



International treaty examination of the Agreement between the Government of New Zealand and the Government of Australia for the establishment of a joint scheme for the regulation of therapeutic products

Report of the Health Committee

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International treaty examination of the Agreement between the Government of New Zealand and the Government of Australia for the establishment of a joint scheme for the regulation of therapeutic products

The Health Committee has conducted an international treaty examination of the Agreement between the Government of New Zealand and the Government of Australia for the establishment of a joint scheme for the regulation of therapeutic products and draws the following matters to the attention of the House. This report sets out the detail of our examination of the treaty and the issues addressed in relation to the treaty. The national interest analysis for the treaty is appended to this report.

Introduction

On 10 December 2003, the Governments of New Zealand and Australia signed a treaty to establish a joint agency to regulate therapeutic products. The treaty cannot be brought into force unless implementing legislation is passed in both countries.

History of proposal

In October 2000, the New Zealand Ministers of Health, Trade Negotiations, and Commerce agreed in principle to the establishment with Australia of a joint agency to regulate therapeutic products. 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 regulating agency with Australia.

New Zealand and Australian 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.

The relevant respective agencies, Medsafe in New Zealand, and the Therapeutic Goods Administration in Australia, 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.

In 2002, the Health Committee resolved to conduct an inquiry into the regulation of therapeutic products by the proposed joint agency with Australia with specific reference to dietary supplements and traditional remedies. We reported on our findings in December

2003.¹ We made 34 recommendations to the Government. Our main finding was that a proposal to regulate complementary healthcare products jointly with Australia should not proceed.² This option was not supported by the Government in its response to our report. Many of our concerns remain unresolved. We hope the implementing legislation will address our concerns. Some of us are concerned that the Government signed the agreement with Australia before we had tabled the report on our inquiry into how best to regulate dietary supplements.

Scope of joint agency

The proposed trans-Tasman agency will regulate therapeutic products in New Zealand and Australia. This includes medicines, medical devices, and complementary healthcare products. The proposed joint regulatory scheme will not extend to aspects of medicines law that include prescribing, dispensing, and wholesaling activities. In May 2004, the New Zealand and Australian Governments announced that the joint agency would also regulate blood, blood products, and blood components.

We note that the treaty states the joint agency will be funded by full cost recovery from pharmaceutical companies and agency users. We note the concern of the Pharmaceutical Management Agency (Pharmac) that the full cost recovery model could mean a significant escalation in the cost of registering medicines in New Zealand. Pharmac has reservations about aspects of the proposal, but supports the joint agency. We note that it views Australia as a natural partner. Pharmac also sees benefits in the agency contributing to the availability of drugs to treat rare disorders.

Pharmac noted a number of concerns about the joint agency proposal, including possible increases in the cost of generic drugs, particularly for small market products, and possible increases in patent terms of medicines. In its written submission to us, Pharmac noted that unless rules were very carefully drafted, the cost of these latter increases as a flow-on effect of the free trade agreement between Australia and the United States of America could amount to between \$85 and \$135 million over 3 years.

We note the estimated cost in fees and charges incurred by the New Zealand industry would be \$20 million.³ We also note that the national interest analysis refers to costs borne by the Crown under New Zealand's regulatory regime. Of the total \$4.2 million currently funded from Crown revenue, \$1.1 million would remain as an ongoing cost to the Crown. The remaining \$3.1 million of costs would, under full cost recovery, transfer to industry and be part of the estimated \$20 million total cost to the New Zealand industry.

¹ Health Committee, *Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products*, I.6D.

² The term "complementary healthcare product" is used in this report to describe dietary supplements and traditional remedies.

³ This figure, provided to us by the Ministry of Health, is based on the agency's proposed budget of \$68 million with 30 percent of product licence holders based in New Zealand.

Structure of joint agency

The treaty provides for a unique and innovative arrangement between New Zealand and Australia. The power given to the proposed agency, and in particular its managing director, is unprecedented, both in law-making terms and in terms of powers of monitoring and enforcement.

A ministerial council comprising the Australian federal Minister of Health and the New Zealand Minister of Health will oversee the proposed agency. The ministerial council will have the power to make wide-ranging rules. The advice we received from the Regulations Review Committee notes a number of points of concern with what is proposed for the delegated legislation regime (see Appendix B to this report).

The ministerial council will appoint a five-member board to be responsible for the agency's strategic and financial direction and its administration, but the board will not be involved in regulatory matters. Regulatory power will be delegated to the agency and its managing director, who will be empowered to make orders for regulatory purposes. The agency is intended to be accountable to both Governments, and will be broadly structured on product type. It will be headquartered in Canberra but there will be offices in both New Zealand and Australia.

We note that a two-stage merits review process will apply to the agency's regulatory decisions. This process consists of a right for those affected by agency decisions to ask the agency to review its decisions, and a further right of review by a merits panel external to the agency. We note that the agency will set and monitor standards for the labelling of products.

Some of us are concerned that New Zealand could have less representation than Australia on the board of the agency. We have considered the implication of a number of issues relating to the joint agency option. These include the representation of New Zealand's interests on the board of the agency if New Zealand has less representation than Australia, and whether the power delegated to the managing director is an appropriate delegation. We note that the Government, in its response to recommendation 21 of our inquiry report, assured us that the powers of the managing director would be consistent with the powers of chief executives in similar agencies in New Zealand.

Legal issues

We note a number of legal issues relating to the joint agency. The agency will be established and have legal status under Australian legislation. This raises further questions about how New Zealand's interests will be protected.

The agency is intended to be accountable in both countries and subject to relevant New Zealand, as well as Australian, legislation. However, there is a lack of clarity in the treaty as to how this will be achieved in practice. We question how equal representation and accountability can be assured, 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 interests. We await, with interest, the details in the implementing legislation in this regard.

Delegated legislation

We wish to ensure that any delegated law-making powers under the joint agency comply with New Zealand's principles applying to delegated legislation. We consider that many of the matters proposed to be covered by rules should be dealt with in primary legislation in New Zealand. If these matters are left to rules, control over significant areas of policy-making will be delegated away from Parliament.

We asked the Regulations Review Committee to consider the regulation-making scheme proposed in the treaty, including the powers of the ministerial council, agency, and managing director of the agency, and make a report to us.

The Regulations Review Committee's report (attached as Appendix B) raises two key concerns. The first is that some of the matters proposed to be dealt with in the rules are matters of policy and principle that ought to be in primary legislation. The second is that there are significant differences between the disallowance of regulations in New Zealand and Australia, and the rules and orders made by the agency need to be subject to the same requirements for scrutiny and disallowance as apply to all other delegated legislation in New Zealand.

The Regulations Review Committee notes that rules and orders should not deal with substantive matters of policy or principle, and should be confined to matters of implementation and detail. Significant policy matters concerning the joint scheme should be provided for in primary legislation. Clear limits should be specified concerning the subject matters of the orders. Primary legislation, not the rules, should determine the subject matters to be covered by orders made by the agency.

The Regulations Review Committee also notes that the New Zealand regime for disallowance of regulations is different to the current Australian regime, which is itself in a state of change. It suggests that the scrutiny and disallowance regime that currently applies to regulations in New Zealand should apply to rules and orders after they have been tabled in the New Zealand Parliament. However, we do not agree with the Regulations Review Committee recommendation that there should be provision for amendment of the rules and orders by the House, as we wish to ensure that rules and orders are agreed jointly between the two Governments.

We consider the Regulations Review Committee's report contains a useful summary of the significant constitutional issues surrounding delegated law-making powers under the agreement, and we endorse that committee's recommendations. We consider any implementing legislation should take full account of the committee's points.

Regulatory impact assessment

We note that regulatory impact statements on the proposed joint agency were released in October 2002 and September 2003. We noted our concerns about these assessments in our inquiry report, so far as complementary medicines are concerned.⁴

We note that the Australian Regulatory Impact Statement states that Australian firms may have an early competitive advantage over New Zealand firms seeking approval for new products under the new system.⁵

We also note that the Australian Government established the Expert Committee on Complementary Medicines in the Health System after the suspension of Pan Pharmaceutical's manufacturing licence. That committee presented recommendations on issues relating to the regulation of complementary medicines.⁶ The Australian Government is due to respond to the Expert Committee on Complementary Medicines in the Health System's recommendations in late May 2004. We note that, subject to the Australian Government's response, these recommendations will be taken into account in the development of the regulation of complementary healthcare products. We note the Government's response to recommendation 1 of our inquiry report: that a separate specialised unit within the agency will regulate complementary medicines.

Some of us are concerned about the impact of increased compliance costs on the complementary healthcare industry and consumers, and we noted these concerns in our inquiry report.⁷ Some of us still consider that a third category regulating complementary healthcare products as a class in their own right, distinct from food and pharmaceutical medicines, would ensure they are regulated in a manner appropriate to their relatively low level of risk, and would facilitate regulation by an appropriately trained and qualified regulator.

Some of us are concerned at the adequacy of regulatory impact assessment when the Government response to our inquiry report acknowledges that there is no reliable data on the size and nature of the industry.

National interest analysis

We are concerned that the national interest analysis does not sufficiently address issues such as increased compliance costs, other regulatory costs, and the impact on industry and prices for consumers. It does point to some concerns in this area, but there is no indication that a full assessment of the competition and related effects of the joint agency has been done or is proposed. We consider that in this instance the accompanying national interest analysis does not adequately address the economic and social costs to New Zealanders.

⁴ Health Committee, *Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products*, I.6D. p.42.

⁵ Australian Government, *Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products: Regulatory Impact Statement*, 2004, p.11.

