty establishing an Australian-New Zealand agency to regulate therapeutic products to the Health Committee for consideration (Page 34)
- that if the Foreign Affairs, Defence and Trade Committee chooses not to refer any treaty establishing an Australian-New Zealand agency to regulate therapeutic products to the Health Committee for consideration, that that committee take into consideration the matters raised in this report in its consideration of such a treaty (Page 34)

Conduct of the inquiry

In September 2002 we received the petition of Sue Kedgley and 30,457 others, requesting that regulations governing dietary supplements not be brought under a single trans-Tasman authority but be regulated on the basis of New Zealand legislation, separate from medicines and medical devices, and that emphasis be placed on quality control and maximum consumer choice.

Partly in response to this petition, and partly because of concerns raised over therapeutic product policy development in New Zealand, on 11 September 2002 we resolved to conduct an inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products.

While we have been considering this inquiry, we are aware that work has continued on the proposal to establish a trans-Tasman joint agency to regulate therapeutic products. The Ministers of Trade, Commerce and Health have been involved in this work.

Terms of reference

We established the following terms of reference for our inquiry:

1. To consider the legislative and regulatory regimes governing dietary supplements and traditional remedies in other countries.

2. To consider an appropriate regulatory framework to govern dietary supplements and traditional remedies in New Zealand, including assessments of:
    - whether this should be by the proposed joint trans-Tasman therapeutic products agency, including an examination of the process followed in developing this proposal
    - the risk created by the use of dietary supplements and traditional remedies
    - the compliance costs that would be imposed, and any added cost to consumers
    - whether indigenous complementary medicinal/rongoā products and extracts used for alternative therapy would be protected.

The inquiry did not extend to pharmaceuticals, over-the-counter (OTC) medicines or medical devices.

Terminology used in this report

There are a range of terms used to describe medicines, medical devices and complementary healthcare products. This section contains definitions of terms used in this report.

The term 'therapeutic product' generally refers to any product used for a treatment purpose and covers prescription and OTC medicines, medical devices and complementary healthcare products.

A 'prescription medicine' is a medicine a registered medical practitioner prescribes that cannot be obtained without such a prescription. Over-the-counter medicines are medicines

that are able to be purchased without a prescription. A medical device is an instrument or apparatus used to diagnose, prevent, treat, or monitor disease, an injury or a handicap.

The term 'complementary healthcare product' is often used together with 'alternative medicine' and may include traditional medicine that is practised in a country but is not necessarily part of the country's own traditions. The term 'complementary healthcare product' is sometimes used to refer to health care that is considered supplementary to 'Western' or 'scientific' medicine.

This inquiry extends only to dietary supplements and traditional remedies. In the report we have used the term 'complementary healthcare products' to refer to these products.

Overview of submissions

The committee received submissions from both individuals and organisations. Submitters came from many parts of the therapeutic industry including manufacturers, distributors and consumers. We heard substantial and sustained opposition from the New Zealand complementary healthcare products industry to the proposed model for the joint agency. We also heard from submitters who favoured a joint regulatory agency with Australia, but not under the proposed framework.

We also received specialist public law and economic advice.

Structure of the report

This report is divided into five parts. Part I contains information relating to the current system of regulation for complementary healthcare products in New Zealand, the process involved in the development of the proposed trans-Tasman agency to regulate therapeutic products, and an outline of the proposed agency's structure.

Part II contains an outline of good regulatory principles. Part II also discusses contemporary approaches to regulation and some public law issues.

In Part III, we discuss options for harmonising with Australia, including mutual recognition and a joint system. This section also contains an outline of overseas regulatory systems. Part III also addresses the terms of reference for this inquiry by examining risk-based regulation, compliance costs and indigenous products.

Part IV explores further issues relating to the joint agency proposal, including Treaty of Waitangi issues. Part V contains our recommendations for regulatory reform.

Part I Current regulatory system and the need for reform

This section contains an outline of the current system for the regulation of therapeutic and complementary healthcare products in New Zealand and Australia. It contains a discussion of problems associated with these systems and the proposed regulatory changes.

Current regulatory system in New Zealand

Complementary healthcare products are either dietary supplements (regulated by the Dietary Supplements Regulations 1985, made under the Food Act 1981) or medicines or related products (regulated under the Medicines Act 1981).

Regulation of dietary supplements

In order for a product to meet the definition of 'dietary supplement' in the Dietary Supplements Regulations it must:

- contain amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins, either individually or in a mixture
- be in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets and
- be intended to supplement the intake of substances normally derived from food.

It cannot make any claim relating to the prevention, treatment, or diagnosis of disease or ascertaining the existence, degree, or extent of a physiological condition; altering the shape, structure, size or weight of the human body; or otherwise preventing or interfering with the normal operation of the physiological function.

The Dietary Supplements Regulations do not require ingredients used in dietary supplements to be assessed for safety prior to the product being placed on the market. These products can be sold without first gaining approval from a regulator, or registering the product. Manufacturers are not required to meet good manufacturing practice standards. However, there are restrictions on the allowable daily intake for some substances. The regulations prescribe labelling requirements for dietary supplements.

Products that are not dietary supplements

Many complementary healthcare products that do not fit the definition of 'dietary supplement' are regulated under the Medicines Act. These include products that:

- contain substances not permitted in dietary supplements (such as prescription medicines) or
- are not in solid or liquid dose form intended for oral ingestion (such as a cream, ointment or eye drop) or
- are intended to be used for a therapeutic purpose.

There are two product categories under the Medicines Act that could cover complementary healthcare products. A 'medicine' is a substance or article that is administered to human beings for a therapeutic purpose. A 'related product' is 'any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a

therapeutic purpose.' This latter category would include products that are primarily foods or cosmetics, but also have a therapeutic purpose.

Medsafe, a business unit of the Ministry of Health, undertakes the regulatory functions relating to administration of therapeutic products, including complementary healthcare products.

All products regulated under the Medicines Act have to be approved before they can be sold under the Act. Approval is subject to a full assessment of the product's safety, quality, and efficacy. Medsafe notes that the current requirements for such applications are consistent with international standards for the regulation of prescription and OTC medicines, but are not appropriate for complementary healthcare products. The application fee for a new medicine is between $7,800 and $15,300, depending on whether the medicine contains a new active substance. The application fee for a related product is $5,500. The data requirements for demonstrating the effectiveness of such products are less onerous, but still present a barrier for many complementary healthcare products.

Current New Zealand regulations not being enforced

Medsafe told us that currently dietary supplements labelled or advertised for a therapeutic purpose, including many herbal products, 'are being distributed without Ministerial consent and in contravention of the Medicines Act', and that 'many products that should be regulated as medicines or related products under the Medicines Act are being sold as dietary supplements under the Food Act, without any quality control or safety assessment'.[1]

It went on to say that the Dietary Supplements Regulations 'are currently not being enforced, as doing so would force a substantial proportion of existing complementary healthcare products off the market. If a product does not meet the definition of dietary supplement or herbal remedy, distributors of complementary healthcare products are required to obtain consent to market their product as a medicine or related product under the Medicines Act 1981. However, the regulatory barrier and cost for registration are currently high, and as a result, many complementary healthcare products are being sold as dietary supplements in contravention of current legislation.' Maintaining the status quo, it said, would mean that 'there would be minimal enforcement and many products would continue to be marketed in contravention of the legislation without penalty.'

We are very concerned by these comments. Legislation passed by or under the authority of Parliament is required to be applied and enforced, otherwise people cannot rely on, or have confidence in, the law. We were unable to establish how this situation has been allowed to develop, and why the regulations, if not the statutes, have not been amended if there were insurmountable resource issues or other obstacles to applying and enforcing them.

We sought clarification about the lack of enforcement under the current regulatory system in New Zealand. The Minister of Health assured us that no illegality is occurring and that proposed new legislation will be more easily enforced. While this may be the case, we remain concerned that this situation has been allowed to continue for so long.

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1 Medsafe submission to the Health Committee, March 2003.

The lack of enforcement was also of concern to submitters. Some were concerned that those manufacturers who were complying with the regulatory system were at a disadvantage compared with those who were not complying. Submitters agreed that some form of functioning regulatory system was needed.

Current system does not adequately regulate the industry

We have been made aware of numerous failings in the current regulatory system. The law does not control for ingredient safety or product quality for dietary supplements. Health benefits are currently being claimed for many products despite this being unlawful under the Dietary Supplements Regulations. The lack of a register makes recalling products difficult. The Medicines Act process creates barriers to appropriately registering complementary healthcare products.

Material supplied with the Medsafe submission states that the current system is a low-cost way to manage public health and safety risks from pharmaceuticals, but that the status quo does not adequately address the risk posed by medical devices or complementary healthcare products. Existing dietary supplement regulations and consumer protection law provide some protection once the product has been marketed, but this is limited.

We are concerned that lack of compliance by manufacturers is creating issues of risk. There is a lack of protection from risks of untried and untested innovative products. The current system also does not provide risk management for issues of health, safety, or product efficacy before the product is marketed.

Proposals for regulatory reform in the 1990s

Review of the legislation governing therapeutic products began in the early 1990s, when the Government began work on new legislation to replace the Medicines Act and the Dietary Supplements Regulations.

In 1994, Cabinet gave approval for risk-based regulation of medical devices and dietary supplements. Drafting instructions for a Therapeutic Products Bill were issued in 1995 and the bill was placed on the legislative programme, with low priority. This bill was never introduced.

By 1998, the proposed legislation was still in a developmental phase. The proposed bill was renamed the Healthcare and Therapeutic Products Bill, but Cabinet approval was deferred while further consultative and policy work was done on dietary supplements.

Trans-Tasman Mutual Recognition Arrangement

In 1996, the New Zealand and Australian governments signed the Trans-Tasman Mutual Recognition Arrangement. Laws relating to complementary medicines (and therapeutic goods generally) are subject to a special exemption under the arrangement (which took effect in 1998). The arrangement provides that a good that may legally be sold in the jurisdiction of one party may legally be sold in the jurisdiction of the other party and, in general, need only comply with standards or regulations applying in the jurisdiction in which the goods are produced or through which they are imported.

The New Zealand and Australian parties have agreed in the arrangement to minimise exemptions and exclusions. Differences in regulatory requirements between the 2 countries that are standing in the way of the application of the arrangement to particular laws are required to be addressed through mutual recognition, harmonisation or permanent exemption. In seeking to achieve that objective, the parties are required to have regard to: (a) the *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies* endorsed by the Council of Australian Governments in April 1995; (b) international regulatory best practice; and (c) the level of risk to public health and safety and the environment.

Joint agency proposed

In October 2000, the New Zealand Ministers of Health, Trade Negotiations, and Commerce agreed in principle to the establishment of a joint agency to regulate therapeutic products with Australia. In February 2001, the New Zealand Government announced that it would shelve previous plans for a Healthcare and Therapeutic Products Bill in favour of pursuing a single joint agency with Australia.

Australian and New Zealand officials developed the joint agency proposal following consultation with a range of stakeholder groups, including industry and consumer representatives and professional associations. This consultation occurred over an 18-month period.

Medsafe and the Australian Therapeutic Goods Administration released a joint discussion document in June 2002. This paper, entitled *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products*, indicated that the project team responsible for developing the joint agency proposal had also considered the strengths and weaknesses of the current regulatory schemes in both Australia and New Zealand. The discussion document detailed the joint agency proposal and sought public feedback. More than 1,600 responses were received from New Zealand submitters.

Medsafe told us that fewer than 15 percent of submitters on the discussion paper addressed the actual proposals set out in the paper, with the remainder responding to 'misinformation'. Medsafe said that submitters who appeared to have read the discussion paper were evenly divided between supporting and opposing the proposal. We are concerned that Medsafe is dismissive of submitters' views. We consider the submitters who presented to our committee were informed and had valid concerns about the proposed regulatory change.

Some submitters told Medsafe that they supported a risk-based approach to regulation of other therapeutic products, but not to complementary healthcare products because they did not think there were any risks associated with them.

Medsafe also notes that in New Zealand the complementary healthcare products industry is large, with an estimated turnover of $144 million including exports of $50 million and imports of $70 million (although reliable figures are difficult to obtain and some estimates go much higher). Therefore, there is much at stake for the industry and the New Zealand consumer in what is proposed.

Changes to New Zealand legislation governing medicine

The proposed joint trans-Tasman agency would regulate therapeutic products in New Zealand and Australia. This includes medicines, medical devices and complementary healthcare products, although this inquiry only examined the regulation of dietary supplements and traditional remedies. The proposed joint regulatory scheme would not extend to aspects of medicines law that include prescribing, dispensing, and wholesaling activities.

The regulation of these activities was the subject of a Medsafe discussion document, *Proposals to amend aspects of New Zealand's medicines law*, released in November 2002. The document covered issues the ministry considered pertinent in the consideration of any law change, and sought industry feedback on the proposed legislative changes.

Concerns about policy development process

We are aware that the consultation process followed in developing the trans-Tasman joint agency proposal has frustrated submitters. Some submitters told us they felt that concerns they had raised during the previous consultation process had not been acknowledged in Medsafe's discussion paper.

These submitters were concerned that although an agreement had been reached between the Government and stakeholders over the Healthcare and Therapeutic Products Bill, it was subsequently announced that this was being put aside in favour of the joint agency proposal. Some felt the reasons for the withdrawal of the proposed bill had never been adequately explained. Many submitters were concerned that they were consulted over the earlier proposed law change but not the proposed trans-Tasman joint agency.

Current regulatory system in Australia

Australia regulates complementary healthcare products as therapeutic products under the Therapeutic Goods Act 1989. This legislation sets out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods. These requirements include advertising, labelling, and product appearance. State or Territory legislation is also able to apply in this area.

The Therapeutic Goods Administration, a unit of the Federal Department of Health and Ageing, administers the Australian regulatory system.

There are 3 key processes in the Australian regulatory scheme: licensing of the manufacturer, pre-market assessment of products, and post-market monitoring. The scheme also imposes a risk management framework for low-risk, higher-risk, and exempt 'special cases' of complementary healthcare products.

The Australian system operates according to a positive list (white list). Products may contain only ingredients that are on this list. Substances are placed on the white list following a safety evaluation. The Australian regulatory system is extensive. Its operation, and even the determination of which products Australian legislation applies to, is highly complex (see Appendix F). This system is not transparent and depends a good deal on administrative discretion.

Perceptions of the current Australian system

Many submitters told us that current Australian legislation is very restrictive and bureaucratic. This is due to expensive and complex procedures for registering new ingredients, high registration and annual renewal fees, and unique labelling requirements.

Several submitters also told us that the Therapeutic Goods Administration rules and regulations were prescriptive and inflexible. One submitter noted that many of the fees charged by the administration are not related to the complexity of the task, and others noted that there are complex rules on product charges. Submitters were also concerned at the costs due to labelling requirements.

They noted that natural healthcare products in Australia are regulated as pharmaceuticals, imposing unnecessary legal, administrative, and financial burdens on consumers, professionals, industry, and Governments. The model in Australia was described as being regulated inappropriately following a 'disease and illness' rather than a 'wellness-centred' paradigm. Some submitters claim that areas of over-regulation result in frustration and inefficiencies and are out of step with the risks posed by complementary healthcare products.

Submitters perceive the Therapeutic Goods Administration as having an expensive and complex procedure for introducing new ingredients. The Australian system requires new ingredients that are freely traded in other countries to undergo assessment, regardless of whether a new ingredient has a long history of safe use.

Some submitters also pointed out that the Therapeutic Goods Act is a federal law, and some states have not yet enacted their own legislation, so Australia is not yet completely harmonised in its own regulation of therapeutic products.

Proposed joint agency structure

A ministerial council comprising the Australian Federal Minister of Health and the New Zealand Minister of Health would oversee the proposed agency. The ministerial council would appoint a five-member board to be responsible for the agency's strategic and financial direction but the board would not be involved in technical matters. The agency would be accountable to both Governments, and would be broadly structured on product type.

It is proposed that a treaty would establish the agency and each country would legislate to implement the arrangements. However, the agency would have legal personality only under Australian law. This proposed treaty would be a unique arrangement between Australia and New Zealand in terms of the powers proposed for the agency. We discuss this issue further on page 35. The discussion document suggests that standards and requirements applying to therapeutic products would be prescribed by both the treaty and legislation.

Regulation of products

We were told that the agency would regulate therapeutic products including:

- prescription and OTC medicine
- medical devices
- products currently regulated in Australia as complementary medicine
- products marketed as dietary supplements in New Zealand (other than food-type dietary supplements), including herbal and homoeopathic medicines.

Therapeutic products would be regulated on a risk-management basis and the degree of regulatory control would be proportional to the associated risk of the product. Regulatory decisions would be open to challenge in two ways: through a two-stage merit review process and through judicial review in the courts of either country.

Prescription and OTC medicines, and complementary healthcare products would be classified into one of the following classes:

- Class I: Low-risk products (most complementary healthcare products and sunscreens)
- Class II: Medium-risk products (most OTC medicines)
- Class III: Prescription medicine and other specified products.

