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

REGULATION IMPACT STATEMENT

In December 2003 the Australian and New Zealand governments signed a treaty to establish a single harmonised scheme for the regulation of therapeutic products[1] in Australia and New Zealand, to be administered by a single agency in both countries.

In 2000 the Australian and New Zealand governments made the "in principle" decision to establish such a scheme, subject to consideration of more detailed analysis of its net benefits. Cost benefit analyses in the form of Regulation Impact Statements were subsequently provided to both Governments. In late 2002 the Australian government agreed to commence implementation of the harmonisation of Australia and New Zealand's regulatory requirements for therapeutic products.

This Regulation Impact Statement (RIS) has two parts. Part 1 focuses on the costs and benefits that were considered when the decision was made to proceed to implement a harmonised scheme to be administered by a single joint Agency. It therefore reflects the situation in Australia and New Zealand in 2002 in relation to therapeutic products. Part 2 is designed to assist consideration of the content of the proposed Treaty between Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products.

PART 1 - HARMONISATION

1.1 BACKGROUND

Under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), therapeutic goods[2] have a special exemption from the TTMRA on condition that Australia and New Zealand engage in a trans-Tasman co-operation program. Under such a program the regulators of the two countries are to collaborate to resolve the exemption which in this instance has been extended to May 2004. Options for resolution include mutual recognition, harmonisation or permanent exemption from the operation of the TTMRA.

In 1999 Australian and New Zealand Health Ministers agreed that formal harmonisation of regulatory requirements was the option they wished considered. This was to include

[1] "Therapeutic products" means products that are used or represented to prevent, diagnose, alleviate, cure or monitor a disease or condition, and comprises medicines (including medicines referred to as complementary health care products and dietary supplements in New Zealand), medical devices and other products such as some sunscreens, blood and blood components.

[2] that is, therapeutic products (the term "therapeutic goods" is used in the TTMRA legislation).

alignment of product and manufacturing standards and conformance assessment requirements. In 2001, they supported exploring particularly the feasibility of establishing a joint agency to regulate therapeutic goods[3] and policy development in this area proceeded (see under *Consultation* below).

Harmonisation through a joint agency arrangement has broad significance for closer economic relations (CER) between Australia and New Zealand. It may be an important precedent for any future development of joint agencies. The successful establishment and operation of this agency should significantly influence the attitudes of both governments regarding any future extension of CER.

Existing regulations

Legislative responsibility for the quality and safety of therapeutic products in Australia lay fully with States and Territories until the *Therapeutic Goods Act 1989* (the TG Act) came into force in February 1991. This created new national legislation where Commonwealth powers applied and where there had previously been only separate non-uniform State laws. It consolidated these provisions with the drug evaluation activity that the Commonwealth was already undertaking. The TG Act and its associated Regulations cover medicines, medical devices[4] and complementary medicines[5]. Unincorporated entities, such as pharmacists operating as sole traders, are currently not covered by the TG Act in Victoria, Queensland, South Australia, the Northern Territory and the ACT.

The subject matter of this particular national legislation is administered by the Therapeutic Goods Administration (TGA). TGA is a business unit within the Commonwealth Department of Health and Ageing, with a staffing complement, including non-ongoing staff, of approximately 440 persons engaged in the regulation of therapeutic products[6]. It operates on a full cost recovery basis with an annual budget of around $50 million collected primarily through annual charges, evaluation fees and licence charges.

In New Zealand, different arrangements exist for the regulation of pharmaceuticals, medical devices and complementary health care products. Pharmaceuticals are regulated under the *Medicines Act 1981* and the *Misuse of Drugs Act 1975* by Medsafe, a business unit of the New Zealand Ministry of Health. Medsafe is responsible for administering these statutes and regulations made under them. It has a staff complement of 56 and an annual budget of $6.9 million. Of this amount, $3.5 million is Crown funding and $3.4 million is third party revenue from fees and charges.[7]

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[3] Therapeutic Goods Co-operation Program Reports to the Council of Australian Governments including New Zealand of 1999 and 2001 respectively.
[4] These include a very wide range of products from rubber gloves, syringes and diagnostic kits, to prostheses and implants such as pacemakers.
[5] These include herbal medicines, vitamins, minerals, nutritional supplements, aromatherapy oils and certain homoeopathic medicines.
[6] As at January 2004.
[7] As at January 2004 (figures provided by Medsafe).

With the exception of condoms and devices containing medicinal substances, medical devices are not subject to assessment in NZ. Medsafe's role is restricted to post-market monitoring with regard to other medical devices.

Complementary health care products in New Zealand are currently regulated as foods under the *Food Act 1981* and the *Dietary Supplements Regulations 1985*. No approvals for market supply are required unless therapeutic claims are made, in which case they are then categorised as medicines and subject to pre-market evaluation by Medsafe. Manufacturing premises for all complementary health care products must be registered under the *Food Hygiene Regulations 1974* as they are not currently required to meet Good Manufacturing Practice standards for medicines.

The nature of regulation of high and medium-risk pharmaceuticals in Australia and New Zealand is similar. However, low-risk pharmaceuticals, complementaries and devices are less closely regulated in New Zealand compared with Australia.

The Therapeutic Products Sector

The groups most affected by the issues under consideration are as follows:

- Consumers - and the wider community (including in regional areas) - Australia and New Zealand. The last National Health Survey for Australia that contained data about all medication use and not just use for specific conditions, was conducted in 1995, and found that in that year 51% of the population used medicines and 25.8% used vitamins and minerals, 9.4% used herbal and natural treatments and 33.4% consulted professionals in relation to health activity[8]. By 1999 the Household Expenditure Survey showed total annual household expenditure on medicines, pharmaceutical products, therapeutic appliances and equipment to be $2.997 billion[9].
- Industry – The industry comprises Australian and New Zealand therapeutic products manufacturers (prescription medicines, over-the-counter medicines, medical devices, complementary medicines) wholesalers and retailers. According to official statistics, the medicinal and pharmaceutical manufacturing industry in Australia had $4.594 billion of turnover and employed 12,500 persons in 1998, exporting some $1.26 billion of production[10]. There is also a large import sector ($3.016 billion) and an extensive distribution and retailing sector. According to estimates by industry analyst IBIS, this had grown to $5.8 billion turnover in 2000-01 with exports of $2.3 billion and imports of $4.7 billion.[11] For pharmaceuticals alone there are more than 120 companies in the industry, with the top ten accounting for 50% of sales[12]. The dominant firms are multi-nationals such as Astra, Merk Sharp and Dohme, Glaxo Wellcome and Alphapharm, but there is a small number of significant local companies such as Sigma and CSL. This sector overall had sales in 1999 of around

[8] Australian Bureau of Statistics, 4377.0
[9] Australian Bureau of Statistics, 6535.0
[10] Australian Bureau of Statistics. Op cit
[11] Ibis World, C2543 – Medicinal and Pharmaceutical Product Manufacturing in Australia, 20 November 2001
[12] Australian Pharmaceutical Manufacturing Industry Association Inc, APMA Facts Book – 1999-2000.

$8.94 billion, with $6.44 billion in pharmaceuticals, $1.06 billion in complementaries, and $1.5 billion in medical devices[13]. Data on the size, numbers and types of firms operating in each other's markets are not available.

- Sector representation - is found through bodies such as Medicines Australia (MA), the Australian Self Medication Industry Group (ASMI), the Complementary Healthcare Council (CHC) and the Medical Industry Association of Australia (MIAA). There is also consumer representation including through the Consumers' Health Forum of Australia (CHF) and the Australian Consumers Association (ACA). Professional groups, particularly in the medical, dental and pharmacy areas, are also seen as stakeholders in these matters.
- Government –Australian, State/Territory, local and New Zealand governments are involved. For Australia, government not only regulates this sector under the TG Act and related legislation but spends significant amounts on the products of the sector. For example, the Australian Government paid $3.07 billion in consumer pharmaceutical benefits in 1999 and further payments are made to industry under the Pharmaceutical Industry Investment Program. The Australian Government is the lead government for these purposes, but coordinates with the States and Territories through Ministerial Councils and committees of officials.
- Trade – trans-Tasman trade in therapeutic products comprises exports from Australia to New Zealand of the order of $208 million and imports from New Zealand to Australia of the order of $75 million. This represents a total volume of trade approaching $300 million annually[14].

Scope of regulation review for therapeutic products

In Australia and New Zealand, the major forms of regulation within the therapeutic products area are:

- Pre-market assessments, licensing of manufacturers and post marketing monitoring and enforcement of compliance with standards;
- Scheduling of chemical substances and associated controls to control access to, and supply of, therapeutic products;
- Monopsony purchasing of pharmaceuticals through government so as to subsidise prices paid by consumers and to facilitate product availability;
- Intellectual property and patent life rules and other industry development regulation (such as parallel importation controls) to enhance innovation in provision of therapeutic products and industry development.

Purchasing arrangements, intellectual property and patent life rules are outside the scope of the proposed trans-Tasman regulatory arrangements for therapeutic products and are therefore not addressed in this RIS.[15] This RIS also does not address issues of legislative

[13] Regulatory Impact Analysis, A single joint Australia and New Zealand therapeutic goods agency, October 2000, New Zealand Institute of Economic Research (NZIER), p25.
[14] Ibid, p51.
[15] Thus, in economic terms, intellectual property and related rules (eg parallel importing controls) address the firm spillover market failure in relation to product innovation; purchasing controls address the access

or regulatory reform to Australian regulation of therapeutic products beyond the trans-Tasman issue, since such issues have recently been the subject of separate review processes within Australia.[16]

1.2 PROBLEM IDENTIFICATION

Removal of barriers to trade and commerce

By their nature separate regulatory controls on therapeutic products restrict trade and/or duplicate effort relative to a common market without such controls. The general presumption of regulation review is that regulatory barriers should be removed unless there are market failure or other public interest reasons to the contrary. Where the barriers are divergent in content and process then firms incur the costs of operating under two systems with different characteristics. Even with the same characteristics simple duplication of processes can be costly.