⁶ *Complementary Medicines in the Australian Health System*, <http://www.tga.gov.au/docs/pdf/cmreport.pdf>, last accessed 21 May 2004.

⁷ Health Committee, *Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products*, I.6D. p.28.

The national interest analysis states that under the joint agency proposal there may be an increase in the price of complementary healthcare products for consumers. It also notes higher compliance costs falling on manufacturers and suppliers may especially negatively affect smaller New Zealand-based companies that only supply the domestic market. The national interest analysis also notes that these effects may decrease consumer choice because some brands may be forced off the market.

Impact of joint regulation of therapeutic products

Industry

Some of us are concerned that the joint agency proposal would regulate two different industries, which are different in their risk profiles, ingredients used, and approach, under a single agency. Some of us consider that the pharmaceutical and complementary healthcare industries require different approaches to regulation: the complementary healthcare industry requires flexibility that a pharmaceutical paradigm does not offer. We asked several complementary healthcare products industry groups to make submissions to us on the treaty. While those who submitted accepted the need for regulation, most opposed the joint agency.

We note that, while the proposed joint agency provides for a risk-based regulatory framework, the regime has the potential to impose excessive, expensive regulation on products that are low-risk. We consider that complementary healthcare products should be regulated on risk. We are concerned at the negative impact on low-risk products.

We note that the Therapeutic Goods Administration, in consultation with the Australian Self-Medication Industry and the Complementary Healthcare Council of Australia, has developed guidelines specifically for complementary healthcare products. The purpose of the Australian Regulatory Guidelines for Complementary Medicines is to: provide information to help sponsors of complementary medicines in Australia to meet their obligations under therapeutic goods legislation; ensure that applications to the Therapeutic Goods Administration, relating to complementary medicines, uniformly meet all essential regulatory requirements so that applications may be processed successfully within minimum timeframes; and enhance clarity and transparency of processes leading to the registration and listing of complementary medicines in the Australian Register of Therapeutic Goods.

Increased costs

We are concerned at the impact of increased compliance costs on small businesses that could result from the regulatory framework. A significant feature of the New Zealand complementary healthcare market is that the market is comprised of many small firms. We are concerned that increased compliance costs may force price increases for consumers. We are also concerned that potential cost increases may impact on the availability of products because they will be more expensive to produce than they had been previously.

Innovation

We are concerned that restrictive legislation and increased compliance costs could reduce research and development by complementary healthcare companies. The Australian positive list system could also be a barrier to innovation for New Zealand complementary healthcare companies.⁸ This may potentially curtail the successful development of both indigenous and innovative products for export, which is possible in the current relatively unrestricted environment.

Accessibility of agency

We are concerned that the needs of the New Zealand complementary healthcare industry and consumers may not be met under an Australia-based agency because it is unclear how accessible the agency would be for the New Zealand-based industry and consumers.

Some of us are also concerned about how the joint scheme will apply to the Australian states and whether New Zealand may be disadvantaged.

Conclusion

We note that the agency will regulate therapeutic products in New Zealand and Australia, including medicines, medical devices, and complementary healthcare products. The agency will also regulate blood, blood products, and components. The joint agency will be funded by full cost recovery from pharmaceutical companies and agency users.

A ministerial council comprising the New Zealand Minister of Health and the Australian Federal Minister of Health will oversee the proposed agency. The ministerial council will appoint a five-member board to be responsible for the agency's strategic and financial direction but the board will not be involved in technical matters. The agency will be accountable to both Governments, and will be broadly structured on product type. The treaty establishes the agency and each country will legislate to implement the arrangements. However, the agency will have legal status only under Australian law.

This treaty is a unique arrangement between New Zealand and Australia including in terms of the powers proposed for the agency. We have noted several issues relating to the powers of the proposed agency in this report. The treaty is in broad and general terms, and much is to be left to delegated legislation.

We note that much of the detail of the scheme will need to be contained in implementing legislation. We consider this implementing legislation will provide an opportunity to address the concerns we have raised in this report, although we have been given advice that it will not be possible for implementing legislation to be contrary to what has been agreed to under the treaty.

We consider that the powers of the joint agency to make rules and orders should be limited to matters of technical detail and that matters of policy and principle should be included in the primary legislation. We have appended to this report a report from the Regulations

⁸ 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.

Review Committee that details concerns about the delegated law-making powers proposed under the treaty. Some of us are particularly concerned that under the present proposal control over significant areas of policy making could be delegated away from Parliament.

We consider it essential that the implementing legislation outline the accountability arrangements of the regime, to allay our concerns about both accountability to Parliament and the accountability of the managing director of the agency. We note that the powers of the managing director of the proposed agency should not exceed the powers of other New Zealand public service chief executives, as promised in the Government's response to our inquiry report's recommendations.

We need to be reassured that all the appropriate risk assessments and evaluations have been undertaken prior to implementation of the proposed agency.

Some of us are concerned about the regulation of complementary healthcare products under this regime, because we consider that these products require a more flexible, risk-based regulatory system. We note that it is proposed to regulate these products in a separate specialised unit of the agency. Some of us are also concerned that the increased compliance costs imposed by the agency may negatively affect both industry and consumers.

Recommendation

We recommend to the Government that it not become party to the Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products unless the following recommendations are met in any implementing legislation. That the legislation:

- a) provides for parliamentary accountability of the agency that is the same as the requirements on other New Zealand crown entities
- b) details the accountability arrangements of the managing director
- c) provides that the powers of the managing director of the agency not exceed the powers of other New Zealand public service chief executives
- d) gives equal recourse to New Zealanders and Australians under the complaints system
- e) provides that the Official Information Act 1982, the Privacy Act 1993, the Protected Disclosures Act 2000, the Public Audit Act 2001, and other relevant New Zealand accountability legislation applies to the agency in no less a manner than they do in New Zealand
- f) contains all matters of significant policy and principle concerning the joint agency scheme
- g) provides for only the implementation and details of those policies and principles to be left to the rules and orders and ensures significant policy matters are not to be dealt with in the rules and orders

(continues)

- h) clearly sets out the limits of the powers to be exercised by the agency, and does not authorise rules to determine the extent of the sub-delegation
 - i) provides for effective parliamentary control of delegated legislation that includes scrutiny by select committee as well as disallowance. The rules and orders should be subject to Regulations Review Committee scrutiny
 - j) ensures that parliamentary control of the rules and orders should extend over the life of the instrument and that there should be no time limits on disallowance
 - k) provides for automatic disallowance of rules and orders as well as disallowance by resolution of the House
 - l) provides for disallowance of the rules or orders in part
 - m) provides for a separate category for complementary healthcare products.
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New Zealand National minority view

New Zealand National is of the view that the Government has failed to address a range of details relating to compliance costs that may adversely affect New Zealand businesses.

The very fact that the Australian Regulatory Impact Statement states that Australian firms may have an early competitive advantage over New Zealand firms seeking approval for new products under the new system is indicative that the New Zealand Government has not put New Zealand businesses in a good position from the start.

We consider that the Government should not have gone ahead and signed the treaty when the main finding of the Health Committee inquiry into complementary healthcare products was that a proposal to regulate complementary healthcare products jointly with Australia “should not proceed”.

We remain concerned that even by using the term “complementary healthcare products” there is an intrinsic implication that these products promote health—when in actual fact there needs to be a definition around these products such as “dietary supplements, where there is no claim to a therapeutic effect.”

New Zealand National is supportive of a regulatory regime that is clear, as simple as possible, and does not impose unnecessary costs. We regard it as fundamental that any treaty should not put New Zealand at a disadvantage. We therefore put a Notice of Motion to the select committee that “we recommend to the Government that it not ratify the treaty unless the concerns raised in this report have been satisfactorily addressed”.

New Zealand First minority view

New Zealand First finds it incongruous that given the Health Committee’s complete rejection of the proposed joint trans-Tasman therapeutic goods agency in September 2003, this same committee would even consider supporting the treaty, which would bring such a body into force.

Our primary concerns are threefold. Firstly, this is a sovereignty issue. To have New Zealand's role in decision-making within this new agency reduced to the level of an Australian state (and even lower when the questions over the lack of a rigid instrument to bind Australian states to the treaty are considered) is an insult to our national sovereignty. This new agency will effectively impose Australia's already rigid regulatory regime on New Zealand. New Zealand First believes that New Zealand is capable of designing and administering its own regulatory regime.

Secondly, we are concerned that complementary healthcare products and dietary supplements come under the purview of this treaty. New Zealand First strongly believes that these should be treated separately as a third aspect of the arrangement, not an integral part.

Our third major concern lies with the impact of this treaty on New Zealand industries involved in this sector. These range from large to very small and yet every impact report on the proposed change highlighted the detrimental impact for New Zealand businesses.

New Zealand First questions the underlying motives of the Government in agreeing to a treaty that has no apparent tangible benefits for New Zealand. We strongly recommend that the treaty not be ratified and that the Government instead explore the options for administering a New Zealand-based regulatory framework.

Green Party minority view

The Green Party is totally opposed to the proposed treaty agreement between Australia and New Zealand to establish a joint scheme for the regulation of therapeutic products. We do not believe it is in the national interest of New Zealand to join the agency and hand over control and sovereignty of the New Zealand therapeutics industry to a highly bureaucratic, Australian-dominated organisation, over which our Parliament will have no effective control.

It is worth remembering that the whole point of pursuing trans-Tasman mutual recognition with Australia was to benefit New Zealand businesses and consumers by eliminating regulatory impediments to trade with Australia. But the effect of "harmonising" with Australia through the joint agency will be to burden New Zealand businesses with increased compliance costs and regulatory impediments, which will be passed onto consumers as higher costs. We are also concerned that the agency will stifle innovation, reduce the range of dietary supplements and medicines on the market, and reduce consumer choice.