The discussion document also outlines other areas of regulation under the proposed joint agency. These include product licensing, the role of an expert advisory committee, licensing of manufacturers, post-market surveillance, clinical trials, export regulations, advertising, and the processes for regulating prescription, OTC, and complementary healthcare products. The proposed agency would also have power to monitor compliance, including enforcement measures such as the ability to impose sanctions and prosecute offenders. A description of the joint agency proposal is contained in Appendix B.

Recommendation

1. We recommend to the Government that it ensure any system for regulating complementary healthcare products establishes a separate category for low-risk complementary healthcare products that do not make therapeutic claims distinct from categories for food and medicine.

Part II Good regulatory principles

Any regulatory system ought to comply with the established principles governing good regulatory practice. Thinking in this area is evolving, with the Organisation for Economic Co-operation and Development (OECD) leading international work on regulatory policies and administrative simplification. Recent OECD publications include *From Interventionism to Regulatory Governance* in 2002 and *From Red Tape to Smart Tape* in 2003.

In both New Zealand and Australia, as with many other countries, regulatory codes or guidelines are now applied. In New Zealand, regulatory impact statements and business compliance cost statements are routinely included in the explanatory notes of bills, and Cabinet Office, and other, guidance material in these areas is extensive.

The *New Zealand Code of Good Regulatory Practice* 1997, recognised as mandatory in the Government response to the recommendations of the Ministerial Panel on Business Compliance Costs in 2001, and relevant requirements from other regulatory codes and requirements, are set out in Appendix D. The Legislation Advisory Committee *Guidelines on Process and Content of Legislation* also set out a series of options to be considered when deciding whether policy objectives can be achieved other than by legislation.

The Council of Australian Governments' *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies* contains important principles governing regulatory action. Those principles make the point that there should be sufficient scrutiny to guard against the imposition of unnecessary regulation, avoidance of excessive requirements on business, and achievement of minimum necessary standards taking into account economic, environmental, health, and safety concerns.

The principles also point to the need to move away from overly prescriptive standards towards performance-based standards that focus on outcomes rather than inputs. They draw attention to an earlier Council of Australian Governments' principle that proposals for new regulation that have the potential to restrict competition should include evidence that the competitive effects of the regulation have been considered, that the benefits outweigh the likely costs, and that the restriction is no more than is necessary in the public interest. Regular review of regulation is another principle that is specified.

Among the features of good regulation identified by the Council of Australian Governments' publication are minimising the regulatory burden on the public, minimising the burden of administration and enforcement of regulation, regulatory measures that ensure the greatest degree of compliance at the lowest cost to all parties, and explicit consideration of secondary effects.

Much of this is backed up by the 1998 *A Guide to Regulation* from the Office of Regulation Review of the Australian Productivity Commission, a document that has official status. It includes much detail on, for example, the full range of costs and benefits that are to be assessed, and sets out a detailed regulatory impact statement checklist that includes asking whether a regulatory scheme can improve the situation.

The starting point in all of this appears to be clear identification and definition of the problem (or market failure), then planning an appropriate regulatory response.

Internationally, much work is being done on alternatives to full government regulation, which is now perhaps increasingly being seen as an option of last resort. The principles of good regulation of the United Kingdom Better Regulation Task Force, under the principle of proportionality, state: 'don't use a sledgehammer to crack a nut' and 'think small first'. One of the task force's tests of good regulation is whether it has broad public support, with the added comment that where such support is absent, compliance is likely to be low.

The United Kingdom has a very extensive regulatory impact assessment that includes a small firms impact test and a competition assessment that in turn includes a competition filter test of 9 questions about the market effects of proposed regulation. Regulatory impact assessments are to be initiated early in the policy-making process, and updated and finalised as a proposal proceeds, a practice which is now also encouraged in the case of regulatory impact statements and business cost compliance statements in New Zealand.

One of the United Kingdom regulatory impact assessment checklists notes that a regulatory proposal that is proportionate overall may be disproportionate for some sectors, especially small business, and points to the need for proponents of regulation to keep an open mind on options.

Internationally, regulators are increasingly being required to consider alternatives such as self-regulation, co-regulation, quasi-regulation, process regulation, and performance regulation. The pros and cons of some of these options are well set out in the Office of Regulation Review guide in relation to industry standards and codes of good manufacturing practice and other codes whether voluntary or mandatory.

In New Zealand, much work is being done on the simplification of regulatory requirements on industry, particularly through the Ministerial Panel on Business Compliance Costs. It is worth noting that among many recommendations made by the panel is one that the joint Australian-New Zealand therapeutics working group take into account the impact of compliance costs on the New Zealand therapeutic/dietary supplements industry in its consideration of the appropriate regulatory framework for the sector. The Government has agreed with that recommendation. It is important that any new regulatory structures are consistent with, and do not cut across, developments arising out of the panel's work.

In that regard, the following comment from the Office of Regulation Review guide is of interest:

> Consideration must be given to the contribution that the proposed option would make to the overall burden of regulation on the community. When a new requirement is added to the existing stock of regulations, the effectiveness of other regulations may be reduced. This may occur simply due to the volume of regulations and requirements that exist — there is a limit to the number of regulations that business can comply with fully, just as there is a limit to the number of regulations that departments/ agencies can enforce fully or effectively.

The guide also notes that when both one-off and recurring (or ongoing) costs on business resulting from a proposed regulatory change are added up, 'even small increases in compliance costs for individual businesses can result in significant economy-wide increases in business costs.' It notes that such costs can distort economic decision-making away from

the most efficient and effective use of resources; divert resources into non-productive uses; diminish the viability of business; and be passed on to consumers through higher prices, with possible distributional and equity consequences. These effects, along with others such as reduced market flexibility, are among what are often referred to as unintended consequences that can arise from regulatory proposals if they are not properly thought through.

Part III Consideration of impact of different regulatory systems

In Part I we discussed concerns about the current system for regulating therapeutic products in New Zealand. In this part we explore some of the implications of changing that regulatory system. We note Medsafe's complaint that the current system is ineffective and considered to be unworkable by both officials and industry. We note there are serious concerns about the adequacy and enforcement of current legislation for the regulation of both medicines and complementary healthcare products, as it is not managing risks from medical devices or complementary healthcare products.

It would be possible to enhance or strengthen the current system. One option is to ensure enforcement of the current legislation. Another option would be to strengthen current legislation to address industry concerns about the current problems with regulation of complementary healthcare products.

The discussion document notes that should the proposed joint agency not be advanced, it would still be necessary for suitable amendments to be made to update existing medicines legislation. Whatever system for regulating complementary healthcare products is agreed on, the current system will not be able to remain unchanged, given the changes that will occur to medicines legislation regarding prescription medicines.

We note the suggestion from the Dietary Supplements Consultative Group that an interim solution could provide regulatory cover for complementary healthcare products while work gets underway on a permanent fix of new industry-specific legislation. This 'quick fix' solution involves replacing the Dietary Supplements Regulations with new regulations made under the Food Act and the Medicines Act that cover 'nutritional supplements' and exempt health claims in relation to such supplements from the 'related product' requirements of the Medicines Act.

Harmonisation with Australia

The Medsafe discussion paper outlines the agreement in principle to establish a joint agency for the regulation of therapeutic products as a means of implementing the Trans-Tasman Mutual Recognition Arrangement between the Australian and New Zealand Governments. The preferred option in the Medsafe submission for resolving the exemption for therapeutic products in the arrangement is harmonisation.

The Government has made it clear it wishes to pursue some form of harmonisation with Australia for regulating therapeutic products. Harmonisation could be through a variety of regulatory options. The joint agency option is at one end of a harmonisation continuum. Mutual recognition, a less extreme form of harmonisation, involves different countries recognising each other's regulatory standards in order to facilitate trade between the countries. Mutual recognition arrangements can take different forms according to the varying degrees of complementarity between different regulatory systems.

Mutual recognition

Mutual recognition is a term used for an agreement between different countries that applies to regulations affecting the sale of goods and the registration of occupations. Such arrangements aim to reduce regulatory obstacles and promote a more unified economic system between the different countries. Therapeutic goods are currently exempt from the Trans-Tasman Mutual Recognition Arrangement.

It would be possible to institute a mutual recognition arrangement without legislative change through the recognition by each country of the other's regulatory regimes.

A mutual recognition option could also involve legislative change, such as repealing the Dietary Supplements Regulations and adopting specific legislation to enhance the regulation of therapeutic-style dietary supplements as therapeutic products.

Australian concerns with mutual recognition

Mutual recognition can apply only if both countries are in agreement. We note it is unlikely Australia would support a mutual recognition option in present circumstances, given New Zealand's current state of regulation. Australia would prefer harmonisation through a joint agency. There would need to be substantial changes to the New Zealand system before mutual recognition could be an option.

Mutual recognition will be able to occur only when there is a reasonable measure of complementarity between regulatory regimes in the respective countries. A significant implication of the failure to apply and enforce regulation in New Zealand is that there is little complementarity between Australia and New Zealand.

One way of looking at mutual recognition is that it is a more limited form of harmonisation. If the respective regulatory systems are too different, industry in the partner with less rigorous standards may gain greater market share at the expense of competitors in the other country who must comply with stricter regulations.

As matters stand, mutual recognition is unlikely to be acceptable to Australia, and we understand that to be the situation under present regulations. The failure to apply regulation in New Zealand has therefore proved to be self-defeating. Lack of regulation in practice means New Zealand cannot now show complementarity of regulatory standards. New Zealand will either need to prove its ability to regulate, or be left to follow some other course of action. In the present case this amounts to fuller harmonisation.

Regulation of complementary healthcare products in other countries

To inform our consideration of different regulatory options we examined the legislative and regulatory regimes governing dietary supplements and traditional remedies in other countries. We were particularly interested in the models implemented in the European Union and Canada.

Our consideration of overseas systems was of some value in evaluating the joint agency proposal. However, it is difficult to make valid comparisons with foreign jurisdictions unless the greatest care is taken to ensure that comparisons are being made in relation to corresponding products. Internationally, definitions of substances and products to which

the relevant legislation applies differ widely. The United States is often cited as one country that has a system with respect to dietary supplements that has broad similarities to New Zealand. It may well be that there is a trend internationally towards stronger controls in this area. Two jurisdictions where there have been recent developments of significance are Canada and the European Union.

In Canada the Natural Health Products Regulations were approved in June 2003 after more than 4 years' development following a parliamentary select committee review in 1997–98. They will be phased in over a 6-year transition period from 2004. Made under Canada's Food and Drugs Act, the regulations treat natural health products more as drugs than food because they are taken for therapeutic purposes rather than for calorific purposes or to address hunger.

Although the Canadian regulations apply to some of the substances included within the definition of dietary supplements in New Zealand (such as minerals, vitamins, herbs, amino acids, and possibly certain homoeopathic and traditional medicines), the fact that the definition of 'natural health product' is tied to therapeutic purposes means that the Canadian regulations concern products more related to those regulated under the Medicines Act than to the Dietary Supplements Regulations.

The Canadian regulatory scheme will be wide-ranging. Prohibitions will apply to the sale and manufacture of natural health products in the absence of product licences and site licences. Detailed information must be provided on products and their ingredients in support of licence applications, and all products will be assigned special numbers. Other requirements relate to good manufacturing practices, clinical trials involving human subjects (including adverse reaction reporting), electronic information, labelling and packaging, inspection, and certification, although in some cases these will be based on existing requirements under Food and Drug Regulations.

Notwithstanding the origins of the Canadian regulations and the fact that they were developed during several rounds of consultation with stakeholders, a question mark remains over the Canadian experience at this point. Health Canada notes that it is particularly mindful that much of the industry consists of small and medium-sized businesses and that a sustained effort will be undertaken to provide them with support.

An accompanying regulatory impact analysis statement notes that most small and micro firms (including cottage businesses) anticipate major increases in costs of facilities and software to ensure compliance with the regulations, and major or minor increases in equipment costs, personnel, and training costs. Product licensing requirements are linked to a possible reduction in the availability and variety of products for sale on the Canadian market. Large firms, on the other hand, are more concerned about the implications for export products and foreign trade.

On the other side, significant benefits to consumers are expected in terms of increased confidence in safe, effective, high-quality products, and possible reduction in medical costs. The regulatory impact analysis statement makes it clear that certain important details of the regime are still not settled and will be dealt with through guidance documents. Moreover, Health Canada has been bearing the regulatory costs to date, and a cost recovery scheme

has yet to be devised. The statement refers to alternatives that were considered at an earlier stage but gives little attention itself to options.

In the case of the European Union, we heard from a German official who is an expert in complementary and alternative medicines and has been closely involved with relevant European agencies. European law operates, and is able to operate, on a different scale from anything in this part of the world, with a focus on the ongoing process of mutual recognition and harmonisation of laws among member states. The legal regime bearing on complementary medicines, comprising a number of European Community directives, regulations and proposals, is complex, difficult, and in an almost constant state of change and development. We list in Appendix E the relevant legislation. The system appears to hinge on extensive research and regulation in which relevant products subject to health claims are treated as medicinal products. It may have some similarity to the Australian system, but we question the value of such an elaborate legal structure as precedent in this part of the world.

Risk created by the use of therapeutic products

There is inherent risk associated with the use of any therapeutic product. The objective of regulation is to protect public health from such risks. A risk-based management approach is aimed at ensuring potential risks are minimised. Currently the Australian system, under the Therapeutic Goods Administration, regulates therapeutic goods by a risk-based regulatory framework.

In the following discussion of risk, we consider a risk-based regulatory framework and related issues that may arise from the implementation of either mutual recognition or a joint agency. Secondly, this section contains an outline of the information relating to risk in the Medsafe submission and submitter responses to this information. We also consider regulation according to the level of risk posed by complementary healthcare products.

Risk-based regulation

In considering the risk imposed by complementary healthcare products, it is important to note that such risks are voluntary, as people make a choice to use a product in the first instance. This is not the same as the risk imposed by a product that affects society as a whole. However, the risks are only truly voluntary if consumers have received adequate and accurate information about those risks. The adequacy and accuracy of disclosure of information is governed particularly by labelling requirements. Labelling requirements are also important in the event of product recall. The voluntary nature of the risk has significant implications for the nature and degree of regulation required.

We consider risk-based regulation of complementary healthcare products to be an appropriate framework to regulate therapeutic products and complementary healthcare products. We believe that the degree of regulatory control should be proportionate to the risk associated with the product. Many submitters supported this view. These submitters agreed that the proposed joint agency should regulate using a risk management approach, as indicated in the discussion document.

Submitters also noted that all complementary healthcare products should meet public safety expectations, and consumers expect and require safe and quality products. Presently

there is no process for assessing risk. A submitter told us that a risk-based, effective, and cost-efficient regulatory system would enhance the credibility of complementary healthcare products, as they would have to consistently meet appropriate standards of safety, quality, and efficacy.

Recommendations

2. We recommend to the Government that it ensure any system for regulating complementary healthcare products takes full account of the voluntary nature of risks accepted by consumers in this area and places an appropriate emphasis on disclosure of adequate and accurate relevant information to consumers.

3. We recommend to the Government that any system to regulate complementary healthcare products has labelling requirements that govern the adequate and accurate disclosure of information.

Risk under mutual recognition

Under mutual recognition, legislation could be designed to meet specific New Zealand needs and could also permit consistency with international trends in regulation of complementary healthcare products. Mutual recognition could still offer the opportunity to institute a risk-based regulatory framework. It could also provide for control of complementary healthcare products both before and after they enter the market.

Such a proposal would apply a risk-based regulatory framework that is consistent with current international trends in the regulation of complementary healthcare products.

Risk under the proposed joint agency

To provide for the establishment of the proposed joint agency, Australia and New Zealand would enter into a treaty. Both New Zealand and Australia would then enact legislation recognising the joint agency as the regulator of therapeutic products and both countries would give effect to the regulatory decisions of the agency. Further detail of the proposed agency structure can be found in Appendix B.

The proposed joint agency would regulate therapeutic products in a different manner to mutual recognition.

The proposed joint agency would apply the Australian system of a positive list (white list). Any natural substance would need to be licensed before it could be used in a product. The proposed joint agency is designed to regulate complementary healthcare products according to the risks posed by the products.

Some submitters were concerned the Therapeutic Goods Administration system of a positive list of approved nutrients would stifle innovation. They commented that New Zealand natural healthcare companies have been successful in developing export markets for innovative products in part due to the current permissive regulatory environment.

We are concerned about how the proposed joint agency will provide for the regulation of internet sales of complementary healthcare products. We believe that there is significant

risk associated with the unregulated and uncontrolled sale of complementary healthcare products and believe this a matter to be considered in any regulatory scheme.

Recommendation

4. We recommend to the Government that it ensure that any system for regulating complementary healthcare products requires all products and their ingredients to be listed by the supplier on a central register.

Regulation should be commensurate with level of risk

While the proposed joint agency provides for a risk-based regulatory framework, we are concerned that the regime would impose excessive, expensive regulation on products that are low-risk.

Submitters told us that complementary healthcare products should not be regulated with prescription medicines, which are demonstrably higher risk and have more incidences of reported adverse reactions. This is consistent with information we received from Medsafe that 95 percent of complementary healthcare products are low-risk. Submitters believed that regulation should be commensurate with the level of risk and we agree. These submitters stated that there have been no deaths as a result of complementary healthcare product use.

