

REPORT ON STAKEHOLDER COMMENT

in response to the

Consultation Paper: A Possible Framework for a Joint Trans-Tasman Agency to Regulate Therapeutic Goods (Including New Zealand Healthcare Products)

Medsafe Ministry of Health New Zealand
And the Australian Regulatory Reform Taskforce
October 2000

1 INTRODUCTION

A Consultation Paper titled *A Possible Framework for a Joint trans-Tasman Agency to Regulate Therapeutic Goods (Including New Zealand Healthcare Products)* was distributed to a targeted group of stakeholders in June 2000. In addition to exploring a possible framework for the establishment of a joint trans-Tasman agency the paper sought comment from stakeholders on:

- A set of essential principles developed for a joint agency, and
- The preferred model of a Single Joint Agency.

This report:

- Summarises the range of views expressed by key industry sectors and professional groups in written response to the consultation paper and in public forums,
- Describes the issues raised by the stakeholders,
- Outlines the Project Team's actions in response to these issues.

2 CONSULTATION PROCESS

The Consultation Paper was developed by a combined Medsafe/Australian Regulatory Review Taskforce project team and peer reviewed by the members of the Trans –Tasman Therapeutic Interdepartmental Committee (TTTIDC). The TTTIDC consists of senior officials from Ministries and Departments of Foreign Affairs and Trade, Commerce, and Health from both sides of the Tasman, as well as representatives of the respective Departments of Prime Minister and Cabinet.

The paper was initially distributed to members of the Liaison Group for Trans-Tasman Co-operation on Therapeutic Goods, an existing consultative body that includes representatives from the prescription medicines, over the counter medicines, complementary medicines/healthcare products and medical device industries. The liaison group also has representation from health professionals associations and consumer groups. A five-week consultation period was allowed for the paper. During the consultation period the paper was further distributed to the expert advisory committees to Medsafe and the TGA, to a limited number of Australian and New Zealand government agencies and to a small number of companies who requested a copy of the paper.

3 RESPONDENTS

A total of 27 written submissions were received from stakeholders: 17 from New Zealand (including six from individual companies) and ten (10) from Australia. A list of respondents can be found at Appendix 1.

In addition to members of the liaison group, submissions were received from:

- Five prescription medicines companies in New Zealand;
- A complementary medicines/healthcare products company;
- A New Zealand based consumers group with a special interest in healthcare products; and
- Three government agencies.

4 CONSULTATIVE FORUMS

As part of the targeted consultative process members of the project team held a series of meetings on both sides of the Tasman with representatives from each of the industry sectors and with consumer groups. A large stakeholders meeting to discuss and clarify the proposal put forward in the discussion paper meeting was also held in Sydney on 21 July 2000.

The Australian Department of Industry Science and Resources (DISR) convened a follow up meeting with stakeholders in Melbourne on 10 August to discuss issues raised at the Sydney forum. The key issue for the DISR meeting was the concern that the joint agency would facilitate parallel importation of prescription medicines by third parties who sought to exploit government pricing differentials between the two countries. (The Outcomes Report from DISR on the Melbourne meeting is attached as Appendix 2).

5 FRAMEWORK FOR ANALYSIS

The submissions received have been collated and the key themes extracted and summarised for this report.

Overall Response to a Single Joint Agency

Medicines

The prescription and non-prescription medicines sectors in both countries are open to the concept of a joint trans-Tasman agency, but not supportive of the model proposed. Reasons for their objection to the single joint agency model are primarily around concerns that the single joint agency would encourage parallel importation of products

between the two countries causing significant negative effects on the industry sectors in both countries.

To prevent parallel importation, respondents in the medicines sector would like to see mechanisms for greater separation of markets, given the different pricing and industry policies of the two countries. Companies wish to be able to separately market their products in each country.

The medicines sector generally considered that Model 2, the Licensing Authority, or Model 3; the Technical Advisory Model would address their concerns better than the single joint agency. A number of respondents suggested hybrid models that combined elements of the various models as alternatives to the single joint agency.

Medical Devices

The two medical industry associations provided opposite responses to the single joint agency model. The Medical Industry Association of Australia (MIAA) supported the single joint agency proposal on the condition that it was not based on full cost recovery (and at least would not lead to any additional cost for Australian Industry).

The Medical Industry Association of New Zealand (MIANZ), however, considers that the creation of a single market would upset the status quo where distribution rights for a medical device are country specific. The creation of a single joint agency could lead to consolidation and rationalisation of distribution arrangements for medical devices. Given the market structures, and corporate law requirements in Australia, that at least one director of a company is an Australian citizen, MIANZ believe that creation of a single joint agency would probably lead to centralisation of distribution of medical device products to Australia. The MIANZ proposes, instead, the adoption of a unilateral recognition model that would allow the sale in New Zealand of any product approved in Australia, the US and the EU as a mechanism to increase product quality and safety while maintaining a separate New Zealand market.