We are concerned that the agency will, in our opinion, have unprecedented powers: not only to set policy for the entire therapeutic products industries, but also to enforce, monitor, and police these industries as well. We are especially concerned that the treaty gives an unelected official, the managing director, delegated powers to make and enforce regulations which will have direct effect in New Zealand, without requiring the approval of Parliament. The treaty also delegates significant matters of principle and policy that ought to be dealt with in legislation in the New Zealand Parliament, to regulation by an agency that is headquartered in Australia and set up under Australian domestic law, and this will inevitably undermine our sovereignty.

It is our understanding that this agency will be the first in the world where an agency in one country will have total control to regulate and enforce an industry in another country.

We have seen no evidence that the new agency will operate differently from the existing Australian Therapeutic Goods Administration, and believe that all the treaty will do is extend the Therapeutic Goods Administration's authority and control to New Zealand.

We are concerned that the agency will operate on a 100 percent cost recovery basis and will cost industry approximately \$20 million a year. We do not understand why the regulation of dietary supplements and pharmaceutical industries is proposed to be 100 percent industry funded, when a similar trans-Tasman body, Food Standards Australia New Zealand, which sets standards for the food industry, is Government funded. We are concerned that total reliance on industry for funding could undermine the independence of the regulator. We also believe the full cost recovery model, along with increased compliance costs and the requirement to obtain individual product licences, will result in the closure of many small dietary supplements businesses.

Pharmac's submission that the higher fees of the new agency may restrict or delay access to cheap, generic medicines in New Zealand is also a major concern. This is further exacerbated by the proposed free trade deal between Australia and the United States of America, which contains provisions that are designed to add further restrictions on the approval of generic medicines by the joint agency. These restrictions will make it more difficult for generic medicines to make it to the market, pushing up costs for Pharmac and hence the New Zealand taxpayer and reducing access to new medicines.

We oppose the regulation of dietary supplements, under the Therapeutic Goods Administration, as medicines, according to a pharmaceutical model. We want to see a third, separate category set up to regulate complementary healthcare products.

The committee was given advice that any implementing legislation will need to conform to what has already been agreed to in the treaty. Given this, we do not believe it will be possible to resolve our concerns.

ACT New Zealand minority view

ACT New Zealand does not agree that the Government ratify the treaty. We feel the concerns raised by the Health Committee during the *Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products* and the subsequent recommendations have not been adequately addressed by the New Zealand Government when formulating this treaty. We are particularly concerned that, in our opinion, a thriving local industry will be disadvantaged with the imposition of the heavily regulated and bureaucratic Australian regime when other, more appropriate, options were available.

We believe that ratification of this treaty will result in increased compliance costs to those in the industry and will particularly affect small businesses. We also fear that innovation and the development of new products will suffer due to the costly and lengthy process that will be imposed on local industry. As the smaller partner, we fear New Zealand interests will be significantly under-represented and increased costs of products and loss of choice of products for New Zealanders will be the consequence.

United Future minority view

United Future views this treaty as a misguided attempt to harmonise one small and poorly regulated industry with another large and overly regulated one. We believe that it would be preferable that harmonisation be the goal not the mechanism for improving regulatory outcomes in both countries, and that mutual recognition provisions would suffice until such time as harmonisation became an obvious and natural progression.

United Future remains unclear about what the main driver is for this treaty. Is it public health and safety or is it trade?

Because harmonisation is being used as an instrument for change, United Future is concerned that the real outcome will be the demise of many current participants in the New Zealand complementary industry.

We have two overriding concerns. Firstly, that the treaty is a dangerous experiment using untried provisions that undermine our national sovereignty. Secondly, we believe that the most alarming provision of the treaty is the linking together under one regulatory umbrella of high-risk pharmaceuticals and extremely low-risk complementary healthcare products. The essential “white list” regulatory tool used for pharmaceuticals is completely unnecessary for low-risk products that would be easily catered for by a “black list” approach.

United Future strongly contends that unless a separate regulatory category is established for complementary healthcare products, all the worst fears of the New Zealand industry will be realised.

Appendix A

Committee procedure

The treaty was referred to us by the chairperson of the Foreign Affairs, Defence and Trade Committee on 31 March 2004. We received 16 submissions and heard evidence from 7 individuals and interested groups (the submitters are listed in Appendix C). Hearing of evidence took 2 hours and 56 minutes and consideration took 4 hours and 16 minutes. We heard evidence on 7 and 28 April, and 26 May 2004.

Committee members

Steve Chadwick (Chairperson)
Darren Hughes
Dr Paul Hutchison
Sue Kedgley
Nanaia Mahuta
Mark Peck
Heather Roy
Dr Lynda Scott
Barbara Stewart
Judy Turner
Dianne Yates

On 26 May 2004, Darren Hughes replaced Dave Hereora as a permanent member of the committee.

Adviser

Allan Bracegirdle, Legislative Counsel

Appendix B

Report from the Regulations Review Committee

Summary of recommendations and concerns

Matters of policy and principle should be in primary legislation

We have two key concerns. First, because some of the matters proposed to be dealt with in the rules (Article 9) are matters of policy and principle they ought to be in primary legislation. We have recommended you consider the following:

1. Matters of significant policy and principle concerning the joint agency scheme should be dealt with in primary legislation. The implementation and details of those policies and principles should be left to the rules and orders.
2. Significant policy matters should not be dealt with in the rules and orders.
3. The limits of the powers to be exercised by the Agency should be clearly set down. The rules should not determine the extent of the sub delegation.

Significant differences between Australian and New Zealand Parliamentary scrutiny

Second, there are significant differences between the disallowance of regulations in New Zealand and in Australia. If the Australian model is generally followed (as appears to be proposed) there will arguably be a significantly lesser degree of parliamentary control than currently applies to all other New Zealand delegated legislation.

We have recommended you consider the following:

4. Effective parliamentary control of delegated legislation includes scrutiny by a select committee as well as disallowance. The rules and orders should be subject to Regulations Review Committee scrutiny.
5. Parliamentary control of the rules and orders should extend over the life of the instrument. There should be no time limits on disallowance.
6. There should be provision for automatic disallowance of rules and orders as well as disallowance by resolution of the House.
7. There should be provision for disallowance of the rules of orders in part.
8. There should be provision for amendment of the rules and orders by the House.

Background

The New Zealand and Australian governments signed an agreement to establish a joint regulatory scheme for therapeutic products on 10 December 2003. The joint scheme will regulate medicines (including complementary medicines) and medical devices. The scheme is expected to come into force in July 2005, subject to the passage of legislation in both countries and ratification of the treaty.

Therapeutic products are currently regulated in New Zealand under the Medicines Act 1981 and the Medicines Regulations 1984. Complementary medicines are currently marketed as dietary supplements and are regulated under the Dietary Supplements Regulations 1985. No therapeutic claims for dietary supplements are permitted. In Australia therapeutic products are regulated under the Therapeutic Goods Act 1989 and associated regulations. It is proposed that existing legislation will be repealed and replaced by the new legislation that will cover the regulation of therapeutic products in both countries.

New Zealand and Australia will need to enact legislation to implement the agreement. The Australian Act will give legal personality to the Agency as well as implementing other obligations in the agreement.

Rules

It is proposed that a single common set of rules made by the Ministerial Council will contain much of the detail of the joint scheme and how it will operate. The Ministerial Council is comprised of the Australian Minister and New Zealand Minister of Health. The detailed list of the matters about which rules may be made is set out in Article 9. These rules are described as being equivalent to regulations.¹ The rules made by the Ministerial Council must be tabled in both the New Zealand and Australian Parliaments. The rules are to be subject to disallowance in whole (not in part) by each Parliament, within a reasonable time from tabling. If the rules are disallowed by either Parliament they will cease to have effect for both countries.

Orders

The rules will specify the matters about which the Managing Director of the Agency will be able to make orders relating to more details of the regulatory scheme. The orders must be tabled in Parliament and are subject to disallowance in whole (not in part) by the Parliament within a reasonable time from tabling. If the orders are disallowed by the Parliament of one country, they will cease to have effect for both countries.

Classification of rules and orders

The scheme will be implemented in both countries under a mixture of primary and delegated legislation. The rules and orders will be made under a delegation of law-making powers by Parliament. Although these instruments are described in the background material as being equivalent to regulations, we consider that it is unlikely that the instruments would fall within the current definition of “regulations” in New Zealand under

¹ Fact Sheet 4, page 2.

the Regulations (Disallowance) Act 1989 or the Interpretation Act 1999. This is because the definition of “regulations” in those Acts focuses on a list of instruments, for example, regulations, rules or bylaws made under enactment by a Minister or Orders in Council bringing legislation into force. The rules and orders, although law-making in character, would not appear to fall within the lists in the definitions. In many instances in New Zealand legislation specifically provides that instruments of a law-making character are deemed or treated as regulations for the purposes of the Regulations (Disallowance) Act 1989. Unless this specific provision is made, the tabling would not cover some instruments of law-making character, publication, or scrutiny requirements that apply to regulations.

The rules and orders proposed under this agreement are unusual being made by a joint Ministerial Council comprising ministers from two countries or by a joint agency established under Australian law. The joint scheme operating through the rules and orders will replace a legislative scheme that is currently operating under primary legislation and regulations. The scheme is novel and does not fit within the general legislative arrangements for delegated legislation in New Zealand, including the Regulations (Disallowance) Act 1989 and the Acts and Regulations Publication Act 1989. We consider that the legislation implementing the treaty will need to provide explicitly for the arrangements concerning promulgation, publication, and scrutiny of the rules and orders in New Zealand.