We consider that any regulatory system should have provision for monitoring and quality assurance. Routine auditing is essential to ensure manufacturers are complying with good manufacturing principles. We suggest one way to audit manufacturers is through a probability sampling method, which uses some form of random selection. This would mean that each manufacturer would have an equal probability of being selected for auditing.

Recommendations

5. We recommend to the Government that it ensure any system for regulating complementary healthcare products is risk-based.

6. We recommend to the Government that it commission an independent risk assessment of complementary healthcare products.

7. We recommend to the Government that it ensure any system for regulating complementary healthcare products requires compliance with good manufacturing principles.

8. We recommend to the Government that it ensure any system for regulating complementary healthcare products includes monitoring, enforcement, and review of quality assurance, with ongoing random sampling and auditing to ensure maximum compliance.

Medsafe submission's analysis of risk

In its submission, Medsafe provided an analysis of the risks associated with complementary healthcare products and identified several types of risks associated with the use of complementary healthcare products:

- intrinsic risks with ingredients
- risks associated with inadequate consumer information
- risks associated with particular population groups
- risks associated with poor quality
- risks associated with therapeutic claims.

Medsafe also provided a 28-page 'table of risks', showing examples of the risks associated with complementary healthcare products, with references to papers in which these problems were discussed. Medsafe stated that there is insufficient data to support claims that there have been no deaths associated with dietary supplements in New Zealand. According to Medsafe many people choose not to tell their medical practitioner that they are taking complementary healthcare products and therefore a large proportion of problems may go undetected and unreported.

Submitters' concerns with Medsafe's assessment of risk

The Dietary Supplements Consultative Group was concerned about the discussion document's analysis of risk. It argued that the discussion paper did not attempt to quantify potential risks from using complementary healthcare products, nor did it make any attempt to relate the level of proposed regulation to the quantum of risk.

The Dietary Supplements Consultative Group provided its own analysis of risks. It believes that potential risks from using complementary healthcare products may arise from ingredients, inferior product quality, inadequate consumer information, or misleading claims. The group also told us that Medsafe, in the absence of a comprehensive risk assessment, has frequently provided anecdotes of alleged actual harm caused by dietary supplements. We were told that the table of risks is a compilation of anecdotes, which is neither a reliable foundation for policy-making nor sufficient justification for the joint agency proposal.

The validity and accuracy of Medsafe's conclusions were also questioned in the submission of the New Zealand Charter of Health Practitioners. The submission questioned the methodology used by Medsafe and commented on the table of risks. It would appear from the Medsafe submission that there is no proper process for risk assessment in New Zealand at present.

There was a high level of concern that a joint agency might not always meet the specific needs of New Zealanders. Differences between Australian and New Zealand perceptions of risk were highlighted by the submission of the Australian Self-Medication Industry. The submission suggested that the fact that some substances can be sold in New Zealand but not Australia is evidence of these differing perceptions. This is because a product may not have been formulated in accordance with good manufacturing principles, the active ingredients may not have been assessed in Australia or the active ingredients may have

been assessed but their eligibility for listing may not have been established for reasons of safety.

Compliance costs and costs to consumers

Any form of regulation results in some costs in complying with that regulation. In the case of complementary healthcare products, such compliance costs could include expenses relating to product listing, labelling, good manufacturing practice, market entry, operational requirements, and surveillance of goods in the market.

These costs will vary according to the regulatory regime followed.

Tools for examining proposed regulation

In New Zealand it is routine practice to prepare regulatory impact statements and business compliance cost statements in connection with regulatory proposals (see Part II). Cost-benefit analysis is a tool used as part of such assessments.

When we initiated this inquiry, Medsafe was not able to provide us with a regulatory impact statement or a business compliance cost statement in accordance with New Zealand requirements. We are aware that Medsafe has subsequently commissioned a business compliance cost study. However, neither the Minister of Health nor the Ministry of Health was able to provide us with this statement, as it forms part of current Cabinet papers. It is difficult for us to fully assess the impact of compliance costs on industry and consumers without this material.

The joint Australian-New Zealand working group commissioned a regulatory impact statement of the proposed joint agency in October 2000, followed by a cost-benefit analysis of the proposed joint agency regulatory system. This was conducted by the New Zealand Institute of Economic Research. The institute's report, *Assessment of Regulatory Options for Therapeutic Products*, was useful in demonstrating the Government's perceptions of the likely costs of each model. However, we were surprised that the report did not explicitly address a mutual recognition regulatory option, although it did consider an enhanced version of the current New Zealand system, which could form the basis of mutual recognition.

In considering the effect of compliance costs, we also received independent economic advice that assessed the cost-benefit analysis performed by the New Zealand Institute of Economic Research. In our specialist economic adviser's opinion, the institute's report met professional cost-benefit analysis standards.

Enforcement of current system would increase compliance costs

The New Zealand Institute of Economic Research cost-benefit analysis states that prices for all therapeutic products would increase under an enhanced regulatory regime. This would have negative effects on both consumers and industry. Consumers would be faced with price increases for all therapeutic products and reduced choice of medical devices and complementary healthcare products. Industry would face higher fees, which would reduce profitability and have consequences for the viability of some businesses.

Our specialist economic adviser told us that the additional costs associated with strengthening the current regime would be offset by unquantifiable benefits. These benefits include reduced self-regulatory costs and reduced disruption when there is product failure. The improvement in consumer information and consumer confidence, and the possibility of quality improvements in products and some reductions in adverse medical events, were also considered unquantifiable benefits.

We were advised that these unquantifiable benefits may exceed identified costs, although the impact of higher compliance costs upon some products may force these to be withdrawn from the market.

Advantages of proposed joint agency

Our specialist economic adviser told us that the cost of regulating therapeutic products can be reduced by an international regime that shares costs with other national agencies. We were also advised that a trans-Tasman agency would reduce compliance costs, compared to an enhancement of the current domestic regulatory regime, on average by between 1.6 and 2 percent. However, both options would incur greater costs over the current domestic regulatory regime. There were also potential unquantifiable benefits of additional exports and unquantified costs such as job losses from New Zealand to Australia, although we were advised that both effects were likely to be minor.

The New Zealand Institute of Economic Research report also found that a joint agency would reduce compliance costs. This was one reason why the institute's report favoured the proposed agency above the other three regulatory options it assessed. The institute's report identified other advantages of the proposed agency to include contributing to closer economic relations objectives by promoting trans-Tasman trade, particularly in the medium to long term.

Another advantage identified in the report is that it would satisfy the need for Australia and New Zealand to have common regulatory standards, facilitating trade between the 2 countries. We were told that common standards would also provide certainty for the industry and confidence for consumers.

Some submitters agreed that the current lack of consistency in regulatory models is costing both the industry and consumers. Some submitters believe the cost of a joint agency would be less than the cost of a New Zealand-only regulatory agency.

Cost-benefit analysis disputed

The New Zealand Health Trust disputed the New Zealand Institute of Economic Research report's findings. Among the trust's concerns were that most benefits and some costs could not be quantified. The trust considered that it was not possible to determine whether any change from the current regulatory system would generate a net benefit to New Zealand. The trust was also concerned that the report defined compliance costs broadly, but did not measure production losses, or the capital or operating costs that regulation is likely to generate. The trust was also concerned that industry turnover was not surveyed.

The Dietary Supplements Consultative Group reiterated the trust's concerns about the report not assessing industry turnover. It told us that by taking an industry average instead of analysing the economic impact on individual companies, the report failed to detect the disproportionate impact of the agency on small companies. The submitter estimated that companies with less than $5 million turnover would not be able to survive in their present form. It was also concerned that the institute's analysis did not include relabelling costs, and did not estimate the effects of increased costs on the capital value of many small to medium-sized businesses.

Some submitters provided us with their own analyses of costs. The Dietary Supplements Consultative Group commissioned an accounting firm to assess the potential impact of the new agency on different businesses. This report suggested that the proposed joint agency would result in the closure of many small businesses.

Mutual recognition option not analysed

The New Zealand Institute of Economic Research report did not include a cost-benefit analysis of any mutual recognition option. The report does comment that under mutual recognition, a precautionary stance may further reduce choice and overseas regulatory decisions may not always suit a New Zealand regulatory regime. The report does assess an option of an enhanced New Zealand system. As we discussed earlier, a strengthened New Zealand system could constitute one option for mutual recognition.

We were advised by our specialist economic adviser to also consider the possibility of a mutual recognition regulatory regime, although we did not receive a separate economic evaluation on the mutual recognition option.

We were disappointed that an analysis of mutual recognition was not undertaken by the joint working group, as it makes it difficult to fully assess regulatory options without such information.

Effects on industry profitability

Submitters are concerned that a joint agency will increase compliance costs for manufacturers and consumers. Some fear that many small businesses will be destroyed by increased costs and that there will be a reduction in the range of products available to consumers. Submitters were also concerned about the increased cost of entering the market with new products and the subsequent impact on business profitability.

We are concerned that restrictive legislation and increased compliance costs could reduce research and development by companies. The Australian positive list system could also be a barrier to innovation for New Zealand complementary healthcare companies, potentially curtailing the successful development of innovative products for export possible in the current relatively unrestricted environment.

Some submitters noted that since the Therapeutic Goods Administration regime was introduced in Australia, many businesses have had to close. Many submitters were afraid that if the agency went ahead many businesses in New Zealand would be jeopardised or destroyed, due to increased compliance costs. It was also noted that it would stop a growing New Zealand export industry worth tens of millions of dollars.

The New Zealand Institute of Economic Research report notes that effects on industry profitability are a concern if increases in compliance costs for manufacturers of medical devices and complementary healthcare products are not passed on to consumers.

Effects on consumers

Submitters are afraid that compliance cost increases that are passed on to the consumer will result in higher prices. Submitters are also concerned at the possible loss of consumer choice. They fear a reduction in the range of products available due to more restrictive legislation and also as some companies would not be able to continue making some products. As discussed previously, submitters are concerned about the impact of the restrictive legislation upon innovation. A reduction in new, innovative products would also reduce customer choice.

Recommendations

9. We recommend to the Government that it takes into account the impact of the cost of complying with any regulatory regime on the New Zealand complementary healthcare products industry.

10. We recommend to the Government that it ensure any system for regulating complementary healthcare products allows for innovation in products and processes and new product entry.

11. We recommend to the Government that it ensure any system for regulating complementary healthcare products is based on a negative list that records which ingredients are not permitted to be used because a safety issue has been identified.

Fees and charges to fund agency

The proposed joint agency would be fully funded by cost recovery through fees and charges. Medsafe stated that many submitters to its discussion paper were concerned at the proposed funding system, claiming that such fees would put small distributors out of business. Medsafe told us that it is exploring methods of cost recovery that can take into account turnover, so that small manufacturers pay lower fees.

Currently the Therapeutic Goods Administration exempts low-volume, low-value complementary products from the annual licensing charge, and low-risk therapeutic products attract much lower fees than high-risk pharmaceuticals. Medsafe stated that under the proposed joint agency, fees and other compliance costs would be kept as low as possible for low-risk products. Medsafe also told us that during a transition period it is proposed there will be no cost for a New Zealand importer or manufacturer to have its ingredients assessed for safety for inclusion on the positive list of substances.

Several submitters discussed the current Therapeutic Goods Administration fees. These fees are substantially more than those imposed by the current New Zealand regulatory system. The Complementary Healthcare Council of Australia told us that when the Therapeutic Goods Administration moved to full cost recovery in 1999, the direct result was the cancellation of whole lines of products and a decrease in new listing applications.

We also note that Food Standards Australia New Zealand is not funded by cost recovery and receives government funding to perform its functions. We note that some cost recovery is available in New Zealand for costs of analysis and other regulatory functions through regulations passed under the Food Act. However, the extensive range of regulatory functions that would be performed by the proposed agency suggests that costs to the industry may be much greater than at present.

Electronic notification system

One effective way to reduce compliance costs is to provide for electronic registration. Submitters agreed that such a system would enhance any regulatory system, a view endorsed by the European Union official brought to New Zealand by Medsafe. In the evidence we received, there was overwhelming agreement that regardless of the regulatory option taken, an electronic notification system should be instituted to facilitate efficient regulation of therapeutic and complementary healthcare products.

Currently the Australian Therapeutic Goods Administration uses an electronic application system called ELF (Electronic Lodgement Facility). It is proposed that this system will be replaced by a new electronic system and this may be adjusted to suit both Australian and New Zealand needs under a joint agency.

The new system would be web-based and provide rapid turn-round for applications. Medsafe told us that this proposed system would be easy to access, simple to use, and well supported. A simple electronic notification system would reduce compliance costs for businesses registering products.

The Complementary Healthcare Council of Australia suggested that any regulatory system should include a simple electronic notification system.

Recommendation

12. We recommend to the Government that it ensure any system for regulating complementary healthcare products includes a simple electronic lodgement and notification system.

Indigenous medicinal (rongoā) products

Our terms of reference included the need for an assessment of protection of indigenous complementary medicinal/rongoā products and extracts used for alternative therapy. We considered both protection of indigenous products and commercialisation.

Treaty of Waitangi issues

Medsafe told us that the joint agency proposal takes account of existing international treaties and national instruments, including the Treaty of Waitangi. Medsafe also states that officials from Te Puni Kōkiri (the Ministry of Māori Development) will continue to consult with New Zealand health officials on any joint regulatory system.

Medsafe notes that submitters were concerned about the implications for Māori and compliance with the principles of the Treaty of Waitangi. Possible Treaty of Waitangi issues are explored further in Part IV.

Protection of indigenous products

The Medsafe submission notes that there is a risk of exploitation and patenting of active ingredients in traditional Māori medicines. Such exploitation could deprive Māori of the right to use traditional products. However, under the proposed joint agency there is no provision for the protection of intellectual property.

Protecting indigenous complementary healthcare products was a concern for several submitters. One view was that it is inappropriate to interfere with Māori herbs and medicines, as their use is governed by longstanding tradition. Rongoā is also an important resource in the future health and economic development of whānau and iwi, and submitters were concerned that the proposed legislation would made it difficult to access, produce, and market rongoā. This is especially true in a market area that is already threatened by the activities of large multinational pharmaceutical companies.

Submitters opposed to protection of indigenous medicine argued that all medicines should meet the same criteria and that it is prejudicial to exempt and protect indigenous medicine. Others submitted that a regulatory framework should cover traditional remedies sold and prepared for commercial gain in order to give consumers a guarantee that the products are safe. Traditional remedies and indigenous medicinal products can be toxic, and they can interact with orthodox medicines to produce an adverse reaction.

We believe that indigenous medicine should be protected under any regulatory agency, although public safety risks need to be managed against such rights of protection.

Commercialisation of indigenous products

We considered whether traditional medicine used in a commercial setting should be treated differently from traditional medicine used within the family group. Currently medicines compounded by a traditional Māori healer to meet the needs of an individual patient are exempt from regulation. This exemption will continue under the proposed joint agency.

The Medsafe discussion document on the proposed joint agency does not contain a proposal to regulate the traditional use of medicinal plants and other substances. Medsafe stated that Māori businesses have the right to commercially manufacture and distribute therapeutic products developed from traditional knowledge. However, Medsafe also states that this right must be balanced against the right of all citizens to receive protection from the risks inherent in manufactured therapeutic and complementary healthcare products. Therefore, the same good manufacturing standards and product licence conditions apply to all goods manufactured in New Zealand, regardless of whether they are based on Māori knowledge or manufactured by Māori business. Ensuring compliance with these standards will enable the entry of indigenous products into overseas markets.

We agree that traditional Māori medicine should be subject to the same good manufacturing and product licensing conditions as other goods manufactured and distributed in New Zealand, as we believe public safety is paramount. We also believe that traditional medicine compounded by a Māori healer for individual use should continue to be exempt from regulation. We are concerned whether traditional Māori medicine will be adequately provided for under Australian law, and whether it is indeed appropriate for foreign law to govern New Zealand indigenous medicine. Some of us are concerned that

while the treaty would lay down high level requirements about the constitution of the agency, a good deal of the detail would be left to the Australian parliament to determine.

Under mutual recognition New Zealand-specific legislation could ensure that our unique indigenous heritage is appropriately regulated.

Recommendation

13. We recommend to the Government that it consider the implications of the section on the Treaty of Waitangi and Māori policy contained in the Ministry of Economic Development guidelines for preparing regulatory impact statements when assessing the impact of any joint agency on Māori.

Part IV General issues arising from the joint agency proposal

This section contains comments on some general issues that were of concern during our inquiry, together with a discussion of the salient points arising from our consideration of issues relating to the joint agency proposal.

Establishment of proposed agency

As noted earlier, it is proposed that provision for a joint agency would be made in a bilateral treaty between the Australian and New Zealand governments. The agency would be established by legislation in both countries to implement the requirements of the treaty. The treaty would bind both governments at international law.

The discussion document identifies three approaches to establishing the joint agency: the national legislation approach, the treaty approach, and the so-called 'blended' approach, a combination of the other approaches that appears to be the preferred option. The difference between each option lies in the extent to which issues relating to the establishment and legal personality of the agency are addressed in either domestic legislation or the treaty. Each approach would still require a treaty setting out the institutional and regulatory framework of the joint agency. Australia and New Zealand would also need to enact domestic implementing legislation under each option. It is not proposed to give the agency the status of an international organisation under international law.