The costs for business of lack of uniformity can be seen as falling into two broad categories:

- those associated with identifying and staying up to date with the requirements in each jurisdiction: and
- those where there is need to comply with different controls imposed by different jurisdictions.

Nature of market failure

One form of removal of barriers would be to remove regulation altogether in both Australian and New Zealand markets for therapeutic products and pursue free trade. This is not under consideration as market failure in these markets is well recognised. This derives in particular from:

- *information asymmetry* – where sellers have greater information and knowledge than buyers in this market to the detriment of consumers;
- *consumer externalities* - where improper use of these substances could result in detriment to other individuals and the wider community, and vice versa for proper use.

These problems are not removed even in the presence of increased public information, increased average education levels, and professional intermediation (though these help

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and equity market inadequacy issue; scheduling and related controls address consumer information asymmetry (and sovereignty) and community externalities at point of purchase.

[16] *Review of Therapeutic Goods Administration*, Department of Health and Family Services, 1997; Industry Commission Review of Devices, Departmental review of Complementary Medicines; *National Competition Review of Pharmacy*, 1999; National Competition Review of Drugs, Poisons and Controlled Substances Legislation, 2001, Productivity Commission Review of Cost Recovery.

greatly[17]) because of the existing and growing complexity of the products and their potential to cause harm to health and safety if used inappropriately.

Protection of public health and safety

The appropriate degree of regulation in these matters for Australia has been the subject of separate review processes within Australia (see footnote 16 above). The outcomes of these reviews must here be assumed to be reflected appropriately in Australian regulation. Accordingly, the issue for health and safety in relation to trans-Tasman regulatory reform is to ensure that such reforms do not diminish previously agreed Australian regulatory standards - unless other compensating economic or public interest benefits are shown to arise from new trans-Tasman arrangements.

Differences in Australian and New Zealand Therapeutic Products Regulation

Australia and New Zealand use a broadly similar approach for the regulation of pharmaceuticals consistent with global harmonisation initiatives. Nevertheless, there are still some significant differences in the scope and the detailed operation of their current regulatory regimes. The unresolved differences in regulatory regimes have been the key reason for the continuing special exemption under TTMRA arrangements, reflecting the complex nature of these commodities in turn and their particular public health and safety dimensions.

The differences between New Zealand and Australia that underpin arguments for benefit from the elimination of difference, such as discussed above, are essentially the following:

(a) Limited coverage of New Zealand's existing regulation

Although much harmonisation between Australia and New Zealand's requirements already exist, both bilaterally and under global initiatives, New Zealand's current approach to therapeutic products regulation is generally not as comprehensive and consistent as Australia's e.g:

- divergence on some specific high risk and medium risk medicines;
- divergence of approach to regulating some aspects of lower risk and over the counter medicines;
- absence of pre-market regulation for most medical devices regulated in Australia; and
- divergence on direct-to-consumer advertising regulation.

(b) Differences in Regulatory Processes

New Zealand processes of regulation also diverge from Australia eg

- treatment of complementary medicines under food not medicines regulation, including in relation to manufacturing standards; and

[17] The legislative and regulatory arrangements under consideration here for harmonisation in relation to therapeutic products do not extend to legislation regulating professional practice.

- limited enforcement of pre-market evaluation requirements even where therapeutic claims are being made for complementary medicines.

These differences of coverage and process imply two major issues. The first is that differences in the administration of the regulatory processes in the two countries created trade barriers[18], so inhibiting the achievement of the objective of the CER trade arrangements as regards these industries. The second is that even simple duplication of common regulatory requirements for medicines creates additional compliance costs for businesses operating in either or both of the two markets. Such costs could be lower with pooling of resources in the presence of common standards[19].

(c) Regulatory Sustainability

One possible gain from harmonisation and elimination of regulatory duplication is the ongoing sustainability of the regulatory capacity and skills in both Australia and New Zealand. [20] The evaluation of new and innovative therapeutic products is becoming increasingly complex, and the pool of skilled resources available to the regulators is diminishing. [21] In New Zealand, lengthening of processing times for pre-market evaluations and the lack of skilled resources to process some complex products (eg genetically modified vaccines) is already being experienced.[22]

Rapid change is being driven by competition, innovation and emerging technologies. For example, the pharmaceutical industry predicts the workload for regulators over the next few years will rapidly increase due to the industry's heavy investment in research and development (R&D) [23]. From 1986-1996, R&D expenditure in the Australian pharmaceutical industry rose sixfold, and its investment in R&D represents 5.5% of its production income. By contrast, the general manufacturing sector invests only 1.1% of its production income in R&D[24].

There has been a consequential burgeoning of new pharmaceutical products entering the market in recent years. The total number of applications to the TGA for product approval increased by almost 50% over the financial years 1995-6 to 1998-9[25]. The strongest growth is evident in applications for approval of high risk medical devices, which increased by 100% over the same period. This very high rate may be due in part to a

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[18] NZIER, op.cit, p17.
[19] The precise number of firms operating in the two therapeutic products markets is unclear, but it will be recalled that the costs impact on a present volume of Trans-Tasman trade in therapeutic products of around $300 million annually and rising (NZIER, op.cit. p51.)
[20] Report of the Regulatory Reform Taskforce, Review of Administrative Arrangements for Commonwealth Public Health and Safety, Department of Health and Aged Care, August 2001, pp.155-161
[21] Commonwealth Department of Health and Aged Care, *Annual Report 2000-2001*, p.378.
[22] Loc Cit
[23] Gunnaway, DJ, "Future Challenges for Drug Regulatory Agencies", *Presentation to International Conference of Drug Regulatory Authorities*, 1999.
[24] Australian Economic Analysis, 1998
[25] Department of Health and Aged Care, *Annual Report*, 1999.

classification change, but high rates were nevertheless evident for all therapeutic products.

(d) Regional and Global Status Issues

A final set of issues revolve around regional and global concerns. These reach beyond narrow economic trade and administrative cost considerations. They are also even harder to demonstrate and quantify, partly because they depend upon strategic considerations that are not deterministic in the manner of some of the simpler competitive economics that often inform benefit-cost analysis. That does not render them less real nor make them irrelevant to a regulation review, as they potentially involve broader public benefits for Australians. Three claims seem pertinent:

- in the trans-Tasman arena the proposals for a joint administrative decision-making agency offer new possibilities for even greater integration in other areas between the two systems than simply that of removal of barriers. If the various legislative, political and administrative considerations are successfully addressed, an important precedent and set of "public good" knowledge for similar joint ventures is created;

- in the global therapeutic products industry, pooling of two previously sovereign markets under a common regulatory framework of high quality, may have symbolic impact beyond the simple advantages of a bigger common market. In particular, pharmaceutical companies attach importance to approvals and hence first release of new products in countries acknowledged as benchmark regulators for quality. It is arguable that a joint agency will help sustain Australia's reputation and position as a so-called "first wave" country for such purposes, with consequent benefits to consumers; and

- success in harmonisation in this complex field for Australia and New Zealand may induce other nations to seek to join the arrangement or to adopt its standards, particularly in the Asia Pacific.

1.3 OBJECTIVES

The special exemption that therapeutic products have from the operation of the TTMRA must be resolved in a way that:

- safeguards public health and safety in Australia and New Zealand by efficiently and effectively regulating therapeutic products in both countries; and
- avoids barriers to trade except where they are necessary to safeguard public health or safety.

1. 4 REGULATORY OPTIONS

Options for resolving the TTMRA special exemption for therapeutic products included mutual recognition of Australia and New Zealand's regulatory standards, harmonisation

of standards or, failing either of these options, permanent exemption from the operation of the TTMRA. Because of the significant differences in regulatory approach, including the different standards that applied to some product groups, mutual recognition was considered unacceptable. Work therefore focussed on the two remaining options that are discussed in more detail in the following paragraphs. In the interim, the special exemption has been renewed annually, following consideration of progress reports on the work being undertaken.

1.4.1 PERMANENT EXEMPTION

This option extends the status quo for Australian arrangements, with therapeutic products being regulated under the current Australian legislation. It elects to adopt a permanent exemption for the regulation of therapeutic products under the TTMRA. Within this option of permanent exemption, account should be taken of the likely effect in Australia of New Zealand's own principal alternatives to harmonisation, viz:

a) the adoption of a system based on limited domestic evaluation but wide unilateral recognition of pharmaceuticals, complementary medicines and therapeutic devices approved by other specified regulatory authorities;
(b) the adoption of a new enhanced regulatory framework with local evaluation of products to international standards and no necessary particular harmonisation with Australia; and
(c) the status quo ie limited regulatory coverage of complementary medicines and medical devices within existing and likely diminishing evaluation capability.[26]

In terms of change, only (a) and (b) are relevant.