In Australia there has been a recent change to legislation governing the making, registration and parliamentary scrutiny of legislative instruments. Because of this new legislation the position in Australia may differ from New Zealand. That recent legislation will focus on the “legislative character” of an instrument, rather than the name that is given to an instrument.² The rules and orders may fall within the standard legislative regime that will apply to promulgation, publication, and parliamentary scrutiny of legislative instruments in Australia.

Delegated law-making powers

The general principles about the division between primary and delegated legislation are well established. Primary legislation should deal with matters of policy and principle. Matters of detail or technical character may be left to delegated legislation. Significant policy matters should not be dealt with in delegated legislation. In general, Parliament should not delegate powers to establish an agency or define its functions, create substantive personal rights, create a power of seizure or search, or create criminal offences resulting in imprisonment or significant fines.³

We consider that these principles are common across all Commonwealth jurisdictions and would apply in Australia as well as New Zealand.

² Legislative Instruments Act 2003, to be fully into force 1 January 2005.

³ Legislation Advisory Committee: Guidelines on the process and content of legislation, 2003 supplement, page 81.

Article 9

The detailed purposes for which the Ministerial Council may make rules are set out in Article 9. Some of the matters that are proposed to be dealt with in rules would normally be found in primary rather than delegated legislation. For example, the substantive principles and policies that relate to the following matters would not normally appear in delegated instruments:

- the governance and accountability of the Agency
- employment arrangements for the Agency
- delegations
- review of Agency decisions
- appointment and removal of Board members
- the matters to be dealt with in orders rather than rules
- rules of interpretation
- publication requirements
- transitional arrangements
- the establishment of expert advisory committees
- appointment and removal of members of a Merits Review Panel
- matters relating to the functions of the Agency.

As a further example, we consider that the following key provisions usually would be set out in the primary legislation:

- Article 9.1(a): The role, governance, and accountability of the Agency.
- Article 9.1(b): Financial matters concerning the Agency including identification of funds, establishment of bank accounts, investment of money and limits on borrowing,
- Article 9.1(c): Employment issues such as arrangements for transfer of existing employees, continuity of employment personnel policies and equal employment opportunity programs.

These examples are not exhaustive. Most of the purposes set out in Article 9 could be examined to separate out the substantive matters of principle and policy. The details and implementation of the policies and principles relating to these matters could be left to rules and orders.

In addition, the entire regime for regulating therapeutic products is also to be left to be determined in rules and orders. Our view is that the principles, policies, or parameters of the regime would normally be determined in primary legislation, not rules or orders.

We are concerned that the agreement does not appear to recognise the fundamental principles referred to above. These principles apply currently in both New Zealand and

Australia. In particular, we are concerned that the agreement proposes that matters of significant policy and principle are to be left to the rules and orders.

Article 10

Under Article 10 the Agency may make orders about matters which are to be identified in the rules. This power amounts to a sub-delegation of undefined subject matters from Article 9. We consider that this type of sub-delegation is undesirable because there is insufficient control or limits placed on the exercise of the powers. The power to make orders under Article 10 would potentially allow delegation to the Agency of all the substantive powers exercised by the Ministerial Council. In our view, sub-delegation is also undesirable because many of the powers to be exercised by the Ministerial Council ought normally to be in primary legislation. The end result is that the Agency could potentially exercise substantive powers which would normally be expected to be prescribed in an Act of Parliament.

Summary

We consider that the rules and orders should not deal with substantive matters of policy or principle and should be confined to implementation and detail. Significant policy matters concerning the joint scheme should be provided for in primary legislation. Clear limits should be specified concerning the subject matter of the orders. Primary legislation, not the rules should determine the subject matter to be covered by the orders made by the Agency.

Recommendations

We recommend that you consider the following, that:

1. Matters of significant policy and principle concerning the joint agency scheme should be dealt with in primary legislation. The implementation and details of those policies and principles should be left to the rules and orders.
2. Significant policy matters should not be dealt with in the rules and orders.
3. The limits of the powers to be exercised by the Agency should be clearly set down. The rules should not determine the extent of the sub delegation.

Parliamentary scrutiny

The accountability arrangements for the joint agency and new regulatory scheme includes ensuring that:

- New Zealand and Australian Ministers have equal oversight of the Agency and operation of the regulatory framework
- the joint agency is just as accountable to ministers, Parliaments, and other stakeholders as comparable public sector organisations in both countries.

Parliamentary scrutiny and control of delegated legislation in New Zealand includes scrutiny by the Regulations Review Committee and disallowance under the Regulations (Disallowance) Act 1989. These are quite separate functions. The Regulations Review Committee's scrutiny of delegated legislation involves consideration of all regulations under

grounds set out in Standing Order 378. The committee may draw the attention of the House to a regulation and make particular recommendations.

We are adamant that it is an essential aspect of parliamentary scrutiny that the rules and orders should be subject to Regulations Review Committee examination either by operation of any future legislative provisions or by changes to Standing Orders.

Disallowance

Articles 9 and 10 require that the rules and orders must be tabled in Parliament and are subject to disallowance in whole (not in part) by the Parliament within a reasonable time from tabling. If the rules and orders are disallowed by the Parliament of one country, they cease to have effect in both countries.

The details of the arrangements are further explained in Fact sheet 5, page 2 as:

- rules and orders will be tabled in New Zealand Parliament within 16 sitting days
- rules or orders could be disallowed by resolution of the House within a reasonable time (three months proposed) from tabling. A rule order could be disallowed in whole but not part and could not be amended.
- Outside the timeframe, a rule order could be referred to a select committee for review. The select committee could raise concerns about the rule or order with the Minister, who could then raise the issue for review by the Ministerial Council.

Differences to the current regime

The proposed regime for parliamentary scrutiny has considerable differences to the current regime for parliamentary scrutiny of regulations. These include:

- disallowance is time-limited
- disallowance could be limited to a resolution of the House if automatic disallowance is not included
- disallowance applies to the whole instrument and not part of the instrument.

The disallowance regime reflected in the agreement is closer to the current position in Australia than New Zealand. In New Zealand the disallowance of regulations is not time restricted. Parliamentary scrutiny and control of regulations exists for the life of the instrument. This complements the New Zealand Regulations Review Committee jurisdiction to examine regulations and receive complaints about regulations at any time.

Under current Australian legislation a notice of motion to disallow a legislative instrument must be given within 15 sitting days of laying the instrument before either House of Parliament. A practice has developed where if the Senate Standing Committee on Regulations and Ordinances has concerns about regulations which are not resolved within 15 sitting days, the committee gives a “protective” notice of motion to disallow an

instrument. If the committee's concerns are satisfactorily resolved these protective notices of motion are withdrawn.⁴

We are concerned that having a time restriction on disallowance in New Zealand would mean that Parliament would have only a limited time period to express its disapproval of a particular instrument. If concerns were raised about an instrument outside that period the instrument could not be disallowed by Parliament. Revocation could only occur by the actions of the Ministerial Council. Although it would be beneficial to have a select committee scrutiny after an initial period as suggested in fact sheet 5, committee scrutiny, and disallowance are quite distinct functions. Continuing parliamentary control over the life of an instrument can only occur if there are no time limits on disallowance.

Automatic disallowance

In New Zealand the Regulations (Disallowance) Act 1989 provides for disallowance by resolution of the House and automatic disallowance where a motion is moved by a member of the Regulations Review Committee. Australian legislation also provides for disallowance of legislative instruments by resolution of the House and automatic disallowance.⁵ In our view, the prospect of automatic disallowance is a significant control on delegated legislation. If a member of the Regulations Review Committee moves a motion of disallowance, the regulation is automatically disallowed unless within 21 sitting days the motion is withdrawn or voted down in the House. Disallowance by resolution of the House requires a positive action of the House and for time to be made available for debate and voting on a motion. By contrast, no action by the House is required for automatic disallowance to occur. Automatic disallowance will occur after 21 sitting days unless a motion is negated by the House. We consider that more effective parliamentary control would be achieved if provision were made for both automatic disallowance of rules or orders as well as disallowance by resolution of the House.

Disallowance in part and amendment

The Regulations (Disallowance) Act 1989 also allows disallowance of regulations in part. We see considerable advantage in allowing disallowance of an instrument in part. This means that a particular clause or provision of a regulation that is of concern could be disallowed. Otherwise the whole instrument would have to be disallowed, even if there was no concern about the majority of clauses or parts of the instrument. By only providing for disallowance of the whole instrument, there would be a considerable disincentive to ever exercise the disallowance provision. Our view is that effective control of the delegated instrument would be better achieved by providing for disallowance in part.

⁴ Senate Standing Committee on Regulations and Ordinances, Annual Report, 2000-01 records that the committee gave notices of motion to allow 47 of 208 instruments of concern, all of which were subsequently withdrawn following satisfactory responses or ministerial undertakings.

⁵ Acts Interpretation Act 1901, s 48 which is to be replaced by the Legislative Instruments Act 2003, s 42, commencing on 1 January 2005.

Currently regulations can be amended by resolution of the House.⁶ Allowing amendment of the rules and orders by the House would give Parliament a more effective control over the instruments implementing the joint agency's scheme.

Summary

In our view the disallowance regime that currently applies to regulations in New Zealand should apply to rules and orders after they have been tabled in the New Zealand Parliament. The New Zealand regime is different to the current Australian regime, which itself is in a state of change. The disallowance regime we suggest should apply would:

- not be time-limited
- allow disallowance by resolution of the House and automatic disallowance
- allow disallowance by whole or in part
- allow amendment of the instrument.