Under the process set out in Standing Orders 384 to 387 for the examination of international treaties by the House (see Appendix H), the Executive is required to present certain treaties to the New Zealand parliament before New Zealand becomes party to them. All treaties presented to the House are subject to scrutiny by the Foreign Affairs, Defence and Trade Committee or any other select committee to which that committee refers the treaty. It is also a requirement under Standing Orders that all treaties presented to parliament be accompanied by a national interest analysis. This analysis provides background information about the treaty, including the advantages and disadvantages of New Zealand becoming party to the treaty, and obligations imposed on New Zealand. The analysis also addresses any economic, social, cultural, and environmental effects of the treaty.

Bilateral treaties are not automatically presented to parliament under this process. However, the Minister of Health assured us that any treaty establishing a joint agency would be presented, prior to any implementing legislation. The proposed treaty would be subject to examination in Australia.

We are concerned that if the joint agency proposal proceeds, it is unlikely that the Health Committee would have an opportunity to scrutinise the proposed treaty, as it has been recent practice for the Foreign Affairs, Defence and Trade Committee to examine all treaties itself, rather than referring them to the relevant subject select committee. We believe that it is important that we scrutinise the treaty, given our detailed consideration of the issues as contained in this report.

Recommendations

14. We recommend to the House that the Foreign Affairs, Defence and Trade Committee refer any treaty establishing an Australian-New Zealand agency to regulate therapeutic products to the Health Committee for consideration.

15. We recommend to the House that if the Foreign Affairs, Defence and Trade Committee chooses not to refer any treaty establishing an Australian-New Zealand agency to regulate therapeutic products to the Health Committee for consideration, that that committee take into consideration the matters raised in this report in its consideration of such a treaty.

Legislation to implement treaty

In the event that full harmonisation with a bilateral treaty was to proceed, implementing legislation would be required before the treaty could take effect. As noted earlier, the legislation would follow presentation of any such treaty.

The discussion paper indicates that legislation would be required for a number of purposes, including with respect to regulatory requirements, prosecutorial and other enforcement powers of the agency, judicial cooperation in relation to offences, and merits and judicial review of agency decisions. It is also being proposed that parliamentary accountability be built into the legislation in both countries. This would be through reporting requirements, financial reviews and the scrutiny of any delegated legislation made by the agency.

We share submitters' concerns about many of these matters. The regulatory and enforcement powers proposed for the agency go well beyond anything that presently applies between New Zealand and Australia. They raise many questions that are not addressed in the discussion paper, including how compliance with important New Zealand statutory and constitutional requirements can be ensured in the case of an agency based in Australia and carrying out its decision-making there. We also question how in practice equal representation can be secured, and responsiveness can be ensured, so far as the interests of New Zealand and New Zealanders are concerned; and whether it is possible to secure sufficient safeguards to protect New Zealand's rights. We explore these issues further below.

In terms of accountability to Parliament, the discussion paper states that the proposed agency would be subject to the same accountability arrangements as a New Zealand Crown entity. These requirements include tabling plans and statements of intent in Parliament, the submission of an annual report to the ministerial council (which would also be tabled in the House) and a joint audit carried out by the New Zealand and Australian Auditors-General. Again, the discussion document does not address important issues raised by these proposals. Such issues include how the financial review processes will be engaged in the case of an agency that is intended to be self-funding, and how the Auditor-General could exercise compulsory powers under the Public Audit Act 2001 in relation to an agency that was based overseas and subject to separate Australian auditing jurisdiction. It seems that the agency would be intended to have two masters, but select committees and other supervisory bodies exercising their usual functions on each side of the Tasman may have different, even conflicting, views of the agency's performance.

In New Zealand Crown reporting entities required to prepare statements of intent and annual reports are named or described in the Sixth Schedule to the Public Finance Act 1989. Presently there is no indication whether the proposed agency would be included in this schedule. Reporting entities listed under this schedule are subject to financial review by a select committee. If the entity is not listed in this schedule, it would not be subject to regular review. We note that it could still be reviewed under a committee's inquiry function, if it were not in the schedule. However, in the event that full harmonisation was to proceed, we consider that a regular review would be essential. Currently the agency is proposed to be self-funded through cost recovery and not a Government-funded entity. Such an entity would not normally be subject to financial review. We believe that regardless of whether the proposed agency is self-funded the agency should be as accountable as any other crown entity through financial and performance reviews.

Recommendations

16. We recommend to the Government that if the joint agency proposal proceeds, it ensure that questions of parliamentary accountability in accordance with New Zealand requirements be resolved in detail in the proposed treaty and implemented appropriately in the legislation of both countries.

17. We recommend to the Government that it consider how the application of the Auditor-General's powers would be preserved under any joint agency.

18. We recommend to the Government that it ensure that any agency with responsibility for the regulation of therapeutic products in New Zealand be covered by the Sixth Schedule to the Public Finance Act 1989 and be subject to the same reporting and accountability requirements as any other Crown entity.

It is proposed that the agency would have legal personality under Australian domestic law but not under New Zealand law, although it is not clear what precisely this means in legal terms so far as New Zealand is concerned. Some of us are concerned that the proposed Act of Parliament would be at a high level of generality and would leave significant areas to delegation. It is proposed that the agency, like Food Standards Australia New Zealand, would be established under its own statute in Australia and governed by Australian legislation concerning public authorities and companies. Although the proposed agency would not have legal personality in New Zealand, it would still be accountable through reporting and other requirements under New Zealand legislation. It is being proposed that both the ministerial council of the agency and the managing director would have the power to make delegated legislation.

The application of the Australian legislation to any joint agency raises further questions about the representation and protection of New Zealand interests. The (Australian) Commonwealth Authorities and Companies Act 1997 requires the bodies to which it applies to keep the responsible Minister and the Minister of Finance in Australia informed of various matters and to carry out the general policies of the Commonwealth Government that are to apply to the body and which are notified to its directors in writing by the responsible Minister. In the case of Commonwealth authorities, additional provisions apply concerning financial matters, and the conduct of officers. We are concerned whether in this situation, both in legal terms and in practice, there could be equality of operation between

Australia and New Zealand of an agency that is exercising important regulatory and enforcement powers with respect to New Zealand.

Scrutiny of implementing legislation

In New Zealand, the passage of any implementing legislation would involve detailed consideration by a select committee. This gives both Parliament and the public the opportunity to scrutinise the proposed legislation. However, the legislation could not be so amended as to become inconsistent with the terms of the treaty it would be implementing.

Scrutiny is particularly important in the case of the proposed joint agency as it contains provisions for far-reaching enforcement powers. These include compliance monitoring, search and seizure powers, and the imposition of penalties.

It is also important to note that while New Zealand would pass its own legislation to implement the treaty, it would have no control over Australian legislation or amendments made to that legislation, providing there was continued compliance with the treaty. The discussion paper notes that the treaty would require the Australian Government not to amend relevant legislation without the consent of the New Zealand Government. It may be possible to devise procedures to involve Parliament (and select committees) in that process in some manner. However, some of us believe the New Zealand Parliament would have no opportunity to debate or seek changes to these amendments.

The Regulations Review Committee considers any regulation-making powers in proposed legislation, including treaty-implementing legislation. As the implementing legislation for any treaty is likely to contain regulation-making powers, the relevant provisions would be subject to the scrutiny of the Regulations Review Committee. The Regulations Review Committee would then report to the select committee that is considering the bill.

Implications of basing agency in Australia

Some of us are concerned at the implications, if full harmonisation proceeds, of the agency having legal personality in Australia but not in New Zealand. Under the joint agency proposal, judicial review would be available in both the New Zealand and Australian courts (although only one court would be able to review any given case). The respective judicial systems could possibly come to different conclusions on the law, however the system was set up. We expect any treaty will have to specify how such conflicts would be resolved. Similar issues arise with respect to service of documents, gathering of evidence, and other legal requirements with respect to agency enforcement. The discussion paper notes that existing schemes for trans-Tasman legal cooperation would provide some assistance, but that further provisions would be required that may also have to break new ground.

We are concerned that the needs of New Zealand industry and consumers may not be met under an Australia-based agency. It is proposed to establish an office of the agency in New Zealand, but we are unclear about how accessible this would be for industry and consumers. The staff and management are likely to be disproportionately Australian and unfamiliar with the New Zealand legal and cultural context.

It is unclear how New Zealand legislation such as the Official Information Act 1982, the Privacy Act 1993, and the Protected Disclosures Act 2000 would apply to the proposed

agency. The discussion paper indicates that each country may apply its laws in such areas. But it is not at all clear how the Ombudsmen's jurisdiction could in practice be extended effectively to an agency based in Australia. Where there is Australian legislation in these areas, it would not be identical. It may not be straightforward to expect a body to operate under two sets of legislation in the same areas.

The proposed board of the joint agency would comprise 5 members: the chair, the managing director, an Australian health sector representative, a New Zealand health sector representative, and a person with broad commercial experience. The discussion document states that the majority of the board members would be Australian.

Some of us are concerned that New Zealand would have less representation than Australia on the board of the agency. Submitters questioned how New Zealand industry would be represented on such a board and told us of their concern about the role of the managing director and how much power would reside in this position.

The discussion paper suggests that the managing director would make regulatory decisions similar to those currently made by the Minister of Health in New Zealand. While a Minister of the Crown is elected by the public and accountable in parliament, through mechanisms such as the select committee process and written and oral questions, the proposed managing director does not have the same level of accountability. We note that the managing director of the proposed joint agency would be even less accountable than public servants under State sector legislation in New Zealand. The proposed role of the managing director of the proposed joint agency raises other problems that we note below.

Recommendations

19. We recommend to the Government that, if it proceeds with a trans-Tasman agency to regulate therapeutic products, it ensure there is a complaints system that gives equal recourse to New Zealanders and Australians.

20. We recommend to the Government that the Official Information Act 1982, the Privacy Act 1993, and the Protected Disclosures Act 2000 apply to any agency that regulates complementary healthcare products in New Zealand.

21. We recommend to the Government that the powers of the managing director of any trans-Tasman agency not exceed the powers of other New Zealand public service chief executives.

Treaty of Waitangi issues

One obvious difference between the Australian and New Zealand legal and constitutional systems is the Treaty of Waitangi. We are concerned how Treaty of Waitangi issues will be addressed under a trans-Tasman joint agency in the event full harmonisation proceeds. In particular, we are concerned that under a trans-Tasman joint agency the rights of Māori would not receive the same protection from a body based in Australia and operating under Australian law as they would in New Zealand.

The principles of the Treaty of Waitangi, to the extent applicable, would still have to be complied with by anyone carrying out activities in New Zealand.[2] However, such laws and policies are of only territorial application and would not apply to any agency in Australia in respect of its decision-making in Australia. If the principles of the Treaty of Waitangi are to be taken into account in the decision-making of any such agency so far as it affects New Zealanders, provision would have to be made in both the proposed treaty and the implementing legislation in both countries. Even then, there may still be questions about how sensitive and responsive any such agency would be in practice to principles of that kind.

The Treaty of Waitangi claims settlement process also has relevance here, particularly the WAI 262 claim filed with the Waitangi Tribunal in 1991 relating to native flora and fauna and intellectual property rights over the use of traditional materials. We were told that issues in this area remain unresolved. Medsafe stated that protection of intellectual property is outside of the scope of the joint agency proposal, and that the proposal is not expected to affect the outcome of the claim on the status of traditional knowledge or traditional medicine unless it is commercially exploited. We are not convinced that protection of intellectual property in this respect should be outside the working group's scope.

Recommendations

22. We recommend to the Government that it ensure the decision-making process of any regulatory regime for complementary healthcare products reflects its Treaty of Waitangi obligations and the interests of Māori.

23. We recommend to the Government that, if it proceeds with a trans-Tasman agency to regulate therapeutic products, it ensure that both the treaty establishing such a regime and any implementing legislation in both countries reflects its Treaty of Waitangi obligations and the interests of Māori.

Delegation of legislative powers

One important area of concern raised with us involves the making of delegated legislation by the proposed agency. This raised serious issues that require further consideration.

It is proposed that under the joint agency the Ministerial Council and the agency's managing director will be given the power to make delegated legislation in the form of rules and orders. The proposed agency would be empowered to enforce compliance through monitoring, have search and seizure powers, and would be able to impose penalties. It is also being proposed that this delegated legislation would have direct effect in both countries, without needing to be incorporated into domestic legislation.

It seems that the rules would be intended to relate to such matters as mandatory licensing requirements and powers, exemptions, governance and accountability processes and arrangements, advertising requirements, import and export requirements, details of enforcement powers, review and complaint processes, and fees and charges. The orders are intended to relate to more 'technical' matters such as manufacturing standards (including

2 This would also apply to the relevant provisions of the New Zealand Bill of Rights Act 1990.

quality and safety), exempt products, permitted substances, product-specific requirements, labelling requirements, and advertising details. In terms of New Zealand constitutional principles, the powers proposed for the managing director are extraordinary powers to be conferring on a non-elected official.

We do not oppose innovation in legislative developments. However, if the joint agency were to proceed, we do not think New Zealand ought to be considering any weakening of its principles and controls relating to delegated legislation in order to accommodate the requirements of the joint agency. Rather, the joint agency ought to be established consistent with such principles and controls. These principles include the distinction between matters of principle and policy being dealt with in the statute, and subordinate matters of detail and implementation in the delegated legislation.[3] In the present case, there is an indication that this distinction is not being followed. It appears both from the intended subject matter of the rules and from the comment in the discussion paper that the rules might address matters that would generally be included in primary legislation in Australia or New Zealand. Matters such as the power to cancel or suspend product licences would instead be contained in rules to ensure uniformity.

We were advised that the proposed rules and orders would constitute what are commonly referred to in New Zealand as 'deemed regulations' rather than 'traditional' regulations. This is because it appears that they are not intended to be subject to important controls to which traditional regulations are subject such as drafting by Parliamentary Counsel, Cabinet approval, and publication in the Statutory Regulations series.

Deemed regulations are not generally encouraged, but may be acceptable where there are good reasons for not having traditional regulations and other controls are in place, particularly publication requirements. In the present case, it appears that the proposals would amount to two tiers of deemed regulations within the one agency. Moreover, the proposal is that the rules might include material that would not ordinarily be contained in delegated legislation but rather in primary legislation.

The proposal that the orders would be made by an official is very unusual for ordinary deemed regulations in New Zealand, and would involve giving very significant, indeed excessive, powers to the managing director. Some of us believe these would bind New Zealanders without the ability of New Zealanders to be directly involved in the process. We are concerned at the extent of the power delegated to the managing director and question whether this is an appropriate delegation. Some of us are concerned at this unprecedented delegation of power to an overseas official.

It is further proposed that the rules and orders be subject to the usual parliamentary scrutiny applied to delegated legislation in both countries. However, we were advised that the scrutiny regimes in New Zealand and Australia are not parallel processes. The Regulations Review Committee of the New Zealand House of Representatives has a number of grounds of jurisdiction set out in the Standing Orders on the basis of which it examines regulations. The corresponding Australian (Commonwealth) committee has fewer grounds. There is the possibility of different conclusions with respect to the same

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3 See the Legislation Advisory Committee *Guidelines on Process and Content of Legislation*, Chapter 10 'Delegation of Legislative Power', and Appendix 5 'Controls over Regulations', 2001, with 2003 Supplement.

regulations, creating a perception of inconsistency. The New Zealand committee also has a complaints jurisdiction that is not replicated in Australia. This raises the possibility of Australian complainants seeking to take advantage of an avenue that is not available to them in Australia.

It is also being proposed that a rule or order that is disallowed in either country would be ineffective in both countries. We were advised that New Zealand and Australia have separate and independent statutory regimes relating to disallowance, and quite different histories relating to the use of this particular remedy.

We note that these problems with the proposed delegated legislation regime are more than mere drafting issues. They are matters of principle that strongly suggest for further consideration the question whether, in the event of full harmonisation, it is best to seek to proceed in the novel way proposed or in a more orthodox manner whereby delegated legislation is made in the usual way in both countries. Given the important convention, upheld in the Legislation Advisory Committee guidelines, that delegated legislation should not deal with matters of policy, some of us have serious constitutional concerns about this proposal.

Recommendation

24. We recommend to the Government that, in the event that it were to decide to proceed with the proposed joint agency, it ensure that the regulatory powers allocated to the Ministerial Council and the managing director are consistent with the principles and controls relating to delegated legislation in New Zealand.

Part V Form of regulation

The joint agency proposal clearly stands at one end of the spectrum of regulatory options. It entails the fullest degree of harmonisation in which it is proposed that a single agency, established by treaty and implementing statutes, would regulate directly and make and enforce laws for both countries. This goes even further than harmonisation in the food area where a single agency, Food Standards Australia New Zealand, prescribes food standards that are separately incorporated into New Zealand law under delegated legislation passed in this country. The joint agency would therefore represent a new departure bilaterally. Furthermore, we are not aware of any international precedent for the arrangement being proposed.

