

## **NATIONAL INTEREST ANALYSIS**

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

### **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 on 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 A 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  - ⌘ The outdated nature of the applicable legislation<sup>1</sup> 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.

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<sup>1</sup> 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<sup>2</sup>. 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

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<sup>2</sup> 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.

approach would also strengthen CER<sup>3</sup> 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.

### **ADVANTAGES AND DISADVANTAGES TO NEW ZEALAND OF THE TREATY ENTERING INTO FORCE**

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,

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<sup>3</sup> The Australia New Zealand Closer Economic Relations Trade Agreement – commonly referred to as ‘CER’

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 products<sup>4</sup> (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 CMs 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)).

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

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 (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 M ori 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.<sup>5</sup>

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<sup>5</sup> 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.

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.

<i>Incremental Compliance Costs</i>	
Annual costs, Midpoint estimates	
	JTA (NZ's share)
<b>Pharmaceuticals (+/- 11%)</b>	
Regulatory fees	\$3.0M
Other business compliance	(\$4.4M)
<b>Total</b>	<b>(\$1.4M)</b>
% of industry turnover	(0.2%)
<b>Complementary Healthcare products (+/- 30%)</b>	
Regulatory fees	\$1.7M
Other business compliance	\$0.9M
<b>Total</b>	<b>\$2.6M</b>
% of industry turnover	2.6%
<b>Medical devices (+/- 30%)</b>	
Regulatory fees	\$5.8M
Other business compliance	\$1.2M
<b>Total</b>	<b>\$7.0M</b>
% of industry turnover	1.1%
<b>Total Sector</b>	
<b>Total</b>	<b>\$8.3M</b>
% 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.

## **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 M ori**

83. Submissions received from M ori rejected any controls that would limit the right of the tangata whenua to access and use native plants in traditional M ori 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 M ori 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 M ori. 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.

National Interest Analysis Prepared by the Ministry of Health