Recommendations

We recommend that you consider the following, that:

4. Effective parliamentary control of delegated legislation includes scrutiny by a select committee as well as disallowance. The rules and orders should be subject to Regulations Review Committee scrutiny.
5. Parliamentary control of the rules and orders should extend over the life of the instrument. There should be no time limits on disallowance.
6. There should be provision for automatic disallowance of rules and orders as well as disallowance by resolution of the House.
7. There should be provision for disallowance of the rules of orders in part.
8. There should be provision for amendment of the rules and orders by the House.

⁶ Regulations (Disallowance) Act 1989, section 9.

Appendix C

List of submitters

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Colin Middleton
Dietary Supplements Consultative Group
Graham Bennett
Health Shop Kerikeri
Janine Kelly
National Nutritional Foods Association
New Zealand Health Trust
New Zealand Charter of Health Practitioners
Ministry of Economic Development
Ministry of Health
Noeline Gannaway
Pharmaceutical Management Agency
Ron Law
Therapeutic Goods Administration

Appendix D

Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products

National interest analysis

Date of Proposed Binding Treaty Action

1 The Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (referred to as “the Agreement”) was signed 10 December 2003. The Agreement will enter into force when both parties have exchanged diplomatic notes confirming that all matters necessary to give effect to the Agreement have been completed. Both New Zealand and Australia will need to pass legislation to implement the obligations in the Agreement before the Agreement can enter into force, and it is expected that this legislation will be passed in both countries by mid/late 2004. At the present time, the projected date that the Agreement will enter into force is late 2004.

Reasons for New Zealand to become party to the treaty

Background

2 The New Zealand regulatory regime for therapeutic products faces increasing difficulties in maintaining the highest standards of public health and safety and dealing with the increasingly complex therapeutic products on the market. Therapeutic products include pharmaceuticals, medical devices and products that are commonly called ‘complementary medicines’. The term “complementary medicine is a collective term that includes products referred to as complementary or alternative medicines (e.g. herbal medicines, homoeopathic medicines), traditional medicines (e.g. Chinese medicines and Ayurvedic medicines) and therapeutic-type dietary supplements (e.g. vitamins, minerals and amino acids).

3 A Regulatory Impact Assessment undertaken by the New Zealand Institute of Economic Research (NZIER) in October 2000 confirmed that New Zealand’s current system for regulating therapeutic products is not sustainable, primarily due to:

- The outdated nature of the applicable legislation¹ which gives rise to significant safety risks, trade barriers and costs to the Crown and industry;
- A lack of sufficient capacity in terms of technical expertise to continue to evaluate the risks and benefits of increasingly complex high-risk products in a timely manner. Such expertise is in demand internationally and is scarce in some disciplines.

¹ The Medicines Act 1981, the Medicines Regulations 1984 and the Dietary Supplements Regulations 1985.

4 Differences in therapeutic product regulation between Australia and New Zealand also stand in the way of stated policy objectives to remove trans-Tasman trade barriers and to integrate the New Zealand and Australian economies under the Trans Tasman Mutual Recognition Arrangement (TTMRA). In relation to the regulation of therapeutic products, the TTMRA provides that a special exemption applies. The special exemption, which means that the principle of mutual recognition does not currently apply to therapeutic products, is only effective for 12 months at a time, and must be renewed each year by the participating parties to the TTMRA.

Pharmaceuticals

5 Pharmaceuticals (ie. prescription and over-the-counter medicines) have significant health benefits, but can present serious risks, especially if used inappropriately. Currently, distributors are required to gain the consent of the Minister of Health in order to offer a product for sale in New Zealand. Applications are assessed by Medsafe (a business unit of the Ministry of Health) to ensure that the benefits outweigh the risks if the products are used appropriately, and to identify any appropriate special requirements or restrictions on supply. New Zealand's current regulatory approach is consistent with international practice, but is unsustainable for the reasons discussed above.

Complementary medicines

6 While New Zealand and Australia have similar regulatory schemes for pharmaceuticals, there are marked differences in the approach taken by each country to the regulation of complementary medicines (CMs). In contrast to Australia, there are currently no pre-market approval requirements for CMs in New Zealand and most of these products are sold as dietary supplements under food legislation (the Dietary Supplements Regulations 1985). Under these regulations, therapeutic claims are not permitted. To lawfully make therapeutic claims, distributors must seek an approval under the Medicines Act 1981. The application requirements and fee for this approval are onerous and not appropriate for low risk CMs. While CMs generally contain ingredients with a low inherent safety risk, recent experience in Australia has shown that there can be significant safety risks for consumers when appropriate manufacturing standards are not met. Risks can also arise from unsubstantiated or misleading claims.

7 In practice, enforcing the prohibition on therapeutic claims for dietary supplements is hampered by a lack of resources and a lack of clarity about whether the enforcement action should be pursued under Food or Medicines legislation.

8 While there is no formal international agreement on what constitutes best practice in the regulation of dietary supplements, there are clear international trends emerging for the application of pre-market controls, licensing of manufacturers, setting requirements for an evidence-base to support therapeutic claims, setting standards for labelling and product information and carrying out post-market activities, including testing and adverse reactions monitoring.

Medical devices

9 Medical devices are products used for diagnosis, prevention, monitoring or treatment of disease, injury or handicap; or for investigation, replacement or modification of the anatomy or a physiological process; or for the control of conception. In contrast to

medicines, they deliver their intended effect through non-pharmacological means (e.g. mechanical, electrical, radiation). Medical devices range from very low risk products such as bandages to high-risk products such as implantable heart valves. In contrast to most developed countries, New Zealand does not currently require medical devices to be approved before being marketed.² Medsafe's role is limited to market surveillance and dealing with safety issues as they emerge rather than preventing sub-standard devices from being used.

The regulatory options

10 A Cost-Benefit Analysis (CBA) undertaken by NZIER in October 2002 in relation to the options available for updating New Zealand's therapeutic products regulatory regime considered a number of options including:

- **The status quo** – this is seen as unsustainable because of a lack of technical expertise available, domestically and internationally, to review medicines in a timely fashion. In addition, the lack of regulation of medical devices and lack of effective regulation of CMs is not resolved under this option. The current regulation of CMs as foods is also inconsistent with trans-Tasman harmonisation of food regulation and this needs resolution;
- **Enhanced Medsafe** - similarly, an enhanced Medsafe is not a viable option because of the lack of expertise available domestically and internationally. In addition, significant extra funding would be required to provide for a sustainable regime under this option;
- **Unilateral recognition** – under this option, local evaluation of therapeutic products would not occur, rather evaluations carried out by competent overseas authorities would be recognised by Medsafe. This option would not provide for New Zealand interests to be taken into account in the making of decisions on the approval of therapeutic products or in the setting of appropriate standards. In addition, trans-Tasman harmonisation would not be achieved by this option;
- **The Joint Agency approach** – this is seen as the only option that provides for sustainable therapeutic products regulatory capacity for New Zealand. Costs to New Zealanders are expected to be lower than under the other two non-status quo options due to economies of scale. The Joint Agency approach would also strengthen CER³ and entrench harmonisation that has been achieved to date.

The preferred solution

11 Overall, the NZIER CBA report concluded that, relative to the other regimes considered in the paper, the creation of a joint agency has the potential to yield a net benefit to government, industry, consumers and other stakeholders in both countries.

² A small subset of devices (condoms, pregnancy test kits and devices containing medicinal substances) does need approval from Medsafe before they are sold in New Zealand, to ensure they meet appropriate standards.

³ The Australia New Zealand Closer Economic Relations Trade Agreement – commonly referred to as 'CER'

Advantages and Disadvantages to New Zealand of the Treaty

12 Advantages that will accrue to New Zealand as a result of the Agreement entering into force include:

- A move away from out-dated legislation to a new scheme which provides for the ongoing, sustainable, cost-effective and timely management of the risks to public health and safety from avoidable harm associated with the use of all therapeutic products;
- Enhanced capacity in terms of technical expertise to evaluate the risks and benefits of increasingly complex therapeutic products;
- Regulation of therapeutic products that is consistent with international best practice, adopting a globally harmonised approach where possible;
- Ensuring that health and safety objectives are met without imposing unnecessary trade barriers;
- The progression of CER along with the facilitation of trans-Tasman trade in therapeutic products;
- The facilitation of exports of therapeutic products beyond Australia;
- The development of the therapeutic products industry in New Zealand, including research and development;
- An enhancement of public confidence in CMs by subjecting them to a regulatory scheme that monitors compliance with standards, thereby assisting the CMs industry;
- The Joint Agency would also potentially have greater regional and global influence over the development of international regulatory standards and harmonisation initiatives, than would New Zealand on its own;
- The Joint Agency would have more to offer other key regulators in terms of information sharing and as a potential partner in Mutual Recognition Agreements, which have the potential to further reduce regulatory capacity concerns and administrative costs, than would New Zealand on its own.