There would need to be genuine give and take in any merging of the different regulatory systems in the area of complementary healthcare products. Australia is likely to be very committed to its present Therapeutic Goods Administration model, even though we were told that the model is not fully applied in all Australian states. We note that complex provisions are contained in the federal act concerning the relationship between the national law and state laws, and the jurisdiction of federal and state authorities in this area.

One Australian company told us that it thought the discussion paper read as if it had been written by the Therapeutic Goods Administration, and another submitter referred to the proposed joint agency as the Therapeutic Goods Administration under another name. The Therapeutic Goods Administration indicated to us that there would be only minor differences between the current Australian system and the proposed joint agency. There appeared to be general agreement that the administration is a restrictive, burdensome and expensive regulatory model. We heard much concern, even fear, expressed about the present Australian system in submissions made to us.

We note recent comments in Australia supporting the present system, in which it was claimed that the Therapeutic Goods Administration has led the world in the way it regulates complementary medicines and that these products must meet the same standards of quality and safety as other types of medicines.

It does need to be recognised that, in practical terms, New Zealand is coming to the joint agency proposal from a very different regulatory history and culture in the case of complementary healthcare products. We understand that Australia would not wish its companies to lose market share. At the same time, New Zealand would naturally be concerned that its industry did not lose market share, whether in New Zealand or in the Australian market or third country markets, through becoming less competitive as a result of the joint agency. This suggests a need for considerable caution about the imposition of any new regulatory model.

In New Zealand's case, a permissive, laissez-faire system presently applies. Regulation is provided for in the Medicines Act if therapeutic claims are made for products that are not medicines, but the fact that it is not being applied by the authorities means that in practice the situation is more like deregulation. A measure of control is available simply through the application of the general law, including consumer protection measures such as the Fair Trading Act 1986. Otherwise, to the extent that there is 'regulation', it is left to industry.

Self-regulation is not necessarily a bad thing, although self-regulation in the dietary supplements sector, unlike other sectors, is apparently limited. The fact that regulation has been left to industry means that the proposed joint agency could be expected, in New Zealand's case, to shift responsibility from industry to regulators and administrators. This is not an intervention in the market that could be expected to be neutral in its effects, but one that would be likely to have real consequences.

Harmonisation may not be the best option for New Zealand

The cost-benefit studies into regulatory options in the therapeutics sector conducted by the New Zealand Institute of Economic Research put considerable emphasis on closer economic relations in terms of the benefits of joint harmonisation. We question whether it is the role of these kinds of assessments to place such emphasis on general trade and foreign policy considerations. We suggest that they ought to be confined to an assessment of the impact of what is proposed on the industry concerned so that decision-makers have that information before them. But in any event, from the point of view of the New Zealand complementary healthcare products industry, the imposition of new regulation could be regarded as running counter to the closer economic relations objective of freeing up trade and adopting an open and outward-looking approach.

We received no information suggesting that a regulatory impact assessment that meets the requirements of the regulatory codes and guidelines referred to earlier has yet been done. The reports by the New Zealand Institute of Economic Research are essentially cost-benefit analyses of certain specified options, and are therefore limited in both scope and depth. They are not systematic in relation to the range of matters that the government now requires to be addressed, and are also not specific to the complementary healthcare products industry (although those products are included in the assessments along with medicines and medical devices). The Council of Australian Governments' *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* makes clear that cost-benefit analysis is only one of the tools for examining proposed regulation, with others including cost-effectiveness analysis, risk analysis, and regulatory impact assessment.

We had recent research drawn to our attention that raises questions about harmonisation, at least on a bilateral basis. It suggests that harmonisation of regulatory systems should be pursued only where it can be demonstrated that the costs of doing so are clearly outweighed by the benefits, and that the New Zealand economy is more likely to benefit from retaining freedom to adopt regulation and law that is optimal in the context of New Zealand, rather than Australian, firms and markets. It suggests that regulatory competition is important for the attraction and retention of investment in New Zealand. But it also points out that mutual recognition will only be achievable where the laws of the participating jurisdictions fall within the tolerance limits for differences in regulatory standards in each jurisdiction. The mutual recognition option itself requires a degree of harmonisation.

Recommendations

25. We recommend to the Government that before it takes any decisions on the proposed trans-Tasman agency to regulate therapeutic products, it ensure that it demonstrates that all of its requirements with respect to best regulatory practice have been fully complied with, including:

a) the five principles and guidelines (efficiency, effectiveness, transparency, clarity, and equity) set out in the 1997 *Code of Good Regulatory Practice* administered by the Ministry of Economic Development and

b) the Cabinet Office and Ministry of Economic Development requirements relating to regulatory impact statements and business compliance cost statements.

26. We recommend to the Government that it consider and assess all options for regulating complementary healthcare products in light of these best practice guidelines:

a) the Council of Australian Governments' *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (as well as *A Guide to Regulation* of the Office of Regulation Review of the Australian Productivity Commission) and

b) international regulatory best practice, including the work of the Organisation for Economic Co-operation and Development, the United Kingdom Better Regulation Task Force on principles of good regulation, United Kingdom Cabinet Office and the United Kingdom National Audit Office on regulatory impact assessment.

27. We recommend to the Government that compliance with New Zealand regulatory requirements be independently verified.

28. We recommend to the Government that it maintain ongoing consultation with the Ministerial Panel on Business Compliance Costs on the regulation of complementary healthcare products and ensure that the panel is satisfied with proposals relating to such regulation.

29. We recommend to the Government that it satisfy itself that the joint agency proposal has been subject to all appropriate regulatory impact and business compliance cost assessments in Australia with respect to complementary healthcare products.

30. We recommend to the Government that it assess the joint agency proposal with reference to the small firms' impact test and the competition assessment (including the competition filter test) contained in the United Kingdom Cabinet Office guide to regulatory impact assessment.

Intensive regulation may not eliminate risk

We received many pages of information from Medsafe pointing to the dangers and risks of complementary healthcare products in the New Zealand market. We also heard from other submitters who disagreed with that information. We do note that if Medsafe's evidence is accepted, a question that might be asked is whether it has been doing its job of protecting the New Zealand consumer.

The recent scare over Pan Pharmaceuticals' products is a demonstration, if one was needed, that intensive regulation does not necessarily provide protection from, or eliminate, risk. We heard different views on that episode, which resulted in the removal of many products from New Zealand as well as Australian shelves. The Therapeutic Goods Administration told us that it pointed to the difficulty of uncovering well-concealed bad practices in this industry. Some submitters said it showed only how New Zealand ought to avoid a system like the Therapeutic Goods Administration that had not been able to ensure protection. One submitter expressed the view that if the joint agency had been in operation, New Zealand would have been much more badly affected by the Pan debacle. However, submitters generally accepted that some form of regulation was necessary.

It is not our place to pass judgement on the Pan matter. Our point is that there is not a single best method of regulatory intervention, and no monopoly on wisdom in such a complex area. Industry cooperation and responsibility are valuable and ought to be built upon in any reforms. As noted earlier, it was common ground among submitters that some regulation is required. However, we note that in response to the Pan recall, Australia is now imposing further significant regulatory controls on therapeutic products, including a 'fit and proper person' test in relation to manufacturing licences, with new prohibitions and heavier penalties. It is heading in an even more restrictive regulatory direction that diverges further from the situation in New Zealand.

The Australian Pan review report contains findings that will have implications for any regulatory regime governing complementary healthcare products in New Zealand and Australia. The review report notes that there has been development of regulatory guidelines for complementary healthcare products. Members from the Therapeutic Goods Administration, the Australian Self-Medication Industry and the Complementary Healthcare Council of Australia comprised a consultation group to assist in the development of a draft of the *Australian Regulatory Guidelines for Complementary Medicines*. The expert committee's report states that these guidelines are expected to provide a basis for regulation of complementary healthcare products under a joint Australian/New Zealand agency.

We consider it important that these guidelines take account of New Zealand interests. This includes our Treaty of Waitangi obligations and the concerns of the New Zealand complementary healthcare industry. We would not like to see Australian guidelines adopted for both countries without further work being done on the appropriateness of their application to New Zealand.

Recommendation

31. We recommend to the Government that it consider carefully the impact that the joint agency proposal would have on the relative positions in domestic and external markets of the New Zealand and Australian complementary healthcare products industries.

One Australia/New Zealand precedent for lighter regulation

There is a recent precedent for moving away from a more intensive overlay of regulation in favour of more 'light-handed' and flexible regulation in this general area. Our attention was drawn to the Australian Codd Report of November 2002 concerning the advertising of therapeutic products.[4] This substantial report is part of the work on the joint agency project. The report comments that there would be a need to ensure that the costs for industry in meeting the regulatory requirements are outweighed by the benefits to the community in terms of avoiding the costs of harm caused by the inappropriate use of therapeutic products.

The report notes that in New Zealand the advertising and media industries have developed a strong self-regulatory, essentially voluntary, system for ensuring that advertisements making therapeutic claims meet a high standard of social responsibility, as well as complying with legislative requirements. It notes that this system was 'borrowed' and adapted from that in Australia, where a similar system prevailed until 1996 when Australia brought in a co-regulatory system. It notes that this latter system 'is seen by most to be unduly complex, open to inconsistency and often too slow to protect the public interest when it comes to public health and safety', and it sets out the option of Australian media and advertising industries 'borrowing back' the self-regulatory model.

The report goes on to recommend that the New Zealand model for pre-approval of advertisements, involving a 'one-stop shop' combined with a system of 'delegated authorities' should, as far as possible, be replicated in Australia.[5] The report notes that a benefit to the industry is enhanced reputation for responsibility if controls over advertising (especially where self-regulatory) are seen to be effective. But it also considers that there is a challenge for small businesses in supporting an effective self-regulatory system, where the costs and penalties of the complaints process can be potentially significant, and that this is a particular challenge for the dietary supplements sector in New Zealand.[6]

We note that different issues arise in respect of regulation of products compared with regulation of their advertising. But if an example is sought for responsibility being left to the industry and for relieving (or not imposing) a burden on regulators and administrators that they may not be well placed to discharge, then lessons may be drawn from the Codd Report and the therapeutics media and advertising industry. In short, if full harmonisation

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4 Toogoolawa Consulting Pty Ltd *Report of a Review of Advertising Therapeutic Products in Australia and New Zealand* (Commonwealth of Australia, Canberra, November 2002).

5 This would be backed up by a complaints process with appeals and sanctions. The report also recommends that the prohibition on the making of therapeutic claims on food products be lifted, and that such claims be governed by the therapeutics advertising code.

6 The report comments that that sector lacks effective self-regulation, unlike Australia where there are well-developed self-regulatory systems in the various industry sectors but not in the media and advertising industry. If so, there is then in Australia, if we understand it correctly, effectively double regulation in the case of complementary healthcare products, comprising self-regulation and government regulation.

were to proceed, the solution in respect of regulation of complementary healthcare products may involve looking not only at raising standards in New Zealand but also at moderating standards to a less onerous level (that is, reducing the regulatory burden) in Australia. Assuming that the products remain compliant with standards for entry to third country markets, harmonisation of that kind ought to make Australian exports a little more competitive without affecting the competitiveness of New Zealand exports.

Recommendation

32. We recommend to the Government that, in the event that it were to decide to proceed with the proposed joint agency and to include complementary healthcare products in the agency's coverage, it consider a more appropriate merging of the regulatory systems that would involve not only a raising of New Zealand's regulatory standards but also a reduction of the regulatory burden in Australia.

2002/2 Petition of Sue Kedgley and 30,457 others

The above petition is before the committee. It requests that regulations governing dietary supplements not be brought under a single trans-Tasman authority but be regulated on the basis of New Zealand legislation, separate from medicines and medical devices, and that emphasis be placed on quality control and maximum consumer choice. As we consider we have canvassed these matters in this report, we have no further matters to bring to the attention of the House.

Conclusions

We do not consider that the case for the joint agency proposal has been made with respect to complementary healthcare products. We have identified the reasons for this conclusion throughout this report. This type of harmonisation arrangement with Australia has no precedent, which makes it difficult to judge whether it could work to the advantage of both countries.

The place of the complementary healthcare industry under the Trans-Tasman Mutual Recognition Arrangement requires further consideration. Our recommendations to the Government set out the regulatory elements that we see as important, while also addressing the steps that we consider the Government must take to satisfy itself in the event that it may wish to continue with the joint agency proposal so far as complementary healthcare products are concerned.

We support, on balance, the option of mutual recognition over a joint agency providing that this step is combined with a strengthening of New Zealand's regulatory regime relating to complementary healthcare products. This does not necessarily mean that standards will need to be identical in each country, but rather that they are consistent or compatible. As matters stand, New Zealand's regulation has not been enforced and therefore will not suffice for mutual recognition purposes with Australia.

We note that one of the purposes of the Trans-Tasman Mutual Recognition Act 1997 is to give effect to the mutual recognition principle that a commodity that may be sold legally in Australia may also be sold in New Zealand, even if there are some differences in standards or regulatory requirements between Australia and New Zealand. We are therefore

confident that if our regulations are strengthened to the point where there is a degree of alignment between the New Zealand and Australian regulatory regimes, mutual recognition should naturally follow.

We note that the joint agency proposal may involve significant limitations on New Zealand's freedom of action and the surrender of control of the complementary healthcare products industry. We are concerned that under the joint agency proposal some policy decisions will be left to powers outside New Zealand. We are also concerned about the commercialisation of traditional Māori herbs being regulated by legislation in an overseas jurisdiction and by an overseas regulator. We consider that such regulation should take account of New Zealand's Treaty of Waitangi obligations.

We believe that aspects of the joint agency proposal do not meet New Zealand's own *Code of Good Regulatory Practice*, and the commitment to reduce compliance costs of small businesses, in particular costs that impact on innovation. We have made recommendations to the Government that highlight the guidelines on good regulatory practice that we expect any regulatory scheme to adhere to.

There are several elements that we would like to see incorporated into a strengthened New Zealand complementary healthcare products regulatory regime. These include a mandatory electronic register of all complementary healthcare products, accessible through the internet; a licensing requirement for all manufacturers, importers, and suppliers of complementary healthcare products; a requirement that all complementary healthcare products sold in New Zealand are produced in accordance with appropriate good manufacturing practice; and a negative list system that prohibits the use of unsafe ingredients.

Finally, we consider a strengthened New Zealand regulatory regime should include a third category that would ensure that complementary healthcare products are regulated as a class in their own right, distinct from food and pharmaceutical medicines. This would ensure they are regulated in an appropriate environment, and would facilitate regulation by an appropriately trained and qualified regulator.

We consider the New Zealand and Australian Governments owe it to the complementary healthcare products industry and consumers in both countries to demonstrate that assessment of possible options has been carried out in a full, proper, and systematic way before final decisions about the regulatory framework are taken. At the same time, the complementary healthcare products industry in New Zealand cannot expect to have it both ways. New Zealand law is clear enough, and companies wanting to make therapeutic claims about their products ought to have been complying with it. Neither the Dietary Supplements Regulations nor, even more so, the Medicines Act represent an unregulated environment in New Zealand, and there were some submitters who urged stronger controls. But, in our view, the fact that regulation has not been complied with or enforced in the past is not a reason to avoid looking at the regulatory framework in the light of all the considerations set out in this report.

We note the lack of support for the proposal from both the complementary healthcare products industry in New Zealand and the majority of submitters to this inquiry. It is unclear what the effect of the harmonisation proposal would be for the New Zealand

industry. However, it is likely that there would be an increase in compliance costs, without sufficient benefits to offset these costs. If the cooperation of industry that is a crucial feature of successful regulatory regimes has not been secured with respect to the present system in New Zealand, we wonder how the new agency can be expected to work when it already faces such significant opposition from industry here. Whatever system for regulation is eventually adopted, significant work will have to occur to engage the industry and gain its support.

We acknowledge that there would be some benefits from harmonising the regulation of complementary healthcare products. Such benefits would include advantages from economies of scale and the pooling of expertise, including technical, scientific, investigatory and other resources. The advantages of sharing capacity and expertise may also extend to vetting products for approval as well as meeting subsequent regulatory requirements. Sharing the regulatory burden with a neighbouring major economy could result in a reduction in duplication of required regulation for New Zealand. We also favour closer economic relations with Australia. We consider it important to secure these benefits for New Zealand in the context of any regulatory system that takes account of the considerations outlined in this report.

The proposal to regulate therapeutic products by a trans-Tasman agency covers the regulation of medicines, medical devices, and complementary healthcare products. This inquiry considered only complementary healthcare products. We consider that joint regulation of medicines and medical devices is appropriate. We will monitor with interest the progress of this joint regulation regime. The knowledge gained from this experience will assist with any future planning for joint regulation of complementary healthcare products. Some of us look forward to the point in the future where New Zealand has a sufficiently robust regulatory environment for complementary healthcare products that enables a joint agency option to be considered once again.

Recommendations

33. We recommend to the Government that it strengthen domestic regulation as the most appropriate method of governing complementary healthcare products in New Zealand.

34. We recommend to the Government that it pursue a mutual recognition regulatory option rather than pursue a joint agency with Australia.