1.4.2 HARMONISATION

This option entails a single harmonised regulatory scheme in Australia and New Zealand to be administered by a single joint trans-Tasman regulatory agency that would replace TGA in Australia and Medsafe in New Zealand (the Agency). A Treaty between the two countries would set out how the Agency would be established under Australian legislation, and its operational framework, including establishment of a Ministerial Council comprising the Australian (Commonwealth) and New Zealand Health Ministers and a five member board responsible for the strategic and administrative direction of the Agency.

The Agency would regulate the full range of therapeutic products ie prescription medicines, over the counter and complementary medicines, medical devices and other therapeutic products including some sunscreens and blood and blood components. Its functions would include pre-market evaluation/assessment and approval, licensing the manufacture of products, scheduling, product standard setting, advertising, post-market monitoring and surveillance. Offices would be established and maintained in each country to provide a local point of contact with the Agency.

[26] NZIER, op cit.

A Managing Director, appointed by the Ministerial Council, would be responsible for regulatory decisions in much the same way as the Secretary of the Department of Health and Ageing is currently responsible under existing Commonwealth legislation. In practice, the Managing Director would delegate the power to make certain decisions to persons with the appropriate expertise and/or functional responsibility. Expert advisory committees would provide advice to the decision-maker.

At the time the joint Agency approach was decided upon, it was contrasted with the one other precedent in this field, the model offered by the Australia New Zealand Food Authority (ANZFA), now Food Standards Australia New Zealand (FSANZ).

The proposed Agency model varies substantially from the ANZFA model principally because of the marked difference between the respective roles of the two agencies.

ANZFA operated as an Australian statutory agency established under Australian legislation. It was responsible for setting and varying food standards that are then adopted and enforced by the States and Territories in Australia and by a separate Foods Safety Authority in New Zealand. ANZFA does not itself enforce compliance with standards in the various jurisdictions.

In contrast, the Agency will administer a single, joint regulatory scheme that will be equally applicable in both countries. The new agency will regulate the import, export, manufacture and supply of therapeutic products in two independent and sovereign countries through pre-market assessment of products, licensing of manufacturers and post market monitoring of compliance with and enforcement of standards. The Agency will make decisions on behalf of two independent and sovereign Governments in relation to therapeutic products and will be empowered to enforce those decisions in both countries. The Agency will be established in Australian legislation but, unlike FSANZ, the Agency will also be empowered to act in New Zealand through legislation in that country.

Under this model the Agency must be equally responsive to both the Australian and New Zealand Governments with neither having the opportunity to unilaterally make decisions or issue directions that could adversely impact the interests of the other.

1.5 ASSESSMENT OF IMPACTS

In assessing impacts of options it is important to recognise that the proposals relate to relatively small agency costs, compared to industry size. TGA is a $50 million per annum agency and Medsafe is a less than $7 million per annum agency. The relevant industry represents around $9 billion in sales in Australia and $1.5 billion in New Zealand. The repercussions of harmonisation here are to that extent limited in overall magnitude. In addition, they will mostly be limited to benefits in respect of trade, estimated to be in the order of $300 million.

Much analysis of impact is of necessity qualitative without detailed quantification or modelling, since large scale economy-wide effects are not likely or discernible. Illustrative or descriptive data are nevertheless used wherever available and appropriate.

OPTION ONE – PERMANENT EXEMPTION

Under Option 1, permanent exemption for therapeutic products under the TTMRA, New Zealand faces three possible choices:

A.- to implement new legislation to cover all complementary medicines and medical devices, with ongoing unilateral recognition of market approval in overseas countries;
B.- to implement new legislation to operate a stand-alone regulatory system to international standards across the full range of therapeutic products; or,
C.- to maintain current New Zealand regulatory arrangements without change.

A. If **New Zealand implements new legislation** to cover all complementary medicines and medical devices, **with ongoing unilateral recognition** of market approval in overseas countries, then the impacts on Australia will be as follows:

Benefits

Australian business: where New Zealand recognises Australia's regulatory approval, there will be reduced compliance costs for those Australian businesses (particularly in the pharmaceutical sector) which currently have to go through any additional approval process for New Zealand. The number of Australian firms which export therapeutic products to New Zealand has not been documented. However, Australian exports are estimated to be of the order of $208 million, compared with sales in Australia of around $9 billion. Exports to New Zealand therefore represent roughly 2.3% of Australian sales.

There will be new transitional marketing opportunities to New Zealand for those firms in the medical devices and complementary medicines sectors which already have approval in Australia. These Australian firms may have an early competitive advantage over New Zealand firms now seeking local approval for new products.

Australian consumers: some additional direct benefits from greater product safety in New Zealand, but where Australian firms have reduced compliance costs, they may pass these on to consumers in competitive markets as lower prices for their products.

Australian government: there may be a very small amount of income flowing as a result of New Zealand contracting TGA to undertake evaluations on its behalf for New Zealand manufactured products. However, Medsafe estimates this to be insignificant, with only 2 or 3 applications per year[27], down from an average of 30 applications per year in past years since other countries' approvals will also be accepted.

[27] Medsafe, email, 5/12/01

Costs

Australian therapeutic products industry: Where New Zealand chooses to recognise overseas approvals other than from Australia, then there would be reduced marketing opportunities to New Zealand for Australian firms. Australian exporters to New Zealand would face increased regulatory and compliance costs for complementary medicines and devices which will now require registration or listing in New Zealand. They will also face greater competition from overseas firms with product approvals already recognised by New Zealand.

Australian consumers: Australian residents travelling to New Zealand may purchase and use therapeutic products, which may now be higher in cost due to the expanded scope of New Zealand regulation under this option.

Australian government: no new costs over status quo.

B. However, if **New Zealand implements new legislation to run a stand-alone regulatory system to international standards across the full range of therapeutic products**, then the further effects on Australia will be as follows:

Benefits

Australian business: no additional benefits over status quo.

Australian consumers: no additional benefits over status quo.

Australian government: no additional benefits over status quo, as this is a continuation of current arrangements for TGA.

Costs

Australian business: Australian firms that export medical devices and complementary medicines which are not currently subject to regulation in New Zealand, would face increased regulatory and compliance costs. Australian evaluation standards may be recognised, but differences in scheduling, packaging, labelling etc are likely to still occur and simple documentation and processing incurs fees, costs and delays even where difference is not present, including in pharmaceuticals.

Consumers: the likely increased costs to Australian business may flow through in part to increased costs to consumers.

Australian government: no new costs over status quo.

C. If **New Zealand does not change regulation of therapeutic products, from current arrangements,** then the effects on Australia under a permanent exemption will be as follows:

Benefits

Australian business: no change

Australian consumers: no change

Australian government: no change

Costs

Australian business: no change

Australian consumers: no change

Australian government: no change

In principle, under the status quo, Australian production and consumption patterns for therapeutic products, and trans-Tasman trade, will develop according to industry and economy imperatives without impact from regulatory change in Australia and New Zealand under TTMRA affecting this.

Other reviews of existing Australian legislation and regulation of therapeutic products (see footnote 16) have examined this regime. It has been affirmed that it meets the test of benefit exceeding cost and of being the least costly form of meeting the regulatory objectives. Some particular reforms are under consideration by government, but they do not constitute proposals for fundamental system change.

However, there is a strongly expressed view in New Zealand that the regulatory status quo there is "unsustainable"[28], and that permanent exemption Options A and B above are more realistic prospects.

OPTION TWO – HARMONISATION

This is the option that was agreed to by both Australia and New Zealand.

Economic Efficiency Impacts: Quantification

The major prior quantification of the economic efficiency benefits from trans-Tasman harmonisation was provided in the earlier NZIER study which estimated that adding New Zealand's market to Australia's on the same terms as for the existing Australian domestic market could deliver potential one-off productivity benefits for the sector of between 2 to

[28] NZIER, op cit, iii.

3 per cent, or $180-270 million[29]. Despite a total trans-Tasman trade only of the order of $300 million, such productivity benefits are, in principle, feasible if they come from a small percentage scale economy gain applied across domestic as well as export production.

The proposed regulatory changes are expected to have a beneficial impact for Australian industry through a reduction in industry compliance costs. The establishment of a single trans-Tasman market for therapeutic products through harmonisation opens export opportunities for the Australian industry that otherwise might not be feasible. It will no longer be necessary for the Australian industry to maintain resources with expertise in the two separate country regulatory requirements or to submit two separate country applications for marketing approval. It will no longer need to meet two different standards of scheduling of medicines and medical devices, or different labelling, packaging and advertising requirements in particular. A single application for marketing approval can be submitted to the Agency that, once processed, will provide an opportunity for quicker market access in two countries rather than one, thus impacting positively on the company 'bottom line'. Consumers will benefit through earlier access to therapeutic advances and a possibly expanded range of products in the marketplace.

Precision in estimating the economic benefits to Australian industry is not possible due to the lack of readily available and relevant data.

Specific savings have been suggested as follows under harmonisation:

Figure 1 **Compliance Activity Scenarios: Trans Tasman Harmonisation[30]**
Scenario 1: Registration of an OTC medicine in Australia and New Zealand currently involves payment of two registration fees. A single fee would be less than the two separate fees.
Scenario 2: Different regulatory requirements in both countries require that different labelling be produced for many products which are otherwise identical. Harmonisation would reduce those costs to business substantially
Scenario 3: Different regulatory requirements in both countries require that different packaging types or sizes (e.g. different number of dose units per blister platform) be produced for many products which are otherwise identical. Harmonisation makes for much more efficient production processes.
Scenario 4: Regulatory staff required to be maintained in one or both countries to cover different regulatory requirements. A staff saving of 1-2 persons saves each company $100k-$200k annually.