13 Disadvantages of the Agreement entering into force include:

- A reduced ability to regulate according to the specific conditions and preferences of New Zealand. However, it is expected that commonalities of interests and preferences are more likely than differences. In addition, the Agreement provides for the Agency to take into account the different circumstances in each country and on that basis provide for a therapeutic product to be supplied in a different manner or subject to different requirements in each country (Article 11(4)). As a further safeguard to address particular national circumstances, New Zealand or Australia may 'depart' (ie opt-out) from the joint regulation provided under the Joint Scheme in specified exceptional circumstances (Article 12);

- Reinforcement of the existing trend for pharmaceutical firms to shift their regulatory activities to Australia as they rationalise their activities, with the flow-on effect of tax revenue being foregone. It should be noted, however, that changes to the regulatory scheme will be only one influence on the trend towards rationalising pharmaceutical companies' operations in Australia where currently they have both Australian and New Zealand operations. It is also expected that companies will retain some technical and marketing staff in New Zealand to interact with prescribers and Pharmac;
- The regulation of CMs may lead to higher prices for consumers and higher compliance costs falling on manufacturers and suppliers, especially among smaller New Zealand-based companies that only supply the domestic market. Those that also supply the Australian market should derive a benefit as they are already subject to a regulatory regime there. However, effective regulation means that consumers can be more assured of the safety and the therapeutic benefits of the product, and therefore they may be more willing to accept such price increases. These effects may also impinge upon the range of CMs which will be available to the New Zealand market in the future. However, it should be noted that this effect would be lower than if New Zealand established its own separate regulatory scheme for these products;
- Similarly, there may be an increase in prices and reduction in choice for medical devices due to those devices becoming subject to regulatory controls. This higher cost may have some fiscal impact on ACC and health budgets. However, if New Zealand implemented its own regulatory scheme for medical devices based on the recommendations of the Global Harmonisation Taskforce on Medical Devices (representing international best practice for the regulation of medical devices), the costs would be considerably higher.

14 On balance, it is in New Zealand's interests for the Agreement to enter into force.

15 It is also important to note that if the Agreement does not enter into force, New Zealand will still need to overhaul its regulatory regime with respect to therapeutic products, particularly CMs and medical devices, for the reasons already outlined. Further, New Zealand would need to continue to seek the agreement of the Australian States and Territories and the Australian Commonwealth to an extension to the special exemption under the TTMRA with respect to therapeutic products every 12 months. While mutual recognition might work in the event that standalone New Zealand and Australian regimes were broadly similar, the cost of proceeding with such standalone arrangements would be considerably higher than those involved in a joint scheme. In the event that a New Zealand standalone regime was not seen by Australia as achieving equivalent protection for consumers, mutual recognition would be excluded as an option, and a permanent exemption is likely to be sought by Australia under TTMRA. This would inhibit trans-Tasman trade and undermine broader CER objectives.

Obligations

The Joint Scheme

16 The Agreement requires New Zealand and Australia to adopt a Joint Scheme for the regulation of the quality, safety and efficacy or performance of therapeutic products⁴ (Article 3). In this regard, the Joint Scheme will cover, inter alia, the:

- Regulation of the manufacture, supply, import, export and promotion of therapeutic products;
- Setting of standards in relation to the quality, safety, and efficacy or performance of therapeutic products and their manufacture, supply, import, export and promotion;
- Post-market monitoring of therapeutic products; and
- Enforcement of the requirements of the Joint Scheme.

17 The details of the regulatory scheme (ie: how medicines, medical devices and CMOs will be regulated under the Joint Scheme) are summarised in the Implementation section of this National Interest Analysis (see paragraphs 63 to 72 below).

Key Organs of the Joint Scheme: Agency, Ministerial Council, Board, Managing Director

18 The Agreement creates a new Joint Agency, which will administer the Joint Scheme (Article 5). The Agency will be responsible for considering and determining any applications for an Approval (see paragraph 66 below) to manufacture, supply, import, export or promote a therapeutic product in accordance with the Rules made by the Joint Ministerial Council. The Agency will also make Therapeutic Product Orders that address aspects of therapeutic products regulation additional to those set out in Rules or Approvals. Other functions of the Agency include:

- Setting standards for therapeutic products;
- Enforcing compliance with the Joint Scheme;
- Monitoring the quality, safety and efficacy or performance of therapeutic products;
- Providing information to the public about therapeutic products;
- Undertaking or commissioning research and monitoring international developments in the regulation of therapeutic products (Article 5(2)).

19 In addition, the Agreement provides that the Agency may engage in activities that fall outside the scope of the Joint Scheme at the request of either Australia or New Zealand (Article 5(3)) and in accordance with terms and conditions approved by the Ministerial Council.

20 The Australian Implementing Legislation for the Joint Scheme will establish the Agency as a body corporate, provide that the Agency has the functions outlined above and that it may engage in other activities that fall outside the scope of the Joint Scheme

⁴ 'Therapeutic product' as defined in the Agreement will cover medicines, medical devices and complementary medicines.

(referred to above) (Article 5(4)). The New Zealand implementing legislation and Australian implementing legislation will confer such rights, powers and privileges on the Agency as are required for the Agency to perform its functions (Article 5(5)).

21 A Ministerial Council of the New Zealand Health Minister and the Australian Health Minister is established by the Agreement (Article 4). The Ministerial Council will:

- Oversee the Agency and Joint Scheme;
- Ensure accountability of the Agency and the Joint Scheme to the governments of New Zealand and Australia;
- Make Rules (akin to regulations – see paragraph 26 below);
- Appoint and remove the members of the Agency’s Board;
- Establish expert advisory committees to advise the Managing Director of the Agency;
- Appoint and remove members of the Merits Review Panel (see paragraph 36 below).

22 All decisions of the Ministerial Council will be made by the agreement of the New Zealand and Australian Health Ministers. This arrangement ensures an equal voice in the operation of the joint agency and regulatory scheme, in contrast to the Australia New Zealand Food Standards Agreement (concluded in 1995) where New Zealand sits alongside the Australian Commonwealth and all Australian states and territories.

23 The Agency will be headed by a Managing Director, who will be responsible to the Board of the Agency for the management of the Agency (Article 7). The Managing Director will perform the regulatory functions on behalf of the Agency.

24 The Board of the Agency will be appointed by the Ministerial Council (Article 6), and will be responsible to the Ministerial Council for the governance of the Agency, but will not be responsible for the Agency’s regulatory functions. There will be five members on the Board. These will include the Chair and the Managing Director of the Agency, who must be appointed on the basis of consensus between the two members of the Ministerial Council, given their key roles in the governance of the Joint Agency. The other members of the Board will be a person with broad experience in relation to public health and regulatory matters in New Zealand, a person with broad experience in relation to public health and regulatory matters in Australia and a person with broad experience in commercial matters. The Ministerial Council shall seek to reach consensus on the appointment of the other members of the Board and appointments to the Board shall be made in accordance with the Rules.

‘Instruments’: Rules, Orders and Approvals

25 There are three main types of legal instruments provided for in the Agreement – Rules, Orders and Approvals. Rules are made by the Ministerial Council, and Article 9 sets out an extensive list of matters about which Rules may be made. Examples of such matters include:

- Financial issues concerning the Agency;
- The fees and charges that may be applied by the Agency;

- Internal reviews of certain decisions of the Agency;
- Board procedures;
- The requirements that must be met in relation to the manufacture, supply, import, export or promotion of therapeutic products;
- Record-keeping and notification requirements.

26 Both Australia and New Zealand are required to provide for the Rules to be tabled in Parliament and subject to disallowance in whole by the Parliament within a reasonable time from the Rules being tabled. Where Rules are disallowed by either Parliament they will cease to have effect for both countries.

27 Orders are made by the Agency, and the Rules will stipulate the matters about which Orders may be made (Article 10). As with Rules, the Orders will be tabled in parliament and subject to disallowance in whole by parliament within a reasonable time from being tabled. Where Orders are disallowed by either Parliament they will cease to have effect for both countries.

28 The Agreement provides that where a Rule requires an Approval in relation to the manufacture, supply, import, export or promotion of a therapeutic product, New Zealand and Australia are required to prohibit that activity unless it is carried out in accordance with the required Approval (Article 3(2)). Article 11 provides that any person may apply to the Agency for an Approval to manufacture, supply, import, export or promote therapeutic products in accordance with the Rules.

29 The Agreement also provides that where a Rule prescribes the manner or circumstances in which a therapeutic product is not to be manufactured, supplied, imported, exported or promoted, New Zealand and Australia are required to prohibit the activity in that manner or in those circumstances (Article 3(3)). In addition, Article 3(4) provides that where a Rule or Order prescribes requirements relating to the manufacture, supply, import, export or promotion of a therapeutic product, New Zealand and Australia are required to prohibit such activity unless it is carried out in accordance with that Rule or Order.

Legislation Implementing the Scheme

30 Article 3 sets out some obligations for New Zealand and Australia in relation to the legislation implementing the Scheme. Article 3(6) requires Australia and New Zealand to consult together effectively in relation to the legislation to be enacted to implement the Scheme and any amendments to that legislation. Article 3(7) requires New Zealand and Australia to ensure that such legislation is not amended or repealed in a manner that is inconsistent with the Agreement or would prejudice the joint nature of the Scheme or its effectiveness.

31 Article 3(8) provides that neither New Zealand nor Australia shall introduce government legislation or government amendments to the legislation giving effect to Article 5 (4) or 5(5) (which relate to the establishment of the Agency and the powers conferred on it) without the written consent of the other country. This consent may be withheld only if that country is of the view that the legislation is inconsistent with the

requirements of Article 5(4) or Article 5(5) and they outline the nature of their concerns in a diplomatic note.

32 Article 3(9) goes on to require each country to use its best endeavours to reach agreement with the other in relation to any other amendments to the legislation that gives effect to Article 5, including, where relevant, reflecting the position of the other country in any papers for the government.

Accountability

33 Article 8 sets out that the accountability requirements that will apply to the Agency may be set out in Rules, in domestic legislation in Australia or New Zealand, or in both. The Board will be required to provide an annual report and financial statements to the Ministerial Council for each financial year. The financial statements of the Agency will be jointly audited by the Auditor-General of Australia and the Auditor-General of New Zealand.