Appendix A

Committee procedure

We initiated this inquiry on 11 September 2002. The closing date for submissions was 13 November 2002. We received and considered 120 submissions from interested groups and individuals. We heard 27 submissions, which included holding hearings in Auckland and Wellington. Hearing of evidence took 12 hours and 19 minutes and consideration took 10 hours. A subcommittee spent a further 56 minutes in consideration. The submitters are listed in Appendix G. We heard evidence from submitters on 13 November 2002, 7 April, 14 and 21 May, 11 and 25 June, and 2 and 23 July 2003.

Committee members

Steve Chadwick (Chairperson)
Dave Hereora
Dr Paul Hutchison
Sue Kedgley
Nanaia Mahuta
Pita Paraone
Mark Peck
Heather Roy
Dr Lynda Scott
Judy Turner
Dianne Yates

On 30 July 2003, Moana Mackey replaced Ann Hartley as a permanent member of the committee.

On 8 October 2003, HV Ross Robertson replaced Moana Mackey as a permanent member of the committee.

On 5 November 2003, Mark Peck replaced HV Ross Robertson as a permanent member of the committee.

On 5 November 2003, Dr Paul Hutchison replaced Judith Collins as a permanent member of the committee.

Advisers

Allan Bracegirdle, Legislative Counsel
Brian Easton

Appendix B

The joint agency proposal

The following information is sourced from the Ministry of Health discussion paper *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products* pp. xii to xvii. The full document can be viewed in the Medsafe website at www.medsafe.govt.nz (last accessed 3 December 2003).

How will the regulatory scheme work?

The Agency would regulate products used for a therapeutic purpose. Therapeutic products would include:

- prescription and over-the-counter (OTC) medicines;
- medical devices; and
- products currently regulated in Australia as complementary medicines; and
- products marketed as dietary supplements in New Zealand (other than food-type dietary supplements), including herbal and homoeopathic medicines.

The regulatory activities of the Agency would include pre-market assessment or evaluation, product licensing, post-market surveillance, licensing of manufacturers, setting of standards and communicating decisions and information.

Whilst the regulatory scheme is designed to deliver common regulatory outcomes in the two countries, it is recognised that the scheme would need to enable either country to 'opt out' of a common regulatory decision in extraordinary circumstances (e.g. to accommodate differing public health policy imperatives).

The Agency would regulate therapeutic products using a risk management approach, in which the degree of regulatory control would be proportional to the risk associated with use of the product.

Prescription and OTC medicines, complementary medicines and dietary supplements (other than food-type dietary supplements)[1] would be classified according to risk into one of three classes based on ingredients, intended purpose and type of product. Class I would comprise low-risk products (e.g. most complementary healthcare products and sunscreens). Class II (medium risk) would include most over-the-counter medicines. Class III products would include prescription medicines and other specified products (e.g. vaccines, biotechnology products, radiopharmaceuticals, injectable dosage forms and products intended to carry indications for serious diseases). The Agency's internal organisation

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1 For convenience complementary medicines and dietary supplements (other then food-type dietary supplements) are referred to in the discussion paper as 'complementary healthcare products', further discussion of the terminology to be used to describe this type of product is provided in Part F of the paper [discussion document].

would be based on a scheme of regulation by type of product. In such a scheme there would be separate regulatory units within the Agency for regulation of prescription, OTC and complementary healthcare products.

Medical devices would also be classified according to risk into one of six classes, using the manufacturer's intended purpose and a set of risk-based classification rules, consistent with the framework recommended by the Global Harmonisation Task Force (GHTF).

It is proposed that the Agency would operate a cost recovery scheme in which cost recovery arrangements would be consistent with government policy and relate to the range of regulatory activities including pre-market evaluation or assessment of products and/or substances, post-market surveillance, standard setting, and the auditing and licensing of manufacturers.

The Agency would consult with industry representatives to ensure that fees and charges accurately reflected the cost of regulating a particular industry sector or a product group and were borne equitably within and across the relevant sector or product groups.

Activities that the Agency may perform under contract (e.g. chemical hazard and risk assessments for Australia or pharmacy audits for New Zealand) would be outside the scope of the joint scheme and would be funded separately from payments under those contracts.

Product licensing

It is proposed that authorisation to import, export or supply therapeutic products would be granted by a product licence issued by the Agency, unless the product was specifically exempted from the requirement for a product licence. The product licence (PL) holder or their authorised agent would be the sponsor of the product.

Each PL would carry a unique number and, generally, a separate PL would be issued for each new product, although it would be possible to 'group' more than one product in the same PL in certain circumstances. The Agency would maintain a register of licensed products.

The product licence document would provide a summary of the particulars of the product and set out or refer to the conditions under which the product could be supplied.

In order to obtain a product licence, the sponsor would be required to submit an application to the Agency. The application processes, data requirements and evaluation/assessment processes would be different for different types of products and different risk classifications. Class I products would be granted a product licence on the basis of self-certification by the sponsor, using an electronic application lodgement and assessment system.

The Agency would set timeframes for evaluating and processing applications. Appropriate mechanisms would be put in place to allow accelerated evaluation to occur in defined circumstances. An orphan medicines programme would facilitate the availability of medicines for use in rare diseases.

Expert advisory committees

Expert advisory committees would be established to provide the Managing Director of the Agency with scientific and regulatory advice. Members would be selected from relevant experts in both countries. Committees would be established to provide advice on matters such as standards for therapeutic products, matters relating to the evaluation and licensing of products (with a separate committee for each broad category of product), adverse reactions and scheduling.

Licensing of manufacturers

Manufacturers of medicines and complementary healthcare products would be required to comply with specified manufacturing principles. The Agency would audit manufacturers for compliance with the code and would issue manufacturing licences. Evidence of compliance with manufacturing principles would also be required for any overseas site manufacturing a medicine or complementary healthcare product.

Post-market surveillance

The Agency would use a systematic, risk-based approach to post-market surveillance of therapeutic products. Post-market surveillance activities would include: random and targeted testing of products; adverse reaction monitoring; medical device incident monitoring; product problem reporting and recalls; auditing of manufacturing facilities; audits of applications (e.g. those relying on sponsor self-certification or self-assessment); and monitoring of products in the market place to ensure they are being marketed in compliance with the terms and conditions of the product licence.

Clinical trials and access to unlicensed therapeutic products

Use of therapeutic products in clinical trials would be regulated under a joint clinical trial scheme. All clinical trials, including those using licensed products, would require the approval of the relevant institutional ethics committee(s) and would have to be notified to the Agency. Clinical trials would also require scientific approval. Comment is sought on different options for obtaining scientific approval of clinical trials.

A number of mechanisms would be put in place to allow patients access to unlicensed therapeutic products in defined circumstances.

Therapeutic products for export

Therapeutic products that are not the subject of a product licence but are to be exported from Australia or New Zealand to a third country would require an export only licence, and the Agency would provide appropriate export certification to meet international requirements. Comment is sought on specific options for administering the export licensing scheme.

Advertising

Under a joint agency, advertisements for therapeutic products directed exclusively to healthcare professionals would be governed by industry codes of practice, which would be consistent with an Australia/New Zealand therapeutic products advertising code.

The regulatory scheme that would apply to direct-to-consumer advertising is currently under review as part of the joint agency project. It is anticipated that the regulatory arrangements for direct-to-consumer advertising of therapeutic products would be co-regulatory and simplified wherever possible. That approach would be based on:

- a single Australia/New Zealand advertising code and advertising oversight body;
- a single pre-clearance system for advertisements;
- single administrative and complaints arrangements; and
- joint (Australia/New Zealand) industry codes of practice.

Scheduling of medicines

The proposals set out in the paper advance the recommendations of the Galbally Review [2] in Australia relating to scheduling.

It is proposed that under a joint agency, there would be a single scheme for the scheduling of medicines and substances in medicines. The initial scheduling decision would be made as part of the evaluation and approval process for the substance or medicine.

An expert advisory committee on medicine scheduling would advise the Managing Director on scheduling matters; would consider proposals to change the scheduling classification of a medicine; and would be able to review scheduling decisions made by the Managing Director.

How will prescription medicines be regulated?

Under a joint agency, the application and evaluation processes and the data requirements for prescription medicines would be similar to those currently applied in both countries, and would be consistent with international best practice. It is proposed that the legislation would set timeframes for processing applications, with cost penalties for the Agency if the timeframes were not met.

Strict criteria would be set down by the Agency in relation to requirements for demonstrating bioequivalence for generic medicines.

How will OTC medicines be regulated?

Under a joint agency, the application and evaluation processes and the data requirements for OTC medicines would be similar to those currently applied in both countries, and would be consistent with international best practice. It is proposed that the Agency would set timeframes for processing applications.

How will complementary healthcare products be regulated?

There is no universally accepted collective term or definition for the groups of products often referred to as complementary healthcare products, complementary medicines or natural health products. These products fall under the broad definition of 'medicine' because of the way in which they act. However, some stakeholders do not agree with the

2 A Review of Drugs, Poisons and Controlled Substances Legislation.

use of the term 'medicine'. Comment is sought on appropriate terminology and definitions to be used in the legislation.

In Australia, complementary healthcare products are regulated as complementary medicines under therapeutic goods legislation. In New Zealand, they are generally marketed as dietary supplements and controlled under food legislation. It is proposed that a joint agency would regulate complementary healthcare products as therapeutic products, using a risk-based approach. Most complementary healthcare products (around 95%) would be low-risk (Class I), and therefore could be licensed quickly on the basis of sponsor self-certification using an electronic system.

Safety of ingredients used in low-risk complementary healthcare products would be controlled by the Agency maintaining a list of permitted ingredients that had been assessed as being safe for use in Class I products. Any products falling into Class II (medium risk) or Class III (high risk) would be evaluated by the Agency for safety, quality and effectiveness before a product licence was granted.

How will medical devices be regulated?

Consistent with the endorsed recommendations of the GHTF, all medical devices would have to meet a set of essential principles relating to their design, manufacture and clinical performance before a product licence could be granted. The level of regulation would be proportional to the degree of risk involved in the use of the device.

For the lowest risk devices, a product licence would be granted on the basis of sponsor self-certification. For the higher risk classes, the Agency would be able to take account of documentation from overseas bodies in which it had confidence. Where adequate evidence was not available, or where the device presented specific types of risks (e.g. contained material of human or animal origin), the Agency would undertake evaluation of the medical device before granting a product licence.

Mechanisms would be developed to allow access to unlicensed medical devices in appropriate circumstances. A medical device exported from Australia or New Zealand to a third country would require an export only licence.

How will compliance be monitored and enforced?

The Agency would have responsibility for monitoring compliance with the regulatory system it administered, and would have the power to request information, to request samples for testing, and to search premises and seize goods. The Agency would also have the power to impose sanctions (e.g. cancel a product licence or recall a product) and prosecute offences.

How will regulatory decisions be reviewed?

It is proposed that the Agency's regulatory decisions would be open to challenge in two ways:

- through a two-stage merits review process, consisting of a right to ask the Agency to carry out a review of one of its decisions, with a further right to ask for a review of a decision to be carried out by a merits review panel external to the Agency; and
- through judicial review proceedings brought in the courts of either country.

What will the transitional arrangements be?

Following the passage of legislation implementing a new joint regulatory scheme for therapeutic products and commencement of operation of the Agency, there would need to be a period of transition to the new system. At commencement of operation of the Agency, therapeutic products legally on the market in Australia could continue to be supplied in Australia and therapeutic products legally on the market in New Zealand could continue to be supplied in New Zealand.

For certain types of products (e.g. medical devices and complementary healthcare products in New Zealand) the initial permission to supply would lapse at the end of a defined transition period. Because these products had not previously been subject to pre-market regulation, continued supply would be subject to the sponsor applying for and being issued with a product licence based on evaluation or assessment in accordance with the requirements of the Agency.

Considerable further work and consultation will need to occur over the next few months as the details of appropriate mechanisms and durations for transition are developed. The following principles have been developed to guide this work.

The transition arrangements would:

- provide adequate assurance about the safety, quality and efficacy of products on the product licence register, without requiring extensive re-evaluation of data, which cannot be justified on public health and safety grounds;
- ensure that manufacturers and sponsors of therapeutic products in both countries are treated in a fair and equitable way, taking into account relevant past regulatory practices;
- impose the lowest possible compliance costs consistent with adequately protecting public health and safety;
- permit sponsors already in the market in either country to continue to market in that country during the transition period without having to apply for a dual country licence; and
- facilitate early reduction of existing trade barriers.

Australian and New Zealand officials will present recommendations on the proposed joint regulatory scheme to their respective Governments later this year after considering stakeholder comments on the proposals in this paper.

Appendix C

Alternative suggestions to the proposed trans-Tasman model for regulating therapeutic products

The following suggestions received from submitters set out alternative regulatory models, and variations on the proposed regulatory regime.

Direct Selling Association: Gas appliance model

The Direct Selling Association highlighted the model used for gas appliance regulation in New Zealand and how this might provide an example of how to establish a regulatory model more suited to dietary supplements. It is based on a mandatory supplier declaration system, and is designed to give the public the maximum assurance of safety while maintaining the lowest appropriate cost structure. Key points about the model include:

- all suppliers are required to 'notify' by a web-based declaration their gas appliances, and conform to a New Zealand standard
- there is an industry-supported reporting system to identify non-compliant appliances and suppliers
- the system is co-regulatory and requires active participation by the industry
- there has been no lessening of safety requirements.

Dietary Supplements Consultative Group model

The Dietary Supplements Consultative Group proposed a two-stage reform. It draws on international best practice, and constitutes a regime that is compatible with trans-Tasman harmonisation or mutual recognition within the requirements of the Government's *Code of Good Regulatory Practice.*

Stage one of reform: a 'quick-fix' of regulations under existing legislation

- new regulations for nutritional supplements under the Food Act (replacing the Dietary Supplements Regulations)
- new regulations exempting nutritional supplements from the Medicines Act (allowing nutritional supplements to make truthful claims, subject to the Fair Trading Act 1986).

Stage two of reform: a 'permanent fix' under separate legislation. This would create complementary healthcare and therapeutic products formally as a separate (third) category of products, in addition to food and medicines—under dedicated legislation. This would recognise that, despite sharing some of the attributes of each, complementary healthcare products are neither foods nor medicines.

The new legislation would:

- state as its purpose that it is to promote the safety of the relevant products
- state as an underlying principle that the industry and the regulator are to work in partnership
- include unilateral recognition of specified international standards for satisfactory, risk-based good manufacturing practice, allowable ingredients, recognised pharmacopoeia, proper labelling, and therapeutic claims
- create a statutory advisory body
- include a simple electronic database through which distributors of products can register themselves and their products, ingredients and claims
- provide an objective risk-classification system for greater flexibility
- include an electronic notification system for new ingredients, allowing the regulator a statutory period in which to challenge an ingredient
- provide a simple disputes resolution procedure
- include enforcement mechanisms and penalties
- allow a transitional period, such as 3 years.

Under the proposal, schedules would nominate countries with acceptable standards for good manufacturing practice, labelling, determining allowable ingredients and dosages, and the making of therapeutic claims. New Zealand would unilaterally accept these standards. The benefits of this would be:

- improved consumer confidence
- improved consumer information
- minimal increase in compliance costs for suppliers of products that are already safe.

Complementary Healthcare Council of Australia

The Complementary Healthcare Council of Australia supported a trans-Tasman agency but not the current Australian model. It proposed that any natural healthcare products agency be comprised of the following core elements:

- a self-assessment registration system based on a comprehensive list of low-risk ingredients
- a simple, timely, low-cost mechanism for evaluating and approving new natural ingredients
- an expert evaluation committee comprising expertise, knowledge, and experience in natural healthcare, including industry representation
- a register of natural healthcare products containing only essential information
- a simple electronic notification system

- good manufacturing practice appropriate to the low-risk nature of complementary healthcare products
- a co-regulatory advertising system that provides a mechanism for control over false and misleading claims and ensures social responsibility
- a post-market surveillance system that reflects the low-risk nature of these goods
- cost recovery that applies only to those activities that provide a service to the industry
- be separate from the offices that regulate pharmaceuticals
- be staffed with people with a background and expertise in natural healthcare.

Medsafe (Ministry of Health)

Medsafe identified 6 options for regulation of complementary medicines that it has considered—ranging from having no specific legislation to applying a risk-based regulatory framework consistent with international trends in complementary medicine regulation:

- Option 1: relying on consumer protection legislation with no specific regulation of products
- Option 2: relying on industry self-regulation, with no specific regulation of products
- Option 3: maintaining the status quo in New Zealand
- Option 4: retaining the Dietary Supplements Regulations, but fully enforcing them so that only those products that fit the definition and were not labelled or advertised with any therapeutic claims could be marketed as dietary supplements
- Option 5: adopting New Zealand-specific legislation to regulate therapeutic-style dietary supplements as therapeutic products, applying a risk-based regulatory framework consistent with international trends
- Option 6: joint agency with Australia.

The advantages and disadvantages of each are summarised in Medsafe's submission. It concluded that only options 5 and 6 are effective regulatory options when the advantages and disadvantages of each option are compared, with the greatest importance given to the impact on appropriate management of public health and safety risks. Option 6 is preferred to 5 as it has a smaller compliance cost impact, as a New Zealand agency would involve unnecessary duplication of effort and expertise that could be avoided if a joint agency is set up with Australia.

New Zealand Health Trust

The New Zealand Health Trust proposed a model that is fully self-funded and aims to ensures public safety through product quality and product information about claims. The proposed regime aims to achieve regulation without high compliance costs.