[29] NZIER, op cit.
[30] Source: Australian Self-Medication Industry, correspondence, January 2002.

Scenario 5: Different regulatory requirements in both countries require that advertising be modified to suit each country's unique requirement. A significant saving in business costs can result.
Scenario 6: A joint agency regime would provide the opportunity for companies marketing products only in Australia to also enter the New Zealand market for very little extra investment.
Scenario 7: Under the current arrangements, more lightly regulated NZ dietary supplements are imported into Australia and potentially erode the more highly regulated Australian complementary medicines market. A level playing field would assist Australian industry.

Administrative Efficiency Impacts: Quantification

The Agency will be required to report to both the Australian and New Zealand Governments and to meet any necessary mandatory standards in both countries. Discussions with respective national agencies are aimed at eliminating unnecessary duplication and reducing associated costs.

Over time, harmonisation is expected to move beyond mere adoption of uniform regulatory coverage, standards and processes to embrace reduction or removal of duplication for common systems, where this exists. This provides an option for administrative efficiency gains to be made. Where regulatory systems and associated administrative processes are developed de novo for activities not currently regulated in New Zealand, particular care will be taken to ensure streamlining for efficiency and effectiveness.

As regards transitional issues, the change from TGA to the Trans-Tasman Agency will have significant associated costs for which government has provided funds, some of which is to be recovered from industry (see below under the heading *Funding of the Joint Scheme* in Part 2 of this RIS).

Other Impacts

The issues raised in terms of impact of trans-Tasman harmonisation for therapeutic products on regional and global governmental and industry outcomes are more difficult to quantify but appear to offer the exciting potential for ground-breaking work in developing arrangements that could support future joint regulatory endeavours.

Review of Separate Harmonisation Options

A. TRANS TASMAN THERAPEUTIC PRODUCTS AGENCY

The analysis of benefits and costs for the single joint agency proposed is considered against the current arrangements for TGA and Medsafe, and assumes that pharmaceutical pricing policies and patent policies in each country remain unchanged. The Agency proposal is for comprehensive coverage of the full range of therapeutic products in both countries. However, the precise degree of benefit and cost will vary with the implementation time path adopted and the extent to which opt-out provisions in the Treaty are exercised (see Part 2 of this RIS for an explanation of the capacity of Australia and New Zealand to each determine, in exceptional circumstances, that they will not regulate specified therapeutic products under the harmonised scheme).

Benefits

Australian business: That part of the therapeutic products industry that exports to New Zealand (approximately 2.3% of Australian sales) will benefit from reduced compliance costs due to single applications rather than dual applications and faster turnaround times. This means that industry will only have to face one application and/or evaluation fee to gain access to two previously separate markets - a world first in therapeutic products regulation. Common packaging, labelling and advertising requirements will apply in Australia and New Zealand. This will mean compliance costs to operate in two markets will be lower. These cost effects will vary with the nature of business but may be particularly important for some business types, eg small trans-Tasman export and import firms with a large product range.

Industry will benefit financially from having products on the market earlier with the potential for enhanced profit. All products currently registered only in one country will also benefit from increased market opportunities.

Consumers: It is expected that Australian consumers will gain earlier access to therapeutic products at a reduced cost as industry passes on costs savings and has products on the market earlier.

Governments: In the longer term, if the joint agency helped better establish Australia as a regional centre for therapeutic product regulation, it might also thereby enhance investment, the manufacturing base, and Australia's potential for exporting.

The creation of the joint agency will provide opportunities for suppliers of therapeutic products to consider Australia and New Zealand as a single market. Over time, this would lead to the greater trans-Tasman integration of business operations and strategies, which is one of the aims of CER. This may serve as a 'blue print' for future cooperation in the Asia Pacific region.

With a single regulatory system, Australia and New Zealand are better placed to influence global and regional standards, for example by seeking admittance to fora such as the International Conference of Harmonisation (ICH) process for pharmaceuticals. It might also be the case that other regional countries might seek to join an Australasian system.

Some economies of scale will be available for the regulator through a combined operation and market, and through other synergies such as allowing greater pooling of technical expertise, permitting greater opportunities for career development, flexibility and specialization. [31]

Given the increasing pressure of demand for the high level complex expertise required for approval and registration of therapeutic products, a pooling of scarce and expensive technical expertise within an integrated agency would provide both countries with assistance in addressing this problem in the medium to long term. Other mechanisms will also help greater global co-operation and harmonisation in this field, but a common pressure is evident: "Science is producing new wonder drugs faster than we can work out how to pay for them"[32]

Costs

Australian business: In the short term there will be increased fees and charges to cover some of the transitional costs such as developing an integrated registration system. This would include the cost of government recovering $7 million from industry over a period of 5 years[33]. However there is an "efficiency dividend" from reduced administrative duplication that in principle is available to fund transition with suitable funding arrangements negotiated with government so as to avoid short term hikes and reversals in fees.

Consumers: no new costs to Australian consumers unless any transition costs in excess of short term benefits exist and are passed on to consumers in prices.

Government: full cost recovery principles are stated to apply, so no budget cost to government is involved.

[31] The importance of enhanced regulatory capacity is illustrated in a report on the PBAC decision-making processes. In relation to a decision on a new rheumatoid arthritis drug, Enbrel, it was said that "Biotech drugs are not new. Insulin has been produced in a similar way for more than two decades. What is new is the incredible complexity of many of the drugs. When compared to insulin, the molecular structure of etanercept (Enbrel's generic name) looks like a cruise liner moored alongside a tugboat." Stephen Brook, "Bones of Contention", *The Australian*, February 2-3, 2002, p.24

[32] Ibid

[33] See under Funding the Joint Scheme in Part 2 of this RIS for more details.

B. THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY (ANZFA) MODEL

One alternative option for harmonisation is the model of the previous food authority, ANZFA (now FSANZ). This model was in operation in 2001. An assessment of the benefits and costs of this model follows.

Benefits

Overall, this model will help to remove regulatory barriers to trans-Tasman trade in therapeutic products as it provides a focus for cooperation between governments, professionals, industry and the community in the regulation of therapeutic products.

Business: benefits are likely for a single agency compared with the status quo, but with less guarantee of the degree of harmonisation both in principle and in practice, as the co-operation of jurisdictions is discretionary (not grounded in a legislative commitment) and the implementation is in the hands of separate arrangements that can develop processes that differ.

It will reduce compliance costs for those Australian businesses (manufacturers, wholesalers, retailers) seeking approval to market approved Australian products in New Zealand, because one application and evaluation would suffice for both countries.

Consumers: will benefit to the extent the harmonisation reduces compliance costs and the costs are passed on.

Government: can better meet general CER objectives than with exemption and retain greater sovereignty than with a single agency - though opt-out provisions, if relied upon in the latter do still allow some independence and localisation.

Costs

Australian business: Under the ANZFA model, ANZFA made recommendations to a Ministerial Council regarding food standards, and the Council had to adopt those standards before they were adopted into the law of the various jurisdictions. If this model was followed, the time taken for products to be approved (whether registered or listed) will be extended considerably because the agency could only make recommendations for approval to the Ministerial Council, and it would need to be approved by the Ministerial Council and undertake some administrative step (eg gazettal) before it would have effect. This would take some time as the Ministerial Council would not realistically meet other than periodically.

This would result in a longer time lag between an application and final approval to market, thus reducing the period of profitability, compared to the current regulatory system. This is a highly competitive industry sector, with new products and variations/improvements to devices having ever shorter developmental phases.

Businesses are dependent on an efficient approvals process to get their products to market before their competitors. It is likely that major global producers of therapeutic products, particularly in the areas of pharmaceuticals and highly complex devices, would avoid applying to market their products in Australia and New Zealand.

Consumers: may not have as timely access to products as under either the status quo or a single agency, and will not have potential for as much cost reduction flow through as with a single agency.

Governments: Ministers, as decision-makers, would have a huge workload in determining approvals, as TGA and Medsafe together approve a very high volume of products each year. Even if the Ministers met in Council frequently, their role as regulatory decision-makers would still take up a considerable amount of time away from their main responsibilities. Under the more recent FSANZ food regulatory model, this cost would fall particularly heavily on those Ministers whose portfolios were not in the health area. Ministers' workloads would also be exacerbated if they made decisions in relation to individual approvals and those decisions were appealed against by aggrieved applicants and subjected to administrative review.

The costs of establishing a Board of approximately 10 members, as in the ANZFA arrangements, to regulate therapeutic products would also be substantially higher than a Board of 5 members as proposed under the joint agency arrangements, though this could no doubt be negotiable. Still involving industry and consumer representatives in the approval process, and decision-making at the political level, may lead to more conflicts of interest, giving rise to more appeals against regulatory decisions. These increase the direct cost to governments, as well as to industry, and are thus likely to result in flow-on increases in charges for applications and in consumers paying increased costs for therapeutic products.

SUMMARY OF OUTCOMES FOR EACH OPTION

Figure 3: RIS Summary of Impacts

OBJECTIVE : To review options for regulation of trans-Tasman trade in therapeutic products, so as to enhance trade, industry and health				
Option	**IMPACT ON AUSTRALIAN**			**Likely benefit/comments**
	Consumers	**Business**	**Government**	
1.Permanent Exemption				
A. New Zealand Unilateral	No change in product standards, availability and price in Australia.	Increased compliance costs and marketing competition for Australian firms in the New Zealand market.	Loss of prestige and influence in international regulatory and trade if New Zealand does not recognise Australian approvals.	Minimal impact on Australia.