34 New Zealand and Australia may provide that the statutory accountability regimes that it applies to similar regulatory agencies should apply to the Agency, in a manner that is consistent with the Agreement (for example, regimes provided for in the Ombudsmen Act 1975 and Official Information Act 1982). New Zealand and Australia will consult each other on how these regimes will be applied to the Agency.

Merits Review and Judicial Review

35 Article 13 outlines a system for the review in New Zealand and Australia of the merits of decisions of the Agency in respect of Approvals, or any other matter specified in the Rules, by a Review Tribunal. Members of the Review Tribunal will be drawn from a Merits Review Panel to be appointed by the Ministerial Council. The transfer of proceedings between Australia and New Zealand will be possible where a Review Tribunal considers that it is in the interests of justice to do so. The procedure to be followed in relation to applying for merits review and conducting merits review will be the subject of consultation between Australia and New Zealand and will be provided for in domestic legislation or the Rules. Provision is also made for both Australia and New Zealand to legislate to provide for a right of appeal to a superior court in respect of a merits review conducted in their territory.

36 Article 14 provides that New Zealand and Australia may provide for judicial review of decisions and Orders made by the Agency.

37 Decisions in respect of merits review or judicial review proceedings in one jurisdiction will have effect in both Australia and New Zealand.

Differences between Australia and New Zealand

38 The Agreement provides that in certain situations an Approval may apply differently in Australia and New Zealand (Article 11). These situations are: where the Rules provide for such differences; where the Agency considers that it is desirable having regard to differences in public health, safety, environmental or cultural circumstances of the two countries; or where it is in conformity with a departure taken under Article 12 (see next

paragraph). The Ministerial Council, and in some cases the Agency, are required to review Approvals which are subject to these differences.

39 Article 12 of the Agreement permits either Australia or New Zealand to exclude or modify the application of the Scheme, through regulations, in respect of a particular therapeutic product or class of therapeutic products where that country is satisfied that it is necessary for it to do so having regard to exceptional public health, safety, third country trade, environmental or cultural factors that affect that country and it is also satisfied that the proposed action will not compromise public health or safety in that country. Such action is referred to in the Agreement as a “departure” from the Scheme.

40 In the case where either Australia or New Zealand decides to depart from the Scheme, before doing so, they are required to notify the other country of their proposed departure and of the reasons for that departure. The other country is then afforded a reasonable opportunity to comment on the proposed departure. After a country departs from the Scheme, they are required to keep the matter under review with a view to determining whether the exceptional factors that affected them continue to apply, and also, at the request of the other country, to enter into consultations to discuss the continuing need for that departure. Any departure cannot be any more trade restrictive than is necessary to take account of the factors causing the departure, and shall not result in therapeutic products imported from the other country receiving less favourable treatment than such products from the country which has implemented the departure, or such products of any other country.

41 In addition, the Ministerial Council is required to, at least once a year, consider any departures, and may make recommendations to Australia and New Zealand in relation to those departures. Article 12(9) provides that in the context of the general review of the Agreement (see paragraph 45 below), the operation of the Article 12 “departures” regime will be specifically reviewed.

Funding

42 New Zealand and Australia have agreed to provide initial funding to the Agency and to transfer to the Agency certain assets (Article 15). The fees and charges applied by the Agency will be set out in the Rules, and they will be designed to cover the full costs of the Agency’s operations and provide incentives for the timely and efficient determination of applications by the Agency, as the Ministerial Council thinks fit.

43 Where the Agency is to engage in activities that fall outside the scope of the Scheme at the request of either Australia or New Zealand, the Ministerial Council will determine the terms and conditions that relate to the funding of those activities.

Consultation, Review, Amendment and Third Parties

44 The Agreement requires New Zealand or Australia to enter into consultations with the other country at their request if that country considers that an obligation under the Agreement has not been, is not being, or may not be fulfilled, or the achievement of any of the objectives of the Agreement is being or may be frustrated (Article 16). A review no later than five years after the date of entry into force of the Agreement is mandated by Article 17. Where New Zealand or Australia considers an amendment to be desirable, they

may request consultations with the other country (Article 18). Other states may be associated with the Agreement in accordance with terms that may be negotiated with Australia and New Zealand (Article 19).

Final Provisions

45 New Zealand or Australia may give notice to the other country of its decision to terminate the Agreement at any time (Article 20). Prior to termination, Australia and New Zealand will work towards agreeing matters which arise out of termination, with an arbitration mechanism (as annexed to the agreement) available if necessary to resolve any outstanding issues arising from termination. Upon termination, the Agency will be governed as specified in Australian legislation (see the section entitled ‘Withdrawal or Denunciation’ for further details).

46 Transitional arrangements will permit, for a specified period, the continued manufacture, supply, import, export or promotion of a therapeutic product that was lawful in the territory of one country immediately before the commencement of the new Scheme, on the same terms and conditions (if any) that applied in respect of that activity before the commencement date (Article 21). Applications that were made but not determined prior to the commencement of the new Scheme will be assessed on the same basis as applied before the commencement of the new Scheme. The details of the transitional arrangements will be set out in the Rules adopted by the Ministerial Council.

47 Article 22 confirms that other laws affecting therapeutic products that are not superseded by the legislation implementing the Joint Scheme, such as laws relating to customs controls, biosecurity, intellectual property and consumer protection laws, will not be affected by the Agreement.

Economic, Social, Cultural and Environmental Effects

Economic Effects

48 The inclusion of CMs and medical devices in the regulatory regime created by the Agreement will have significant effects on those industries domestically. Given that they have been subject to a lesser degree of regulatory control, there will be significant increases in compliance costs for manufacturers and distributors of CMs and medical devices in New Zealand. Where domestic operators also supply the Australian market, regulatory costs should reduce because market entry requirements for Australia and New Zealand will be rationalised. However, the public is also entitled to expect that therapeutic claims made about products can be substantiated, and that the goods they purchase or are treated with are manufactured to standards ensuring their safety and performance. Given that a risk-based approach to their regulation will be undertaken, it is considered that the adverse impacts on the domestic CMs and medical devices industries will be to some extent offset by the increase in consumer and purchaser confidence that regulation of the industries will bring, and that this is likely to be reflected in increased sales.

49 As has already been noted, because the new regime will be based upon total cost recovery, there will be further costs imposed on the domestic therapeutic products market. This will especially affect companies that supply only the domestic market. Amongst those companies that supply wider markets (including Australia), the tendency for those companies to shift their operations to Australia may be reinforced. This may to some

extent be balanced by increased consumer confidence in therapeutic products (especially CMs and medical devices) and ease of access for domestic companies to the Australian market (where CMs and medical devices are already regulated).

Social Effects

50 A major reason for adopting the Agreement is to ensure that the public is safeguarded from undue risks associated with the use of therapeutic products. The regulatory scheme should promote increased consumer confidence in therapeutic products as a result of the application of a risk-based approach to regulation, where those products with inherently lower risks to consumer safety (like many CMs for example) will not become subject to the stricter controls that apply to the other higher risk products like prescription medicines.

Cultural Effects

51 It is possible that there may be some cultural effects as a result of the Agreement, primarily in relation to traditional healing methods. The effects have been minimised, however, by drawing a distinction between the traditional uses of medicinal knowledge and the commercial manufacture of products based on traditional knowledge. It is not intended that the scheme will cover the regulation of the traditional use of medicinal plants and other substances. Medicines compounded by a practitioner (such as a pharmacist, herbalist, traditional Chinese medicine practitioner, traditional Māori healer, etc) to meet the needs of an individual patient are at present exempt from regulations and it is proposed that the current provisions that exempt such practitioners (and the products they supply) from regulation will continue.

52 However, it is proposed that the Joint Agency will regulate the commercial manufacture and distribution of medicines that may be derived from traditional knowledge. This is because all citizens are entitled to protection from the risks inherent in manufactured therapeutic products. For these reasons, the same good manufacturing practices and product licensing requirements would apply to all products for commercial manufacture and distribution, including those that are based on traditional knowledge and manufactured by businesses. These requirements would also ensure that the products could be exported to Australia and other jurisdictions.

Environmental Effects

53 No environmental effects are anticipated. It should be noted however that in the event that regulation under the Joint Scheme raises particular environmental concerns for either country, appropriate action can be taken by the Agency (Article 11) or the relevant country (Article 12).

Costs

54 Compared to the current Crown costs of \$4.2 million, the Crown would continue to face fiscal costs of approximately \$1.1 million per annum. The difference, a saving in the order of \$3.1 million, would be a transfer of cost to industry. The ongoing \$1.1 million cost to the Crown consists of:

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

- An estimated \$500,000 for the Ministry of Health to monitor the Joint Agency.⁵

55 Estimates of annual regulatory fees and other business compliance costs are shown in the following table (NZIER, 2002). The table assumes that Joint Agency costs are shared, based on an estimate that about 30% of all product licences will be held by New Zealanders. The incremental estimates are indicative only and do not include the costs of manufacturing licences and audits for manufacturers of pharmaceuticals and complementary medicines.