The New Zealand Health Trust believes that full harmonisation with Australia will limit New Zealand's ability to trade with other major trading partners. The New Zealand Health

Trust plans to enable New Zealand to trade freely with all major trading partners as required by, and in keeping with, the World Trade Organization rules.

Scope of regulation:

- license all manufacturers, importers and suppliers of dietary supplements in New Zealand
- all products compulsorily listed by the supplier of the product
- the listing systems does not involve pre-market approval or vetting
- dietary supplements must be assessed on their own merits and regulated in line with their own risks
- dietary supplements do not fit within any pharmaceutical framework
- prohibited products to be regulated by a negative list
- regulators to co-ordinate an impact reporting system to encourage reporting of positive or negative experiences with dietary supplements.

Fees and licensing:

- fees will include an application fee for new licences and an annual renewal fee
- system will provide for various cost recovery from non-complying businesses
- model could be self-funding but could also accommodate government funding
- each business pays only one fee a year: the size of the fee will vary between businesses.

Good manufacturing practice standards:

- recognises the need for the system to ensure products created for human use must be of consistently high quality
- good manufacturing practice to be mandatory for all manufacturers and suppliers of dietary supplements
- as many businesses already abide by such standards, the system will not impose any further obligations on business.

Internet-based product directory:

- the proposed model contains an internet-based products directory
- it provides regulators with accurate and up-to-date information about all products available in New Zealand
- easily accessible information in the event of a product recall
- ensures consumers have access to high quality, consistent and current information about any product.

Enforcement:

- licensing fees will fund random paper-based audits to confirm good manufacturing compliance
- if areas of non-compliance emerge then the cost of audits or testing will be charged to the business concerned and so will the cost of any follow-up testing
- a series of offences and penalties will be created as part of the legislation and will be staggered to be commensurate with the severity of the offence
- penalties include monetary fines and loss of licence.

Appendix D

Regulatory codes and principles

The following information provides a summary of regulatory codes and principles in New Zealand, Australia, the United Kingdom, and the Organisation for Economic Co-operation and Development (OECD). Where relevant, website addresses are included.

New Zealand

1. Code of good regulatory practice

Regulation in New Zealand is required to take account of the general principles in the New Zealand *Code of Good Regulatory Practice*. The code was approved by Cabinet in 1997 and is recognised as mandatory in the Government response to the recommendations of the Ministerial Panel on Business Compliance Costs.

The New Zealand *Code of Good Regulatory Practice* is reproduced below. It can also be found at: www.med.govt.nz/buslt/compliance/regprac.html[7]

Code of Good Regulatory Practice (1997)

Efficiency

Adopt and maintain only regulations for which the costs on society are justified by the benefits to society, and that achieve objectives at lowest cost, taking into account alternative approaches to regulation.

Efficiency Guidelines

- *Consideration of alternatives to regulation*: regulatory design should include an identification and assessment of the most feasible regulatory and non-regulatory alternative(s) to addressing the problem.
- *Minimum necessary regulation:* when government intervention is desirable, regulatory measures should be the minimum required, and least distorting, in achieving desired outcomes.
- *Regulatory benefits outweigh costs*: in general, proposals with the greatest net benefit to society should be selected and implemented.
- *Reasonable compliance cost*: the compliance burden imposed on society by regulation should be reasonable and fair compared to the expected regulatory benefit.
- *Minimal fiscal impact*: regulators should develop regulatory measures in a way that minimises the financial impact of administration and enforcement.
- *Minimal adverse impact on competition*: regulation should be designed to have a minimal negative impact on competition.

7 Last accessed 3 December 2003.

- *International compatibility*: where appropriate, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices, in order to maximise the benefits of trade.

Effectiveness

Regulation should be designed to achieve the desired policy outcome.

Effectiveness Guidelines

- *Reasonable compliance rate*: A regulation is neither efficient nor effective if it is not complied with or cannot be effectively enforced. Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest possible cost to all parties. Incentive effects should be made explicit in any regulatory proposal.
- *Compatibility with the general body of law,* including the statute which it amends, statutes which apply to it, and the general body of the law of statutory interpretation.
- *Compliance with basic principles* of our legal and constitutional system, including the Treaty of Waitangi, and with New Zealand's international obligations.
- *Flexibility of regulation and standards*: regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change.
- *Performance-based requirements that specify outcomes* rather than inputs should be used, unless prescriptive requirements are unavoidable. This will help ensure predictability of regulatory outcomes and facilitate innovation.
- *Review regulations systematically* to ensure they continue to meet their intended objectives efficiently and effectively.

Transparency

The regulation making process should be transparent to both the decision-makers and those affected by regulation.

Transparency Guidelines

- *Problem adequately defined*: identifying the nature and extent of the problem is a key step in the process of evaluating the need for government action. Properly done, problem definition will itself suggest potential solutions and eliminate others clearly not suitable.
- *Clear identification of the objective of regulation*: the policy goal should be clearly specified against the problem and have a clear link to government policy.
- *Cost benefit analysis*: regulatory proposals should be subject to a systematic review of the costs and benefit. Resources invested in cost benefit estimation should increase as the potential impact of the regulation increases.
- *Risk assessment*: regulatory proposals should be subject to a risk assessment which should be as detailed as is appropriate in the circumstances.

- *Public consultation* should occur as widely as possible, given the circumstances, in the policy development process. A well-designed and implemented consultation programme can contribute to better quality regulations, identification of the more effective alternatives, lower costs to business and administration, ensure better compliance, and promote faster regulatory responses to changing conditions.
- *Direct approaches to problem*: In general, adopting a direct approach aimed at the root cause of an identified problem will ensure that a more effective and efficient outcome is achieved, compared to an indirect response.

Clarity

Regulatory processes and requirements should be as understandable and accessible as practicable.

Clarity Guidelines

- *Make things as simple as possible, but not simpler, in achieving the regulatory objective.*
- *Plain language drafting*: where possible, regulatory instruments should be drafted in plain language to improve clarity and simplicity, reduce uncertainty, and to enable those affected to better understand the implications of regulatory measures.
- *Discretion should be kept to a minimum*, but be consistent with the need for the system to be fair. Good regulation should attempt to both minimise and standardise the exercise of bureaucratic discretion, in order to reduce discrepancies between government regulators, reduce uncertainty, and lower compliance costs.
- *Educating the public* as to their regulatory obligations is fundamental in ensuring compliance.

Equity

Regulation should be fair and treat those affected equitably.

Equity Guidelines

- *Obligations, standards, and sanctions* should be designed in such a way that they can be imposed impartially and consistently.
- *Regulation should be consistent with the principles* of the New Zealand Bill of Rights Act 1990, and the Human Rights Act 1993, and the expectations of those affected by regulation, as to their legal rights, should be met.
- *People in like situations should be treated in a similar manner, s*imilarly, people in disparate positions may be treated differently.
- *Reliance should be able to be placed on processes and procedures of the regulatory system:* a regulatory system is regarded as fair or equitable when individuals agree on the rules of that system, and any outcome of the system is considered just.

2. Regulatory impact statements

All policy proposals submitted to Cabinet that result in government bills or statutory regulations must be accompanied by a regulatory impact statement, unless an exemption applies. A regulatory impact statement is a method of systematically and consistently examining potential impacts arising from government action and communicating the information to decision-makers. Completion of a regulatory impact statement helps provide the government with an assurance that new or amended regulatory proposals are subject to proper analysis and scrutiny as to their necessity, efficiency, and net impact on community welfare.

The following information provides a summarised version of the New Zealand Cabinet guidelines on what should be included in regulatory impact statements. The full guide can be found at: www.dpmc.govt.nz/cabinet/guide/index.html[8]

Cabinet Step by Step Guide

- State the nature and magnitude of the problem and the need for government action.
- State the public policy objective(s).
- State feasible options (regulatory and/or non-regulatory) that may constitute viable means for achieving the desired objective(s).
- State the net benefit of the proposal, including the total regulatory costs (administrative, compliance, and economic costs) and benefits (including non-quantifiable benefits) of the proposal, and other feasible options.
- State the consultative programme undertaken.
- Should be prepared following consultation with affected parties and, to obtain maximum benefit from the process, once an administrative decision is made that new regulation may be necessary, and prior to policy decisions.

Ministry of Economic Development recommended guidelines

The following information is a brief summary of the government-approved guidelines for preparing regulatory impact statements administered by the Ministry of Economic Development. These provide guidance on how to approach the development of a regulatory impact assessment. The full document can be found at: www.med.govt.nz/buslt/compliance/regimpact/regimpact-01.html[9]

- Problem definition includes making use of a checklist that includes consideration of why the market will not provide a satisfactory outcome and preliminary assessment of the likely costs in maintaining the status quo, and a framework for determining market failure (problems associated with the government not intervening) and government failure (problems associated with government intervention).
- Analytical framework, specifying desired objectives and key principles and identifying key impacts.

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8 Last accessed 3 December 2003.

9 Last accessed 3 December 2003.

- Options to be considered comprise: standards, no government intervention, the status quo, extending current legislation of general application, increasing enforcement, information and education campaigns, economic instruments, voluntary standards/codes of practice, self-regulation, and co-regulation.
- Impact assessment, comprising cost-benefit analysis, identifying all significant impacts (including direct and indirect, tangible and intangible, administrative and compliance, and domestic and international), avoiding 'double counting' errors, resource allocation and distributional impacts, and comparison of options.
- Formal cost-benefit analysis techniques include: calculation of net present value, application of appropriate decision criteria including risk analysis and sensitivity analysis, determining cost-benefit break-even point, and cost effectiveness analysis.
- Public consultation.
- Treaty of Waitangi, and Māori policy.

3. Business compliance cost statements

Compliance costs are the administrative and paper work costs to business in meeting government requirements. The following information outlines the objectives and content requirements that apply in relation to business compliance cost statements. It is a summary of information contained on the Department of Prime Minister and Cabinet website. This can be found at: www.dpmc.govt.nz/cabinet/circulars/co01/2.html[10]

Cabinet Office Circular (2001)

- Applies to administrative burdens and all other compliance costs in meeting government requirements, including costs associated with identifying and understanding the regulatory requirements, increased liability, and non-monetary effects.
- Principles comprise: compliance cost assessment as an integral part of the policy development process, reduction of costs as a dynamic process that includes ongoing monitoring of existing legislation as well as assessment of the impact of substantive changes, recognition of costs as a charge against the scarce resources of the private sector, critical assessment of compliance requirements in terms of their absolute necessity to achieve the objectives of the policy, and recognition of cost assessment as a clear departmental responsibility and integral part of departmental management accountability.
- Statements should identify: the source of any compliance costs; the parties likely to be affected, by sector and size of firm; quantitative and qualitative estimates of costs (both in aggregate and upon individual firms, persons); longer term implications of the costs (for example, whether one-off or recurring and, if the latter, reducing over time); risks associated with any estimates and the level of confidence in the cost assessment; key issues relating to costs identified in consultation; any compliance requirements overlapping with other agencies; and steps taken to minimise compliance costs.

10 Last accessed 3 December 2003.

Additional Ministry of Economic Development guidelines for New Zealand government departments (2001)

The following information is a brief summary of government-approved guidelines for business compliance cost statements administered by the Ministry of Economic Development. It can be found at: www.med.govt.nz/buslt/compliance/guidelines/guidelines-02.html[11]

- Importance of compliance cost reduction, including consideration of cumulative effects and the disproportionate burden that costs may impose on small to medium-sized enterprises.
- Recognition of causes of excessive compliance costs, and offset costs against the expected benefits of regulation to society as a whole.
- Three elements to compliance cost process: consultation, early consideration of costs and ways to reduce them, and quality assurance (peer review) of business compliance cost statements.
- Best practice, comprising: reduction of information burdens, use of electronic technology, use of test panels, helping business to comply, and different compliance cost implications of different regulatory standards.

Australia

Public servants in Australia are required to take account of the following government-approved principles and guidelines.

1. Council of Australian Governments' *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (1995, as amended 1997)

The parties to the Trans-Tasman Mutual Recognition Arrangement are required, under that arrangement, to have regard to these principles and guidelines in addressing exemptions and exclusions relating to regulation. The following is a brief summary of principles and guidelines. The full document can be found at: www.dpmc.gov.au/pdfs/coagpg.pdf[12]

- Consider need for regulation, and include quantitative analysis comprising risk analysis, cost-benefit analysis and cost-effectiveness analysis.
- Principles of good regulation: minimises its impact, minimises impact on competition, predictability of outcomes, meets international standards and practices, does not restrict international trade, includes regular review of regulation, flexible standards and regulations, and standardises exercise of bureaucratic discretion.

11 Last accessed 3 December 2003.

12 Last accessed 3 December 2003.

- Features of good regulation: minimises regulatory burden on the public, minimises administrative burden, includes regulatory impact assessment, accountability, compliance strategies and enforcement, consideration of secondary effects, inclusion of standards in appendices, performance-based regulations, plain language drafting, date of effect, advertising introduction of standards and regulations, and public consultation.
- Certification of completion of regulatory impact assessment, and review.
- Attached requirements of regulatory impact statements, including regard to principles of simplicity, equity, efficiency, avoiding excessive rigidity, and periodic review of relevance and performance.
- Consider if government intervention is required, and quantify the impact of government action through methodical risk analysis and detailed cost-benefit analysis and/or cost-effectiveness analysis.

2. Office of Regulation Review's (Australian Productivity Commission) *A Guide to Regulation* (1998)

The following information is a brief summary of this guide to regulation that has been approved by the Australian government. It sets out the objectives and content of regulation. The full guide can be found at: www.pc.gov.au/orr/reports/guide/reguide2/reguide2.pdf[13]

- Identification of options, comprising self-regulation, quasi-regulation, co-regulation, explicit government regulation, alternative instruments, and alternative compliance mechanisms or enforcement regimes (includes a checklist for assessment of use of self-regulation, quasi-regulation, and explicit government regulation).
- Assessment of impacts of each option, including identification of affected groups, assessment of costs and benefits (including risk analysis and assessment), addressing restrictions on competition, and assessment of impacts on small businesses and on trade and exporters.
- Consultation undertaken, and provision for review of regulation.
- What is the problem being addressed, and why is government action needed to correct it, together with the objectives of government action.
- Circumstances of regulatory intervention.

13 Last accessed 3 December 2003.

United Kingdom

Regulators in the United Kingdom are required to take account of the following government-approved general practices with respect to regulation.

1. *Better Regulation Task Force: Principles of Good Regulation* (1998, as revised 2000)

The following is a summary of the information contained in the United Kingdom Government's *Better Regulation Taskforce: Principles of Good Regulation* report, which concisely sets out the objectives and content of regulation. The full document can be found at: www.brtf.gov.uk/taskforce/reports/PrinciplesLeaflet.pdf[14]

- Five principles of good regulation: proportionality, accountability, consistency, transparency, and targeting.
- Tests of good regulation and pitfalls to be avoided: be balanced and avoid knee-jerk reactions; seek to reconcile contradictory policy objectives; balance risks, costs and benefits; avoid unintended consequences; be easy to understand; have broad public support; be enforceable; identify accountability; and be relevant to current conditions.
- Includes options for achieving policy objectives. Alternatives include do nothing and using the market.
- Foregoing principles and tests have been summarised in the following way: is the regulation necessary, is it fair, is it simple to understand and easy to administer, is it affordable, is it effective, and does it command public support?

2. Cabinet Office *Better Policy Making: A Guide to Regulatory Assessment* (2003)

The following information is a brief summary of the United Kingdom official guide for public servants in preparing regulatory assessments. It sets out the types of regulatory impact assessments and the expected content. It can be found at: www.cabinet-office.gov.uk/regulation/scrutiny/ria-guidance.pdf[15]

- Initial, partial, and full/final regulatory impact assessments (RIA).
- Initial RIA (early policy development stage): early/informal consultation, consider risk, identify options and alternatives, sunsetting and review of legislation, consider issues of equity and fairness, analyse benefits and costs, sustainable development, competition assessment, and small firms' impact test.
- Partial RIA: risks, options, costs and benefits, competition assessment, small firms' impact test, enforcement and compliance, sanctions, monitoring and evaluation, use of RIA and consultation.
- Full/final RIA: including implementation, small firms, guidance, and approval.

14 Last accessed 3 December 2003.

15 Last accessed 3 December 2003.

- Alternatives to legislation: do nothing, self-regulation, code of practice, co-regulation, quasi-regulation, information and education campaigns, market-based instruments, tradable property rights, and standards
- Competition assessment, including competition filter test of 9 questions with respect to each market to be affected by proposed regulation, leading to more detailed assessment as required by the outcome of the test.
- Cost and benefit analysis includes: identification and quantification, identifying business sectors and other groups affected and disproportionate impacts, costs and benefits over time, testing robustness of assumptions, and separating policy and implementation costs.