OBJECTIVE : To review options for regulation of trans-Tasman trade in therapeutic products, so as to enhance trade, industry and health				
Option	**IMPACT ON AUSTRALIAN**			**Likely benefit/comments**
	Consumers	**Business**	**Government**	
B. New Zealand Stand Alone	No change in product standards, availability and price in Australia.	Increased compliance costs for Australian firms seeking market approval in New Zealand.	Some small agency savings through no longer providing free evaluations to NZ.	Minimal impact on Australia.
C. Status Quo	No change in product standards, availability and price in Australia.	No change in compliance costs for Australian business	No change in government impacts for Australia.	Makes permanent the current exemption arrangements.
2.Harmonisat-ion				
A. joint Agency	No change in standards of products. Prices same or small decrease over time.	Enhanced market due to reduced compliance costs and fees for registration in both countries allowing more economies of scale and scope.	Improved economies of scale for regulators, but within full cost recovery environment. Longer term: Maintenance of regulatory capacity by pooling expertise; potential to establish Australia as regional centre for therapeutics regulation.	Removes trans-Tasman trade barriers, and provides greater net benefits for industry, consumers and governments compared to the alternatives considered. Preferred option. Provides greater economic efficiency, administrative efficiency and regional and global status.
B. ANZFA Model	Reduction in timely availability of all products, especially new prescription medicines and advanced devices.	Likely reduced compliance costs for Australian firms seeking market approval for New Zealand. Significant increases in approval times, likely to act as strong disincentive for major global producers to market new products in Australia.	Some reduced duplication in regulatory administration. Possible increases in appeals costs.	While it helps remove trans-Tasman trade barriers, full harmonisation and administrative integration is not guaranteed.

1.6 CONSULTATION

Australian and New Zealand officials have worked closely and consulted widely with stakeholders:

- Consultation was conducted with relevant Australian and New Zealand Government Departments, and the Regulatory Reform Taskforce.

- In June 2000 an initial consultation paper was released in Australia to the Liaison Group for Trans-Tasman Co-operation on Therapeutic Goods, which comprised representatives from the medicines and medical device industries, healthcare professional associations, consumers and key government agencies. 27 submissions were received in response.

- In October 2000, an initial report on the potential economic impacts of a joint Agency was prepared jointly by the New Zealand Institute of Economic Research (NZIER) and Applied Economics and released.

- In mid-2001, a Trans Tasman Project Team of officials from TGA and Medsafe was established, to progress the establishment of a joint agency.

- Industry consultations were held in the latter part of 2001, including a formal meeting in Sydney in December 2001 to discuss the release of a consultation paper prepared by the team entitled "Establishment, Governance and a Proposed Regulatory framework for a Trans Tasman Therapeutic Goods Agency" which was subsequently released on 17 December 2001 to a targeted group of Australian and New Zealand stakeholders. 24 submissions were received in response.

- Input into the development of the RIS that was provided to Government in February 2002 on issues relating to harmonisation was invited by earlier letter (including a survey questionnaire) and by direct follow-up both before and after the December 2001 meeting.

- A meeting with key stakeholders was held in Auckland in March 2002, at which further verbal comment was provided on the proposals - this meeting was followed by focus group meeting with key industry groups to discuss specific aspects of the regulatory framework.

- Based on the outcomes of the stakeholder feedback, a public discussion paper entitled "A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products" was published in June 2002 by the Commonwealth Department of Health and Ageing and sent to over 240 stakeholders. Letters publicising its release and seeking submissions were also sent to all sponsors of therapeutic products on the Australian Register of Therapeutic Goods. Forty written submissions were received from Australian stakeholder groups in response.

Overall, government, industry and consumer bodies are supportive of the proposed single joint agency. Some saw this as being beneficial for trade, while others highlighted the benefits of lower compliance costs flowing from a single entry point for product registration and approval processes. Particular issues raised are being taken into account in the development of the regulatory scheme and its framework.

1.7 CONCLUSION AND RECOMMENDED OPTION

Harmonisation through the establishment of a single joint agency is the preferred option to its alternative - making a special TTMRA exemption for therapeutic goods regulation permanent.

There are a number of key advantages for Australia and New Zealand in creating a joint agency for the regulation of therapeutic goods. A joint agency, involving a high degree of regulatory harmonisation, would:

- deliver greater efficiencies through reducing transaction costs of meeting different regulatory requirements and through reducing duplication where common requirements apply in separate jurisdictions. This will allow in turn improved economies of scale and related synergies which will facilitate trans-Tasman trade through the provision of common regulatory outcomes for the two countries, consistent with the broader objectives of Australia New Zealand Closer Economic Relations Trade Agreement (ANZCERTA). This will deliver improved domestic production and cheaper domestic supply to the extent that cost savings generated by merger efficiencies have any flow on effect other than to those firms exporting to New Zealand;

- deliver public health benefits for both Australia and New Zealand by creating an enhanced and sustainable regulatory capacity in the medium and longer term. This would assist the two countries to meet the increasingly difficult challenge of maintaining necessary regulatory capacity at current or higher standards in the face of the expanding range and increasing complexity of therapeutic products; and address the need to safeguard against a loss of critical mass in a highly technical and competitive field; and

- enhance the influence of each country in regional and global regulatory and trading environments. This would have the benefit of gaining greater global status for industry and global standards responsiveness to Australian local needs. It would also facilitate the potential for Australian standards and processes to influence the determination of global standards, thereby reducing adjustment costs for Australian agencies, industry and consumers.

The option of new permanent exemption arrangements is not a preferred option. It maintains the barriers to trans-Tasman trade in therapeutic goods, and hence forgoes trade and industry development improvement. Nor does it assist with the problems of

keeping up with demand expected from emerging technologies or maintaining regulatory capacity.

Ongoing costs under permanent exemption could actually be relatively higher for Australia than at present if New Zealand were to implement its option for new legislation as a stand-alone agency, or if it were to adopt the new legislation option with unilateral recognition of countries other than Australia. However, were New Zealand to adopt unilateral recognition of Australia, then the ongoing costs to Australia under the status quo would be lower.

Within a harmonisation approach, the ANZFA model is also not a preferred option. Compared with ongoing exemption, it would have the positive effect of trade and industry improvements through reducing regulatory barriers to trans-Tasman trade in therapeutic goods, but with less certainty and commitment than a joint Agency would achieve. It would most likely incur significantly greater costs in time taken for processing recommendations which have to be forwarded to Ministers for decision-making. It would also not deliver the full administrative efficiencies of avoiding duplication and pooling resources, as would a joint Agency. Implementation and enforcement would remain as separate responsibilities in Australia and New Zealand. Nor would it be as convincing to global industry and regulatory networks in terms of enhancing Australia's role or influence.

1.8 IMPLEMENTATION AND REVIEW

The Agreement Between Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (the Treaty) was negotiated in 2003 and signed in December 2003 as a first step towards implementing harmonisation (Option 1) through the establishment of a single joint Agency. The implementation and review of the arrangement agreed to under the Treaty is discussed further in Part 2 of this RIS.

PART 2 – THE PROPOSED TREATY

This second part of the RIS has been prepared to assist the consideration of the Agreement between Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (the Treaty) signed on 10 December 2003.

It analyses the proposed operational arrangements for the Agency provided for under the proposed Treaty under the following headings:

- the governance of the Agency;
- the accountability of the Agency;
- the legislative basis of the joint Scheme;
- merits review of Agency decisions; and
- departures from the joint Scheme.

2.1 BACKGROUND

The principle objective of the Treaty is to safeguard public health and safety in Australia and New Zealand by establishing and maintaining a joint Scheme (the Joint Scheme), consistent with international best practice, for the regulation of the quality, safety and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export or promotion. Therapeutic products comprise prescription medicines, over the counter and complementary medicines, medical devices and other therapeutic products such as some sunscreens and blood and blood components. This part of the RIS outlines the key aspects of the Joint Scheme and analyses the impact they will have when the Treaty enters into force.

The proposed Joint Agency and Scheme

The Treaty specifies that a joint Agency (the Agency) will be established by Australian legislation, in the manner specified in the Treaty, to administer the Joint Scheme. The Agency is expected to commence operation in mid-2005 and will replace the TGA in Australia and the Medsafe Unit of the Ministry of Health in New Zealand.

The Agency will regulate the full range of therapeutic products manufactured or supplied in, or exported from, Australia and/or New Zealand to ensure they meet appropriate standards of quality, safety and efficacy. Its functions will include pre-market evaluation and approval, licensing and auditing manufacturers of products, post-market monitoring and surveillance, the oversight of advertising arrangements for therapeutic products, and the setting and monitoring of standards (eg quality and labelling). The Agency will function on a full cost recovery basis.

The Joint Scheme will be based on a risk management approach, in which the degree of regulatory control would be proportional to the risk associated with use of the product.

Products will be evaluated or assessed according to their risk, ranging from low risk products (most complementary medicines) to higher risk products (prescription medicines, vaccines and implantable devices).

Consistent with current Australian requirements, the Agency will issue product licences, and have the power to suspend and cancel product licences if sponsors breached compliance requirements. Each product will be uniquely identified, consistent with current practice in Australia, to ensure traceability of products in the event of product failure and the need for recalls, and to ensure that only licensed products (unless specifically exempted) are available for supply in Australia and NZ. The Agency will have sufficient enforcement and monitoring powers, including the power to request information, take samples for testing, search premises and seize goods, impose administrative sanctions and refer alleged offences for prosecution.