Incremental Compliance Costs

Annual costs, Midpoint estimates

	JTA (NZ's share)
Pharmaceuticals (+/- 11%)	
Regulatory fees	\$3.0M
Other business compliance	(\$4.4M)
Total	(\$1.4M)
% of industry turnover	(0.2%)
Complementary Healthcare products (+/- 30%)	
Regulatory fees	\$1.7M
Other business compliance	\$0.9M
Total	\$2.6M
% of industry turnover	2.6%
Medical devices (+/- 30%)	
Regulatory fees	\$5.8M
Other business compliance	\$1.2M
Total	\$7.0M
% of industry turnover	1.1%
Total Sector	
Total	\$8.3M
% of sector turnover	0.5%

Source: NZIER, October 2002

56 Further work was undertaken by NZIER to refine estimates of costs relating to the complementary medicines industry. The results of this work indicate that regulatory costs (for product and manufacturing licences), based on updated estimates of industry turnover, would be of the order of 1.5% of revenue from domestic and export sales, with incremental regulatory costs of the order of 0.9% of sales revenue.

⁵ It is assumed that there will be a small unit focused on monitoring the Joint Agency, consisting of a team of 3 senior staff at an average salary of \$80,000 and with an overhead multiplier of 2.

Future Protocols

57 There is no present intention to negotiate a future Protocol to the new Agreement but such a Protocol could be negotiated should the need arise.

Implementation

58 Implementing the new Agreement in New Zealand will require the passage of new legislation and the amendment and/or revocation of the Medicines Act 1981, the accompanying Medicines Regulations 1984 and parts of the Dietary Supplements Regulations 1985.

59 Implementation also requires the Australian Government to give legal personality to the Joint Agency in Australian domestic law as well as to implement the other obligations in the Agreement.

60 The Ministry of Health will continue to have a role in the regulation of therapeutic products, but a much more limited one. It will include the administration of medicine control functions (such as the monitoring of aberrant prescribing and the licensing of pharmacies) and the monitoring of the Joint Agency. The Joint Agency will maintain fully functioning offices in both countries, to be located in Wellington and Canberra. The head office of the Joint Agency will be located in Canberra, but the Wellington office will also house senior managers of the Joint Agency. It is envisaged that Medsafe staff will have the option of either joining the Joint Agency or transferring to another branch of the Ministry of Health, once the Joint Agency becomes operational. The details of the transitional and implementation arrangements for the new office will be finalised with Australia in due course.

An illustration of how Therapeutic Products will be regulated under the Joint Scheme

61 The Joint Scheme would regulate therapeutic products under two broad categories – medicines and medical devices.

62 The regulatory scheme would be risk based and consistent with international best practice. Medicines (which include prescription medicines, over-the-counter medicines and CMs) would be divided into risk classes according to the level of risk associated with their use. The level of regulatory control would be consistent with the risk class of the medicine. Due to the lower inherent risks associated with complementary medicines, they would be subject to lighter regulation, as compared with prescription medicines, for example.

63 Similarly, the regulatory framework for medical devices would be based on the recommendations of the Global Harmonisation Task Force where medical devices are also divided into classes according to the level of risk associated with their use. Regulatory control is also applied consistent with the class of risk of the medical device.

64 A sponsor wishing, for example, to sell a medicine or medical device in New Zealand would be required to obtain a product licence (called an Approval in the Agreement). An Approval would authorise the supply of that product in both New Zealand and Australia, subject to the conditions on the Approval. The application requirements and assessment processes would be different for different risk classes.

65 For low-risk medicines and medical devices, sponsors would be required to enter information into a web-based system, providing basic details about the products being sold, declaring that the products meet certain standards and certifying that they hold the necessary information or documentation to support their declaration. Low risk medicines that are self-certified in this way would only be allowed to contain substances from a permitted list and there would be restrictions on the therapeutic claims that can be made for a low risk medicine.

66 For higher risk medicines and medical devices, the sponsor would be required to submit an Approval application for evaluation by the Agency. The application requirements and the type and level of evidence required would vary according to the type of products and the risk class.

67 An Approval would remain in force indefinitely provided the appropriate annual fee (used to fund post-market monitoring activities) is paid and the Approval is not suspended or revoked. The Joint Agency would maintain a register of Approvals that will be open to the public.

68 There would also be certain exemptions from the requirement to hold an Approval, for example, where therapeutic products are used in clinical trials, imported for personal use or made by a practitioner, traditional Maori healer or other classes of natural healers (such as naturopaths) in response to the needs of a particular patient.

69 Manufacturers of medicines would also be required to meet Good Manufacturing Practice (GMP) standards and would be audited and licensed to ensure compliance. There would be post-market monitoring of adverse reactions and product testing. The Joint Agency would have the power to require a therapeutic product to be recalled or to suspend or revoke an Approval in the event of a serious safety concern.

70 The Joint Scheme would also impose controls on the standards that apply to therapeutic products; the advertising of therapeutic products; and the provision of information about medicines (including labelling, information for prescribers and for consumers). Access controls would apply to the prescribing or sale of those medicines that require the intervention of a qualified health professional to assure safe use.

Consultation

71 The Ministry of Health (Medsafe) has consulted widely in developing the proposal for a Joint Agency with Australia. A number of Government agencies have been consulted, including the Ministries of Health, Foreign Affairs and Trade, Economic Development, Justice, Agriculture and Forestry, Women's Affairs, and Consumer Affairs, the Ministry for the Environment, Treasury, the Customs Service, Te Puni Kokiri, the Department of Prime Minister and Cabinet, the State Services Commission, the New Zealand Food Safety Authority, and the Parliamentary Counsel Office.

72 In 2000, Medsafe published a discussion document seeking comment on the proposed form of a joint therapeutic products agency. This informed decisions by Ministers in December 2000. In further developing its proposals, Medsafe has held meetings with consultative groups comprising representatives of the key stakeholder groups affected by the proposal, primarily therapeutic products' suppliers. In December

2001 and June 2002, Medsafe distributed further discussion documents, seeking feedback on the design and role of the proposed agency.

73 While a large number of responses was received, fewer than 15 percent of responses to the June 2002 discussion paper commented on the proposals set out in that paper. Government departments, representative bodies, consumer groups and those in the pharmaceutical and medical device industries broadly supported the proposals.

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

75 Opinion expressed in submissions on the proposals contained in the June 2002 discussion paper ranged from strong support for the proposals, to support for some aspects and concern about others, to outright rejection of any proposal to enter into a joint agency arrangement with Australia. All sectors of industry rejected the concept of 100 percent cost recovery, and there was considerable concern about Australian domination and loss of voice for New Zealand, although much of this concern was based on a misunderstanding of both the current system and the proposed governance and accountability arrangements.

Pharmaceutical sector

76 The pharmaceutical industry generally supported the proposals, although there was some concern about loss of expertise within New Zealand. Most of the comments related to more detailed aspects that would be the subject of further consultation with stakeholders as the Ministerial Council Rules and Managing Director's Orders are developed.

Medical devices sector

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

Complementary medicines sector

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

79 Much of the negative comment centred on the current Australian regulatory scheme, which was seen as bureaucratic, expensive and overly restrictive. There was considerable concern about the impact of compliance costs on small businesses, with claims that

hundreds of small distributors would go out of business if the proposed Scheme were introduced.

80 The larger manufacturing companies are broadly supportive of the Joint Agency concept and the overall approach to regulation. Most of their concerns relate to the detail of how the Scheme would be administered and how the Agency's accountability to the fee-paying industry would be ensured.

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

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

Consultation with Māori

83 Submissions received from Māori rejected any controls that would limit the right of the tangata whenua to access and use native plants in traditional Māori medicine. Some submitters felt that a joint agency, dominated by Australians, would not take adequate account of cultural issues in New Zealand. They felt that the costs of licensing products and meeting quality standards would be prohibitive, making it impossible for Māori to commercialise traditional medicines if they wished to do so. Other submitters seemed to be concerned about the impact on traditional practices that would be covered by the proposed practitioner exemption. There was also concern about the impact of regulation on employment opportunities for Māori. One submission opposed the proposal on the basis that it ignored the rights of the tangata whenua to possession of all taonga and the authority to manage their own affairs.

84 As noted above, the Agreement permits the Agency to take into account cultural circumstances in deciding that a therapeutic product should be supplied in a different manner or subject to different requirements in New Zealand (Article 11(4)), and also that New Zealand may make regulations to exclude or modify the application of the Scheme on the grounds of exceptional cultural factors (Article 12)).

Withdrawal or Denunciation

85 Either New Zealand or Australia may at any time give notice in writing through diplomatic channels of its decision to terminate the Agreement (Article 20). Upon notice being given, the Agreement will terminate on a date to be agreed by Australia and New Zealand. It may be agreed that the Agreement will terminate on different dates in respect of different classes of therapeutic product, or in the absence of such agreement, the Agreement will terminate on the later of:

- Any date specified in the notice of termination as the date on which the termination is to be effective; or
- Three years after the date on which the notice of termination was received.

86 Upon termination of the Agreement:

- The Agency will cease to be governed in accordance with the Agreement, and will be governed in such a manner as may be specified in Australian legislation;
- New Zealand will have no interest in the Agency or its assets, except as may be agreed between Australia and New Zealand in relation to matters arising out of termination, or as determined through arbitration.

87 Prior to the termination of the Agreement Australia and New Zealand are to use their best endeavours to reach agreement in relation to matters arising out of the termination, including:

- Arrangements for use by New Zealand of the intellectual property of the Agency and information held by the Agency, as at the date of the termination;
- Assistance to be provided by the Agency in connection with the new arrangement for the regulation of therapeutic products in New Zealand; and
- Financial arrangements in connection with the termination of the Agreement.

88 If agreement cannot be reached on these matters arising out of termination, either Australia or New Zealand may request that the difference between them be referred to arbitration in accordance with the arbitration mechanism set out in the Annex to the Agreement.

89 In the event of the Agreement coming into force and at some point being subsequently terminated, there are likely to be significant fiscal costs in creating a new regulatory system to replace the existing system in New Zealand.

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