3. National Audit Office: *Preparing Regulatory Impact Assessments – Checklist*

The following information is a summary of the United Kingdom National Audit Office's checklist for preparing regulatory impact assessments. It can be found at: www.nao.gov.uk/publications/nao_reports/01-02/0102329checklist.pdf[16]

- Initial RIA: start early, identify objectives, plan the process, consult early, assess risks being addressed, identify a wide range of options, consider compliance.
- Partial RIA: think through the consultation process, obtain representative views from small businesses, analyse separately how costs and benefits apply to different sectors and types of businesses, place the RIA on the web, quantify costs and benefits appropriately, keep an open mind on options, and consider compliance in detail.
- Final RIA: firm up on compliance and enforcement, summarise results of consultation, and explain arrangements for any review.

Organisation for Economic Co-operation and Development

The following information is the main Organisation for Economic Co-operation and Development guidance for member states of the organisation on regulatory decision-making. It is included in the National Audit Office *Better Regulation: Making Good Use of Regulatory Impact Assessments,* which can be viewed at: www.nao.gov.uk/publications/nao_reports/01-02/0102329.pdf[17]

Reference Checklist for Regulatory Decision Making (1995)

1. Is the problem correctly defined?
2. Is government action justified?
3. Is regulation the best form of government action?
4. Is there a legal basis for regulation?
5. What is the appropriate level (or levels) of government for this action?

16 Last accessed 3 December 2003.

17 Last accessed 3 December 2003.

6. Do the benefits of regulation justify the costs?

7. Is the distribution of effects across society transparent?

8. Is the regulation clear, consistent, comprehensible and accessible to users?

9. Have all interested parties had the opportunity to present their views?

10. How will compliance be achieved?

Appendix E

European Union legislation relevant to complementary healthcare products

This appendix contains a summary of relevant European Union legislation relating to complementary healthcare products.

Directive 2001/83/EC of 6 November 2001 on the community code relating to medicinal products for human use

1 Regulates marketing authorisations (including detailed product information and a procedure for mutual recognition of authorisations), manufacture (including qualifications of manufacturers, and principles and guidelines of good manufacturing practice) and importation, labelling and packaging, classification of products, wholesale distribution, advertising, pharmacovigilance (adverse reaction reporting), supervision (including inspection and sampling), and sanctions, and other miscellaneous matters, with a technical annex on the testing of medicinal products.

2 Applies to substances represented as being for therapeutic use. It applies to homoeopathic medicinal products prepared from homoeopathic stocks in accordance with the European Pharmacopoeia. These latter products are subject to a special regime in Chapter 2 of the directive, including a simplified registration system if certain conditions are met, which carries with it freedom from the requirement to prove therapeutic efficacy. However, by virtue of Articles 16(3), 53, 68, 85, 100, 119, and 124, the great part of the regulatory regime applies to homoeopathic medicinal products as it applies to other medicinal products.

3 Proposals from the European Commission (dated 17 January 2002, as amended 9 April 2003) are before the European Parliament and the European Council for amendments to the Directive as regards traditional herbal medicinal products. It is proposed to define 'herbal medicinal product' and set up a list of such products, with a view to a single market for herbal medicines. There would be a simplified registration system for traditional herbal products that would include reliance on community herbal 'monographs', but these products would have to meet the same quality requirements as other medicinal products. To avoid unnecessary testing and burdens on firms, it is proposed to avoid new pre-clinical and clinical trials when sufficient knowledge already exists about a particular product. (An earlier resolution of the European Parliament pointed to the growing demand for herbal medicinal products and the importance of this sector of the pharmaceutical industry for employment opportunities, especially in small and medium-sized enterprises.)

4 Other proposals (dated 3 April 2003) are also before the European Parliament and the European Council for miscellaneous other amendments to the Directive, including in relation to homoeopathic medicinal products.

Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC

5 Replaced the annex to the earlier Directive to adapt its detailed scientific and technical requirements to new developments.

6 In recognition that herbal medicinal products differ substantially from conventional medicinal products in so far as they are intrinsically associated with the very particular notion of herbal substances and herbal preparations, separate provision was made with respect to the testing of homoeopathic medicinal products and herbal medicinal products. Extensive technical information is required to be provided in the latter case.

Directive 2003/94/EC of 8 October 2003 laying down principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use

7 Lays down principles and guidelines of good manufacturing practice for medicinal products, as provided in Article 47 of Directive 2001/83/EC, and replaces an earlier Directive of 1991.

8 Applies to homoeopathic medicinal products in the same way as it does to other medicinal products.

9 Accompanied by detailed guidelines published by the European Commission in line with the principles, as also provided in Article 47.

10 Makes reference to manufacturers' conformity with good manufacturing practice standards, compliance with marketing authorisation, quality assurance system, personnel, premises and equipment, documentation system, production operations, quality control system, work contracted out, system for complaints and recalls, self-inspection practices, and labelling practice.

Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the member states relating to food supplements

11 Lays down specific rules with respect to composition (including maximum safe levels), labelling, and advertising of food supplements.

12 Applies to food supplements marketed as foodstuffs and presented as such, and does not apply to medicinal products as defined by Directive 2001/83/EC. 'Food supplements' are defined as foodstuffs the purpose of which is to supplement the normal diet and that are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in certain dose forms. 'Nutrients' are defined as vitamins and minerals. Permitted vitamins and minerals are listed in annexes to the directive.

Proposed regulation of nutrition and health claims made on foods

13 A proposal from the European Commission (dated 16 July 2003) is before the European Parliament and the European Council for regulation of nutrition and health claims made on foods.

14 The proposal would apply to food but also apply to nutrients (including vitamins and minerals) and other substances with a nutritional or physiological effect (including antioxidants and probiotic bacteria).

15 The proposal recommends detailed regulation of the circumstances when 'nutrition claims' and 'health claims' may be made on foods. Nutrition claims are claims that a food has particular nutritional properties due to its calorific value or the presence or absence of nutrients or other substances. Health claims are claims about a relationship between a food category, a food or one of its constituents, and health. Detailed nutrition claims and accompanying conditions are specified in an annex. Health claims would be subject to assessment by the European Food Safety Authority and authorisation by a Standing Committee of the European Commission (certain therapeutic-type claims, even if implied, are prohibited). The commission would also maintain a community register of nutrition and health claims made on food.

Appendix F

Australian legislation: Application to complementary healthcare products

The following information is a summary of Australian legislation that relates specifically to complementary healthcare products. A fuller account can be found at: www.scaleplus.law.gov.au/home.html[18]

Therapeutic Goods Act 1989

Section 3 includes in the definition of 'therapeutic goods', goods—

a) represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use or for use as an ingredient or component in the manufacture of therapeutic goods or

b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or use as an ingredient or component in the manufacture of, or as a container or part of a container for, such goods or

c) declared to be therapeutic goods under an order in force under section 7 (which provision gives the Secretary to the Department of Health and Ageing, either on his or her own motion or upon application, discretion to declare, by order published in the *Commonwealth of Australia Gazette*, that particular goods or classes of goods are or are not therapeutic goods, including in cases when they are used, advertised, or presented for supply in a particular way)—

but excludes from the definition, goods—

a) declared not to be therapeutic goods under an order under section 7 or

b) subject to such an order under section 7, when used, advertised, or presented for supply in the way specified in the order or

c) for which there is a prescribed standard in the Australia New Zealand Food Standards Code or

d) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

The definition of 'medicine' in section 3 relates primarily to therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by

18 Last accessed 3 December 2003.

pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal.

The Secretary to the Department of Health and Ageing is to maintain a register of therapeutic goods in 3 parts setting out registered goods, listed goods, and medical devices (section 9A). Regulations may prescribe the goods or classes of goods to be included in each part, the ways in which goods may be transferred between the registered and listed parts, and the assigning of registration or listing numbers to goods. The relevant Minister may, by notice in the *Gazette*, require that specified therapeutic goods be included in the part for listed goods (subject to such conditions as may be specified).

The secretary may, by order in the *Gazette*, determine that a group of therapeutic goods is a gazetted group because the goods in it have common characteristics (section 16A). (Goods with various different characteristics are to be taken separate and distinct from other therapeutic goods.)

Regulations may, subject to conditions, exempt all therapeutic goods (in relation to prescribed classes of persons) or specified, or a specified class of, therapeutic goods from the operation of the part of the Act concerning registration, listing, and public notification and recovery of therapeutic goods (section 18).

Therapeutic goods are to be listed where applications meet certain requirements, unless the secretary is satisfied that the goods ought not to be listed on one of a number of prescribed grounds, including where goods are not safe for their purposes, do not conform to applicable standards, or have not been manufactured to acceptable procedures (section 26).

A Complementary Medicines Evaluation Committee is established, with functions prescribed in regulations (section 52G). For that purpose, 'complementary medicines' are defined as therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and either a traditional use or any other use prescribed in regulations (section 52F). An 'active ingredient' is defined as the therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action, and a 'designated active ingredient' is defined as an active ingredient, or kind of active ingredient, mentioned in Schedule 14 of the regulations. There is also a definition of 'traditional use' in relation to a designated active ingredient, being its use that is well-documented or otherwise established according to the accumulated experience of many traditional health care practitioners over an extended period of time and that accords with well-established procedures of preparation, application and dosage.

Therapeutic Goods Regulations 1990

Regulations provided for in section 9A of the Act specify that therapeutic goods, and classes of goods, set out in Schedule 3 are registered goods, and those set out in Schedule 4(1) are listed goods (regulation 10).

Regulations provided for in section 18 of the Act specify that exemptions apply to therapeutic goods, or classes of goods, set out in Schedule 5 and, where conditions apply, to those set out in Schedule 5A (regulation 12).

Therapeutic goods specified in Schedule 7 are exempt from the part of the Act concerning manufacturing requirements pursuant to section 34 of the Act, unless the goods are supplied as pharmaceutical benefits (regulation 17). Similarly, persons specified in Schedule 8 are exempt from the manufacturing requirements (regulation 18).

The Complementary Medicines Evaluation Committee is given the functions of evaluating and reporting to the relevant minister or secretary about complementary medicines, ingredients or kinds of ingredients in complementary medicines, or therapeutic goods referred to the committee under the regulation. It may include in its reports whether complementary medicines should be included or remain on the register and whether ingredients should be included in Schedule 14 or mentioned in Schedule 4 (regulation 42ZE).

Long and complex lists of therapeutic goods (and substances) are contained in the schedules. For example, Schedule 4 on listed goods includes preparations containing as their therapeutically active ingredients only specified vitamins, minerals, or herbal substances (with quantity limits), and certain homoeopathic preparations. Schedules 5 and 7 also make specific reference to certain homoeopathic preparations. Schedule 8 includes herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine, and certain homoeopathic practitioners, where preparations are supplied within certain limits.

Among the designated active ingredients specified in Schedule 14 are amino acids, plant or herbal material, homoeopathic preparations, minerals, lipids, bee products, and vitamins.

Details with respect to fees payable are contained in the regulations (regulation 43 and following regulations), and they include a list of fees set out in Schedule 9. (Separate legislation, the Therapeutic Goods (Charges) Act 1989 and the Therapeutic Goods (Charges) Regulations 1990, sets out annual charges in relation to the registration and listing of therapeutic goods.)

Appendix G

List of submitters

Jeanette Mann
David and Jo Ragusa
Caroline Etches
RF James
Laurence and Rhona Burns
Healthy Options
BE Bright
Wendy King
CD King
William Parker
Highset Quality Health and Fitness Products
The Light Clinic of Natural Medicine
Thompson Nutrition
J Davies
Garry and Marie Mulvanah
Elma Davidson
B and J Humphrey
Georgina Marara Maxwell
New Zealand Self-Medication Industry Association
Mayne Consumer Products
Blackmores
Complementary Healthcare Council of Australia
New Zealand Association of Medical Herbalists
Reichian Therapy and Bioenergetics
Fonterra Co-operative Group
Citizens for Health Choices
Nutra Life Health and Fitness
Australian Ayurvedic Practitioners Association (NZ)
Direct Selling Association of New Zealand
Pharmaceutical Society of New Zealand
Neil Fitzgibbons
New Zealand Dietetic Association
Healtheries
Carolyn Mettrick
Hope International NZ
Glenyss McQueen
Vicki Lowther
Diana Hardwick-Smith
Health and Herbs International
ARTEMIS
Association of New Zealand Advertisers
New Zealand Medical Association
Department of Nursing and Health Studies, Waikato Institute of Technology
Robin Fisher
Leslie Charnley
New Zealand Register of Acupuncturists
Barbara Charnley
Francesca Griffin
Organic Living Healthfoods
Nigel van Dorsser
HO Ewart
Corrinne Hale/O'Connor
Mother Earth
Jan Lindenmayer
Weleda Medicine and Bodycare
Golden Neo-Life Diamite
Solgar Vitamin and Herb
G R Gardner
Maria Iseke
Nicola Barltrop
Darryl R Marriner
Janacia Trust Associates
Support Network for the Aldehyde and Solvent Affected
New Zealand Charter of Health Practitioners
Helen Burrell
Mary Moorhouse
Canterbury Manufacturers' Association
Medical Council of New Zealand
Judith Daniels
Barry Blake
Newspaper Publishers' Association
Denise and Geoffrey Taylor
Kerstin Allan
Cynthia Magner

Julie Reid
International Nutritional Products Association (NZ)
Pauline and David Bailey
Baerbel Leeker
Patricia Fielding
The Sharda Trust
Carol Mosedale
The House of Malcolm Harker Herbal Products
Comvita
Regene Kenevan
Josette Bishop
Jennifer Sadler
Connie Winslow
Penelope A Barrott
Advertising Standards Authority
Heather Bell
ED Ashby
RL Schofield
Peter Bankers
New Zealand Sports Drug Agency
John and Annemarie Kuindersma
John and Sarah Mann
TG Janes
Karen Henkel
Angus Napier
Laura Szalay
Chris Fowlie
Faith Read
Yolande Manson
Dianne Ashby
Rosalind Guthrey
Hylda Weston
Gay Tait
Trevor Smith and Sara Dickon
Kim Coughey
Pauline Sheperdson
Strauss Herbs New Zealand
Rachel Penniall
Anne Broadbent
SPARC
Australian Self-Medication Industry
Barrier Gold
New Zealand Natural Health Practitioners Accreditation Board
Colin Middleton
Stephen Yee
Lotus Centre for Healing and Education
Natural Therapies
Debbie Chase
New Zealand Vitalife Organic Health
Herb Foundation of New Zealand
Lavender Hill
Robin Grierson
Dietary Supplements Consultative Group
Marie Lockie
E Parker
Medsafe, Ministry of Health
New Zealand Health Trust

Appendix H

Standing Orders 384 to 387

384 Presentation and referral of treaties

(1) The Government will present the following international treaties to the House—

(a) any treaty that is to be subject to ratification, accession, acceptance or approval by New Zealand:

(b) any treaty that has been subject to ratification, accession, acceptance or approval on an urgent basis in the national interest:

(c) any treaty that has been subject to ratification, accession, acceptance or approval and that is to be subject to withdrawal or denunciation by New Zealand:

(d) any major bilateral treaty of particular significance, not otherwise covered by subparagraph (a), that the Minister of Foreign Affairs and Trade decides to present to the House.

(2) A national interest analysis for the treaty, which addresses all the matters set out in Standing Order 385, will be presented at the same time as the treaty.

(3) Both the treaty and the national interest analysis stand referred to the Foreign Affairs, Defence and Trade Committee.

385 National interest analysis

(1) A national interest analysis must address the following matters—

(a) the reasons for New Zealand becoming party to the treaty:

(b) the advantages and disadvantages to New Zealand of the treaty entering into force for New Zealand:

(c) the obligations which would be imposed on New Zealand by the treaty, and the position in respect of reservations to the treaty:

(d) the economic, social, cultural and environmental effects of the treaty entering into force for New Zealand, and of the treaty not entering into force for New Zealand:

(e) the costs to New Zealand of compliance with the treaty:

(f) the possibility of any subsequent protocols (or other amendments) to the treaty, and of their likely effects:

(g) the measures which could or should be adopted to implement the treaty, and the intentions of the Government in relation to such measures, including legislation:

(h) a statement setting out the consultations which have been undertaken or are proposed with the community and interested parties in respect of the treaty:

(i) whether the treaty provides for withdrawal or denunciation.

(2) In the case of a treaty that has been subject to ratification, accession, acceptance or approval on an urgent basis in the national interest, the national interest analysis must also explain the reasons for the urgent action taken.

(3) In the case of a treaty that has been subject to ratification, accession, acceptance or approval and that is to be subject to withdrawal or denunciation by New Zealand, the national interest analysis must address the matters set out in paragraph (1) to the full extent applicable to that proposed action.

386 Select committee consideration of treaties

(1) The Foreign Affairs, Defence and Trade Committee may itself examine a treaty referred to it or refer the task of examining the treaty to any other select committee.

(2) If the Foreign Affairs, Defence and Trade Committee is not due to meet within seven days of the presentation of a treaty, and the subject area of the treaty is clearly within the terms of reference of another select committee, the chairperson may refer the treaty to that committee for examination and report to the House.

387 Reports by select committees on treaties

(1) A select committee must report to the House on any treaty that has been referred to it.

(2) In examining a treaty and the accompanying national interest analysis, the committee considers whether the treaty ought to be drawn to the attention of the House—

(a) on any of the grounds covered by the national interest analysis, or

(b) for any other reason.

(3) The committee must include the national interest analysis as an appendix to its report.