Reasons for the Joint Scheme

The reasons for establishing the Joint Scheme are set out in Part 1 of this RIS. In summary, by signing the Treaty, the Australian Government has decided that a joint Scheme with New Zealand for the regulation of therapeutic products should be established. It is anticipated that the Joint Scheme will:

- resolve the TTMRA special exemption for therapeutic products regulated under the Joint Scheme;
- meet the overall objectives of the ANZCERTA by facilitating trans-Tasman trade;
- ensure sustained capacity for the regulation of such products in Australia in the present and in the future;
- reduce industry compliance costs by increasing regulatory cost efficiency;
- benefit consumers by increasing the timely availability of therapeutic products potentially at a reduced cost; and
- provide Australia, together with New Zealand, with greater capacity to influence international regulatory policy and standards.

Funding of the Joint Scheme

In the 2003-04 Budget the Australian government agreed to provide $8 million (in the form of $5.4 million in 2003-04 and $2.6 million in 2004-05) for the 'establishment and implementation costs' of the trans Tasman proposal. $5.1 million was provided to the TGA to work in partnership with New Zealand officials to develop the Treaty, establish the joint regulatory framework (including community and industry consultation) and facilitate the establishment of the new agency. The remaining $2.9 million represented Australia's contribution to new financial, administrative and regulatory infrastructure that would be required by the joint agency to operate independently from both governments (to be matched by the New Zealand government). The infrastructure funding was appropriated to the TGA in 2003-04.

In agreeing to provide the additional funding, the Australian government assessed the case for cost recovery from industry. Activities relating to the drafting of the Treaty and

harmonisation were assessed as being in the nature of policy and ought not be recovered from industry (in accordance with Commonwealth Cost Recovery Guidelines for Regulatory Agencies). These activities were estimated to cost $1 million. The government subsequently agreed that the remaining $7 million would be recovered from industry over five years, commencing from 2005-06.

In addition to matching Australia's $2.9 million contribution to the infrastructure needs of the new agency, the New Zealand government has undertaken to resource its officials to participate in the development of the Treaty and the development of the regulatory framework, and has also undertaken to contribute $3.44 million towards a reserve fund to meet the working capital needs of the new agency (effectively matching the estimated balance of the TGA's reserves when the new agency is formed).

The impacts on industry of the changes to cost recovery, including consistency with the Government's cost recovery policy, will be addressed through a Cost Recovery Impact Statement prior to determining the final level and structure of the fees and charges.

2. 2 PROBLEM IDENTIFICATION

The problem to be addressed is the establishment of a workable framework for the harmonisation of regulatory arrangements between Australia and New Zealand. A treaty between Australia and New Zealand is proposed to set out a workable framework for the Scheme, including the method of establishment of a joint regulatory agency, which meets the needs of both countries

2.3 OBJECTIVES

The objective is to address the problem of establishing a workable framework for the Scheme through a Treaty that puts in place a framework for the Joint Scheme that meets the needs of Australia and is acceptable to New Zealand. The Government was advised of some suggested guiding principles for the Joint Scheme:

- both countries are to have appropriate voice in shaping and modifying the joint regulatory Scheme eg by scrutiny by both Parliaments;
- regulatory decisions are to:
  - be based on parallel legislation in both countries;
  - have effect in both countries; and
  - be enforceable in both countries;
- the Joint Scheme is to have at least the same regulatory coverage as that of the current Australian therapeutic goods legislation;
- there is to be a capacity for both countries to 'opt out' of the joint regulatory arrangements in exceptional circumstances in order to safeguard their sovereignty eg where required by differing cultural factors;

- regulatory decisions are to be made by the regulatory body acting on the advice of experts in relevant fields;
- Australia's existing high regulatory standards and international reputation are to be maintained;
- a joint agency is to be created, in accordance with terms set out in a treaty, as a body corporate under Australian legislation but is to be recognised in New Zealand law so that it can operate in both countries;
- the Joint Agency is to be fully accountable to the Governments and Parliaments of both countries and, in Australia, to the same level as the TGA currently is;
- there is to be direct accountability to the Health Ministers of both countries for the performance of the Agency through a governing body which would oversee the administration of the Agency; and
- there are to be common regulatory review and appeal mechanisms suitable for decisions regarding therapeutic products which will have effect in both countries and which are accessible to industry in both countries.

2.4 REGULATORY OPTIONS

Decisions were made when developing the proposal for the Joint Scheme concerning the most appropriate arrangements to be set out in the Treaty for:

- the establishment and governance of the Joint Agency that will administer the Joint Scheme;
- the accountability of the Agency;
- the legislative basis for the Joint Scheme;
- merits review of Agency decisions; and
- departures from the Joint Scheme.

The proposed arrangements agreed to in these areas are explained below, together with an analysis of their costs and benefits, compared to alternative arrangements.

2.5 ASSESSMENT OF IMPACTS

2.5.1 IMPACT GROUP IDENTIFICATION

The groups likely to be affected by the arrangements are:

- Industry – Australian and New Zealand manufacturers, importers, exporters and suppliers of prescription medicines, over-the-counter medicines, medical devices and complementary medicines;
- Consumers – in Australia and New Zealand
- Government –Australian, State and Territory and New Zealand.

2.5.2 IMPACT ANALYSIS

The Governance of the Agency

Background

The Agency's governance arrangements must ensure that:

- there is direct accountability to the Health Ministers of both countries for the performance of the Agency through a governing body;
- Australia's existing high regulatory standards and international reputation are to be maintained; and
- the joint Agency is fully accountable to the Governments and Parliaments of both countries and, in Australia, to the same level as the TGA.

Problem

How best to achieve governance arrangements for a bi-national organisation that meets the needs of both Australia and New Zealand in relation to the making of regulatory decisions and corporate governance.

Objective

To determine governance arrangements for the Agency that meet the needs of Australia and New Zealand with respect to corporate governance of a bi-national regulatory agency.

Option 1

To set out governance arrangements for the Agency in Australian or New Zealand legislation, or both, and not in the Treaty.

Option 2

To set out the governance arrangements for the Agency in the Treaty.

The governance arrangements outlined in the Treaty can be summarised as follows:

- the establishment under an Australian Act of a trans-Tasman therapeutic products **Agency**, in the manner set out in the Treaty, to administer the Joint **Scheme**;
- the establishment under the Treaty of a **Ministerial Council** comprising the Australian and New Zealand Health Ministers to, among other things, oversee and account to both Parliaments for the Agency and the Joint Scheme, and make Rules to give effect to the Scheme;
- the establishment under the Treaty of a **Board** of five members responsible for the finance and administration of the Agency, and its efficiency, effectiveness and strategic direction, and for reporting to the Ministerial Council about these matters; and

- a **Managing Director** to manage the Agency and perform its regulatory functions (in practice, the Managing Director would delegate the power to make certain decisions to persons with appropriate expertise and/or functional responsibility. Expert advisory committees would be established to provide advice to the decision-maker).

Impacts of Option 1

Benefits

This option does not promote a harmonised approach. Governance arrangements could be changed by the Parliament of the country that is to consider the legislation in a manner that may not be acceptable to the other country.

Costs

If these arrangements were outlined in either Australian or New Zealand legislation, or both, the parliamentary legislative process of either country might change those arrangements so that they are unacceptable to the government of the other country or to stakeholders.

The cost of establishing the governance arrangements will be recovered from industry. Industry is likely to pass this cost on to consumers. The funding costs of this option are likely to be the same as for Option 2.

Impacts of Option 2

Benefits

Outlining these arrangements in the Treaty which is to be formally agreed to by both countries will ensure that they are acceptable to both the Australian and New Zealand governments.

Other stakeholders will benefit from having the roles and responsibilities of the Ministerial Council, the Board and the Managing Director, and their linkages, clearly outlined in a single place (the Treaty) which would not be the case under Option 1 if the governance arrangements were outlined in either the Australian or New Zealand legislation.

Costs

With a treaty, both governments would have to agree to changes and the process of negotiating amendments to a treaty would be slow.

The accountability of the Agency

Background

The financial and administrative accountability arrangements for the Agency should provide for no less accountability to stakeholders than for an Australian Commonwealth authority or a New Zealand Crown entity. Accountability arrangements are needed for matters such as:

- planning and reporting requirements to both Parliaments and Governments;
- the submission of annual reports to the Ministerial Council, including audited financial statements for tabling; and
- audits by the Australian and New Zealand Auditors-General.

Problem

The Agency needs to be accountable to government in a way that is acceptable to both Australia and New Zealand.

Objective

To determine accountability requirements for the Agency that are acceptable to both Australia and New Zealand which are cost-effective and with which the Agency can comply.

Option 1

That the Agency be accountable only to the Australian government or to the New Zealand government.

For example, like FSANZ, the Agency could be accountable to the Australian government under the *Commonwealth Authorities and Companies Act 1997* and the Agency, as part of funding and performance arrangements with New Zealand, contracted to provide specified services to New Zealand in accordance with specified performance measures.

Option 2

The accountability arrangements for the Agency outlined in the Treaty.

The Treaty outlines the following principles for the accountability of the Agency:

- it shall be accountable to Australia and New Zealand for the performance of its functions;
- the level and type of accountability for the Agency is that which would normally apply to a regulatory agency established by the legislation of each country; and

- there should be no unnecessary duplication in accountability requirements that apply to the Agency.

The Agency will be fully cost recovered.

The accountability requirements that will apply to the Agency will be set out in Australian or New Zealand legislation, or in the Rules, or in both the legislation and the Rules.

The Treaty specifies that the Agency Board is to provide to the Ministerial Council an annual report on the activities of the Agency and financial statements of the Agency, which will be jointly audited by the Auditors-General of both countries. The Agency will also prepare and provide to the Ministerial Council planning documents, reports, and information as specified in the Rules.

Both Australia and New Zealand may apply to the Agency statutory accountability regimes that apply in the territory of that Party to similar regulatory agencies, but can modify those regimes in a manner consistent with the Treaty, and in particular the accountability principles noted above. The two countries will consult in relation to this.

It is anticipated that the requirements of the *Commonwealth Authorities and Companies Act 1997* (the CAC Act) will be applied to the Agency to the greatest extent possible. Given the joint nature of the Agency and the Scheme there will also be a need for additional accountability requirements to apply to the Agency to accommodate New Zealand's particular needs. It is anticipated, however, that there will be only one set of financial statements to be audited by the Australian and New Zealand Auditors-General.

Impacts of Option 1

Benefits

Option 1 would ensure that there would be no duplication of accountability requirements (eg there would need to be only one audit conducted by a single auditor).

There would therefore be no increased costs due to any duplication of financial statements or auditing.

Costs

As the Agency will be established under Australian law, it is likely, should this approach be adopted, that it would be only the Australian accountability legislation that would apply to the Agency. These costs could be lower than under Option 2.

New Zealand would be expected to have significant concerns with this approach, given the bi-national nature of all other aspects of the Agency, apart from its method of establishment.

Impacts of Option 2

Benefits

Australian industry will be regulated by an Agency subject to the greatest extent possible to the accountability requirements applicable to an Australian government statutory regulatory authority. The planning documents, reports and information to be provided to the Ministerial Council will be publically available and accessible to industry.

The Treaty would ensure that the Agency would be fully accountable to the Governments of both Australia and New Zealand as it would be reporting to the Health Ministers of both countries in relation to its activities and finances. This would enable the Ministerial Council to monitor the Agency's financial operations, and ensure that the Agency performs the activities required of it by both Governments.

It is envisaged that under this option only one set of financial statements would be prepared.

Costs

A key principle of the accountability arrangements for the Agency is that there shall be no unnecessary duplication in accountability (eg reporting) requirements. The circumstances in which there would need to be duplication, given the novel nature of the need for the Agency to report to two Governments, are still being finalised. It is unlikely that there will be a significant increase in the reporting requirements for industry.

There will be some additional costs to government to establish the new accountability requirements, just as there will be costs involved in establishing other aspects of the Agency arrangements.

The legislative arrangements for the Joint Scheme

Background

Australia and New Zealand need to agree to a legislative framework for the Joint Scheme by outlining in the Treaty the framework that will be used.

Problem

The legislative framework needs to meet the following applicable key parameters for the Joint Scheme:

- both countries are to have appropriate voice in shaping and modifying the joint regulatory Scheme eg by scrutiny by both Parliaments;
- regulatory decisions are to:
  - be based on parallel legislation in both countries;

- have effect in both countries; and
- be enforceable in both countries; and

- the Agency is to be fully accountable to the Governments and Parliaments of both countries.

Objective

To determine a workable legislative framework for the Joint Scheme that meets the needs of both Australia and New Zealand.

Option 1

Continued separate legislative arrangements in Australia and New Zealand
ie separate Acts and regulations, with possibly a single set of Orders made by the Managing Director of the Agency to be referenced in both Acts or regulations.

Option 2

The legislative arrangements for the Joint Scheme outlined in the Treaty.

The Treaty provides that the Joint Scheme will be set out in three forms of legislation:

Acts of the Australian and New Zealand Parliaments – to be drafted in the same terms as much as possible;

Rules – to be made by the Ministerial Council before being tabled in both the Australian and New Zealand Parliaments, to be disallowable by either Parliament and, if disallowed by a Parliament, to be of no effect in either Australia or New Zealand; and,

Orders – to be made by the Managing Director, but in other respects to be subject to the same tabling and disallowance requirements as Rules.

The **Rules** made by the MC would contain the details of pre-market application procedures for the major product groups to be regulated – prescription medicines, over-the-counter medicines, complementary medicines and medical devices and other therapeutic products including some sunscreens and blood and blood components. They would also include other components of the regulatory process such as good manufacturing practice (GMP) requirements, product licences, scheduling, advertising, import and export requirements, and fees and charges. The Rules would also set out the details of the expert advisory committees and accountability requirements.

Orders made by the MD would include items such as product quality and safety standards, lists of exempted goods, GMP details, labelling and advertising requirements and lists of substances permitted for use in low-risk medicines.

Australia and New Zealand would commit under the Treaty to legislate to provide that Rules can only be disallowed within a reasonable time from tabling, that they can be disallowed only in whole (and not in part) and that Rules and Orders commence either when they are published (shortly after they are made by the Ministerial Council), or on any date specified in the Rules, whichever is the later date.

The two countries have also agreed that the effect of any disallowance will be prospective only. This arrangement will be reflected in the Rules.

Under this option, a balance will need to be struck between matters to be located in the Acts and matters to be located in the Rules and Orders. For example, substantial offences will need to be in the primary legislation while the bulk of the regulatory requirements will be in the single set of Rules.

Impacts of Option 1

Benefits

There would be no perceived loss of sovereignty to either Australia or New Zealand under Option 1 as neither Government would have to agree that regulatory requirements in a disallowable instrument with which it is satisfied, but with which the other Government is not satisfied, will cease to have effect if that instrument is disallowed by the other country.

There would appear to be no other benefits to industry, consumers or government.

Costs

Separate legislative arrangements could lead to loss of uniformity of requirements resulting in added costs to business in order to comply with two sets of differing requirements eg for product registration and labelling.

Impact of Option 2

Benefits

The arrangements for legislation outlined in the Treaty providethe best chance of establishing truly harmonised regulatory arrangements. Industry need comply with only one set of requirements in both Australia and New Zealand.

Costs

The option would be more costly to the government of the country which assumes primary carriage for drafting the implementing legislation though both countries would have to commit resources to the negotiation and consultation processes. These costs would not be recovered from industry.

There may also be a perceived loss of sovereignty to both Australia andd New Zealand under this Option as both Governments would need to agree that regulatory requirements with which it is satisfied, but the other government is not, will cease to have effect if disallowed by the other country.

Merits review of Agency decisions

Background

Principal regulatory decisions under the *Therapeutic Goods Act 1989* are currently reviewable by the Administrative Appeals Tribunal (AAT) following a statutory internal review process. In New Zealand, an appeal against a licensing decision under the *Medicines Act 1981* is heard by the Medicines Review Committee appointed under that Act. The Medicines Review Committee may confirm, reverse, or modify a licensing decision.

The frequency of cases in Australia is small and there has been none in New Zealand for more than five years, where challenges to decisions are reportedly settled within an informal process of internal review.

New Zealand does not have a centralised administrative review framework equivalent to the Commonwealth AAT system but has a system that is more ad hoc in nature. New Zealand has established individual tribunals to review particular legislation, such as the Human Rights Review Tribunal, the Medical Practitioners Disciplinary Tribunal, and Trans Tasman Occupations Tribunal. The Department of Courts services these bodies.

Problem

The Joint Scheme must provide Australian and New Zealand stakeholders with a right to merits review of the regulatory decisions of the Agency that is acceptable to both Australia and New Zealand.

Objective

To determine a cost-effective mechanism for independent, impartial and transparent merits review of Agency decisions by an appropriately qualified review body in accordance with the rules of procedural fairness, which will result in decisions that will apply in both Australia and New Zealand.

Option 1

A new bi-national trans-Tasman merits review body.

Under this option, there would be a single standing body with membership appointed by the Ministerial Council that would have an appropriate range of expertise, including a

convenor. The convenor would convene a suitably qualified review panel from the membership of the standing body whenever a review was required, and each review panel would operate in accordance with procedures set out in the Ministerial Council Rules.

There would be no diminution of the rights currently available to applicants for review of decisions by the AAT in relation to therapeutic goods. Equivalent decisions under the new Scheme would be reviewable by the bi-national trans-Tasman merits review body. Mandatory internal review of Agency decisions would be provided for before external merits review.

The procedure for reviews (and thus the form of procedural fairness to be afforded to applicants by such a bi-national review body) and membership of the standing body would need to be agreed by Australia and New Zealand.

Regulatory decisions of the Agency would be given effect under Australian and New Zealand legislation. If such regulatory decisions are reviewed, the decision of the bi-national merits review body would be similarly given effect in place of the original decision.

Option 2

Merits review of regulatory decisions by the Agency as outlined in the Treaty.

Australia and New Zealand would legislate to provide for review of regulatory decisions made by the Agency by separate Review Tribunals in each country with panels drawn from a common pool of members. The Australian Review Tribunal would be the AAT, with potentially some additional members with expertise in relevant areas. New Zealand would need to set up a new Review Tribunal.

There would be no diminution of the rights currently available to applicants for review of decisions by the AAT in relation to therapeutic products. Equivalent decisions under the new Scheme would continue to be reviewable by the AAT as it will be the Australian Review Tribunal under this proposal.

There would be a Principal Member for each Review Tribunal. It is proposed that the Principal Member nominated for Australia will be the President of the AAT. The common pool of members of the two Tribunals (known as the "Merits Review Panel") would be established and maintained by the Ministerial Council.

In Australia, the rules of procedure for the AAT that are set out in the *Administrative Appeals Tribunal Act 1975* (and thus the form of procedural fairness to be afforded to applicants) would apply to the Australian Review Tribunal. The rules of procedure for the New Zealand Review Tribunal are expected to be based upon the AAT rules of procedure. New Zealand officials have advised that they are broadly comfortable with adopting much of the procedural requirements from the AAT system.

There will be a capacity to also set out procedural requirements for the two Tribunals in the Ministerial Council Rules. It is envisaged that these would comprise any modifications to the usual procedures that are necessary to take into account the joint nature of the Scheme and enable the two Tribunals to work together cooperatively.

Internal review of Agency regulatory decisions would be mandatory before external merits review. Regulatory decisions of the Agency would be given effect under Australian and New Zealand legislation. If such regulatory decisions are reviewed, the decision of the Review Tribunal conducting the review would be similarly given effect in place of the original decision.

Impacts of Option 1

Benefits

A specialised bi-national review body would have members chosen specifically for their expertise in areas relevant to review of the types of specialised decisions made by the Agency. It would also avoid divergency of approach to decisions that might flow from the establishment of two tribunals proposed in Option 2.

Costs

The costs to government in establishing and maintaining a bi-national body are hard to determine but would probably be significant. Establishing an international tribunal is a difficult task and involves some sensitivities on issues of sovereignty.

There would be costs involved in determining the functions of the new body and its procedural rules, developing and implementing an administrative infrastructure for the new body, and appointing and remunerating both members of the body and administrative support staff. All these matters would also involve significant negotiation with New Zealand.

All stakeholders would incur costs relating to familiarising themselves with the new procedural requirements of a new a body.

Impacts of Option 2

Benefits

Australian stakeholders are familiar with the operation of the merits review scheme proposed by Option 2, as the existing AAT system would be used for the conduct of merits reviews in Australia. They would also be assured of the continued protection afforded by the principles of procedural fairness that underpin the conduct of reviews by the AAT. For example, parties will be able to appeal to the Federal Court from decisions of the Review Tribunal on questions of law (eg on the grounds of bias, or lack of a fair hearing), just as they can at present in relation to AAT decisions.

It is expected that review applicants in Australia would continue to pay the fees applicable under the AAT fee structure.

All stakeholders would benefit from merits review of Agency regulatory decisions by reviewers drawn from a common pool of reviewers with expertise in medicine, therapeutic products, public administration or law - expertise specifically relevant to the review of the types of specialised decisions to be made by the Agency. Stakeholders would also benefit from the experience of the AAT in conducting general merits review.

Government will benefit from maintaining a consistent approach to merits review in Australia by retaining the AAT as the review tribunal for Australia of decisions relating to therapeutic products.

Costs

As the AAT will continue to conduct merits review of regulatory decisions concerning therapeutic products in Australia, there should be no additional cost to the Australian government, other than possible costs relating to the appointment of any additional members of the Merits Review Panel who are not already on the AAT. The appointment of such additional members would, however, need to be approved in accordance with the legislative requirements for appointment to the AAT by the Governor-General.

Departures from the Joint Scheme

Background

The Joint Scheme will achieve the objectives of the TTMRA in relation to therapeutic products as it will harmonise Australia and New Zealand's regulatory arrangements for the great majority of therapeutic products. However, there will still be a need for arrangements within the Treaty for departures by either Australia or New Zealand from the harmonised Scheme in exceptional circumstances.

Problem

Australia and New Zealand must retain the right to unilaterally regulate specified therapeutic products where, in exceptional cases, either government considers this necessary. On the other hand, the actioning of this right should not undermine the efficient operation of the Joint Scheme itself and the benefits that will flow from the harmonised regulation by the two countries of therapeutic products.

Objective

To enable timely and administratively effective departures from the joint regulatory Scheme in relation to specified therapeutic products that will not undermine the operation of the Joint Scheme and which is acceptable to both Australia and New Zealand.

Option 1

Departures from the Joint Scheme to be made in accordance with the arrangements under the *Trans-Tasman Mutual Recognition Arrangement* for exemptions from the operation of that Arrangement.

This would mean that short term departures from the Joint Scheme for a specified therapeutic product or class of therapeutic product would be available by means of a temporary exemption unilaterally invoked by either jurisdiction on the grounds available under the TTMRA (a threat to health, safety or the environment) by means of a regulation. Such a departure could be extended up to twelve months with the agreement of two thirds of the Australian jurisdictions and NZ when the Australian Health Ministers and the New Zealand Health Minister decide upon the future of the exemption. Permanent exemptions for such products would also be available with the agreement of not less than two thirds of all jurisdictions.

Option 2

The arrangements for departures from the Joint Scheme that are set out in the Treaty.

Under these arrangements, both Australia and New Zealand could opt out from the joint regulatory arrangements in exceptional circumstances by means of regulations. The application of the Joint Scheme in respect of a therapeutic product, or class of therapeutic product, could be excluded or modified by legislative action. However, this could only be done by either country if it 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 the party.

The Treaty ensures that the other country can comment on a proposed departure before it occurs, that the Party that made the departure is to keep it under review and consult on the continuing need for it at the request of the other Party, that the Ministerial Council annually review any departures, and make recommendations in relation to them to the two countries where necessary.

It is expected that these arrangements will need some form of exemption from the operation of the TTMRA to ensure that products which are no longer regulated under the Joint Scheme, or to which a modification of the Scheme applies, cannot be imported into the country that has not departed from the Scheme. The States and Territories have been advised of the arrangements proposed in the Treaty and the need for some form of exemption from the TTMRA for them to operate.

Impacts of Option 1

Benefits

Some stakeholders may see a benefit in any departures from the Joint Scheme in relation to particular products or classes of therapeutic products being able to be made only on the grounds available for departure under the TTMRA. These opt out arrangements would maintain the sovereignty of both countries. Parliament would also have the capacity to scrutinise any departures from the Joint Scheme.

Costs

Following the TTMTRA process involves resources costs in consulting the States and Territories.

Impacts of Option 2

Benefits

Departures under these arrangements would be less time consuming and easier to implement administratively than departures under the TTMRA system. They would provide the joint Agency with the ability to deal with exceptional circumstances in a timely and administratively effective manner.

These arrangements assure consumers that therapeutic products can still be unilaterally regulated by their own country to take into consideration any health, safety, environmental or cultural matters specific to that country in the highly unlikely situation where that country considers that such matters have not been adequately taken into consideration by the Joint Scheme.

The opt out arrangements in the Treaty also maintain the sovereignty of both countries. Parliament would also have the capacity to scrutinise any departures from the Joint Scheme as departures would be actioned by means of regulations.

Costs

No additional costs, unless the regulatory arrangements put in place by the country departing from the Scheme to replace the joint regulatory arrangements impose additional costs. Any additional costs of such alternative arrangements would of course depend upon the nature of those arrangements.

2.6. CONSULTATION

In June 2002, Medsafe and TGA distributed joint discussion documents, seeking feedback on the design and role of the proposed agency. A discussion paper entitled A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products was distributed in June 2002 in both Australia and New Zealand. The discussion paper outlined not only the content of the proposed joint regulatory Scheme but possible methods for establishing the Agency and the Scheme in Australian and New Zealand law. The paper included an outline of the proposed content of the Treaty.

Forty Australian submissions were received in response to that paper, including submissions from Medicines Australia, the Consumer Health Forum, the Australian Self Medication Industry, the Medicines Industry Association of Australia, the Complementary Healthcare Council of Australia, the Pharmaceutical Society of Australia and the Pharmacy Guild, and the Australian Consumer and Specialty Products Association. Only three of the Australian submissions opposed the joint Agency proposal and none provided any substantial comment regarding the proposed content of the Treaty.

States and Territories have been provided with a copy of the proposed Treaty through the Standing Committee on Treaties and have provided comments.

The only significant area of concern raised by jurisdictions has been the potential for the Australian Government to use the external affairs power under the Treaty to eliminate the State and Territory role in the scheduling of drugs and poison scheduling. The Government has assured the States and Territories that it has no intention to vary the current role of States and Territories in regulating access to, or the availability of, scheduled drugs and poisons.

Industry is aware that the Agency will fully recover the costs of its activities under the Joint Scheme. Consultation with industry and consumers on the specific amount of fees and charges will occur in 2004-05 prior to the Agency commencing operation.

Consultation conducted prior to June 2002 is described above under the heading *Consultation* in Part 1 of this RIS.

2.7 CONCLUSION AND RECOMMENDED OPTION

That Option 2 for all the key aspects of the Joint Scheme be adopted.

2.8 IMPLEMENTATION AND REVIEW

Exposure drafts of the two Implementing Acts will be released for public comment together with an explanatory document providing details of the proposed Scheme. Consultation will occur on the Rules as they are developed.

Officials from Australia and New Zealand are working on the development of transitional arrangements necessary to achieve the smoothest possible transition to the new legislation underpinning the Joint Scheme established by the Treaty. These transitional arrangements will cover both the regulatory requirements (eg expansion of TGA's current list of substances approved for inclusion in low-risk complementary medicines, to assist New Zealand complementary medicines to qualify for a self-assessed product licence); and administrative arrangements. A new IT data and information base will be developed to support the range of regulatory processes in both countries.

The Treaty provides for a review by Australia and New Zealand of the effectiveness of the Scheme and of the Agency, with a view to agreeing to and implementing any necessary improvements, no later than five years from the entry into force of the Treaty.