Complementary Healthcare Products

The complementary medicines/healthcare products sector supports the concept of a single joint agency but generally opposes the single joint agency combined medicines, medical devices and healthcare products model as proposed in the Consultation Paper. The sector generally argues for the establishment of a separate single joint agency for complementary medicines/healthcare products (lower risk products) that separates the regulation of their products from that of medicines. One Australian organisation representing members of the industry explores and then resolves against the concept of a separate office due to costs, the absence of an international best practice model for those products and the expectation that it would be associated with a reduction in permitted claims and lower capacity to compete with medicines.

One submission calls for a permanent exemption under the Trans Tasman Mutual Recognition Arrangement and asks that New Zealand continue to pursue a similar regulatory regime to the one in place presently.

Consumers

Generally consumers were open to joint regulatory arrangements where the focus is on improved health outcomes for consumers but felt that greater consultation with their members would be required before they could take a position on a model. One New Zealand organisation saw a separate agency for complementary medicines/healthcare products as more appropriate.

Health Professionals

The overall response to the single joint agency from New Zealand pharmacy associations is supportive. There is concern however, that compliance and monitoring activities would be less effective under a single joint agency. Maintaining local staff to perform these activities in each country was suggested as a method of maintaining the efficacy of monitoring activities.

Australian professional associations believe they have not received enough information to either support or reject the single joint agency.

Project Team Response

A number of issues have been raised in this section. Many of the specifics raised, however, are resolved in the discussion of the essential principles (below).

Essential Principles

Respondents are generally of the view that the Essential Principles are acceptable and cover most points. It was emphasised by consumer respondents that implementation of the Essential Principles must ensure that there is no lowering of standards for the quality, safety or efficacy outcomes currently enjoyed by consumers.

Several respondents however did not want to comment on the essential principles until the rationale behind each one was more fully articulated by the Project Team. There is a particular need to more fully articulate the meaning of the principles relating to “enhancing health and safety” and “encouraging industry.”

Some proposals for additional essential principles were made including:

- Optimisation of resources to avoid duplication, increase transparency and accountability, and contain cost;
- An agreed definition of therapeutic goods for both countries.
- An independent statutory office holder; and
- Adequate representation of non-pharmaceutical and non-medical industries on relevant committees.

Payment for activities that relate to “public good” under full cost recovery ‘off budget’ was widely challenged by industry respondents.

Public health and safety

While there was general agreement that enhancing public health and safety was an important goal for a single joint agency, a number of concerns were raised that pursuit of this principle could be used to increase standards or regulation to achieve a better level of public health and safety in contravention of the COAG principles.

A number of respondents also suggested that parallel importation if enabled under the single joint agency Model would threaten the continued stream of innovator medicines for New Zealand and therefore produce a negative effect on public health and safety.

One submission proposed extending the principle of enhancing public health and safety to include the quality use of medicines in the assessment/decision-making criteria. New Zealand pharmacy groups indicated a desire to ensure the continued monitoring of aberrant prescribers, auditing and licensing of wholesalers and quality audits of pharmacies, currently undertaken by the regulatory agency in New Zealand.

Regulatory Approach and Outcome

There is a desire for openness and accessibility to be reflected in the overall approach of any joint agency. There is a general call for international standards should be applied in a uniform, open, transparent and consistent manner. Within the pharmaceuticals sector there was an overall preference by the New Zealand respondents for Medsafe’s regulatory culture over that of the TGA. Several respondents raised questions about how current differences in approaches to subjects such as scheduling and pharmacovigilance activities will be resolved during the creation of a joint agency

Specific comment was made regarding the approach to local health differences, i.e. the needs of ethnic groups, would be approached and resolved. It is considered that this is an issue that requires more detail.

Most of the submissions on this subject, however, concerned regulation of the complementary healthcare sector. Consumer groups were keen to ensure that creation of a single joint agency should not be a “back door” for the importation of poor quality imports, and the main consumer groups support the regulation of complementary medicines under a combined therapeutics agency as proposed for the single joint agency. As consumers take complementary healthcare products with a therapeutic intent several groups believe that the standards that are applied to these products should be on the same ‘level playing field’ as the standards applied to the other medicines with which they compete. Allowable claims for complementary medicines/healthcare products and their promotion are a key issue for regulatory control.

The complementary healthcare sector presents a different perspective on regulation and does not support the views expressed by most consumer groups. Some respondents from

the complementary sector suggest that complementary healthcare products should be regulated under a Fair Trading Act/Fair Practices Act, rather than therapeutic product legislation with no need for an advertising code.

Other complementary healthcare respondents argued for a single joint agency approach based on a simple notification to register products rather than any form of pre-market assessment of safety or efficacy. The notification scheme would permit any product onto the market unless it was already recognised as posing health or safety issues. In this model it was proposed that all products already on the market in each country would be grandfathered by the single joint agency and would become available in both countries automatically. The sector is keen however, to have an 'opt out' from marketing in both countries, (with an accompanying reduction in fee).

Several respondents identified the quality of complementary healthcare products as an important issue. Most respondents from the sector support the application of 'appropriate' Good Manufacturing Practice (GMP) standards to control the quality of complementary healthcare products. Some members of the complementary healthcare sector accept that products that are assessed as having higher risk need to be assessed against the higher standards of pharmaceutical quality GMP. One member of the sector rejects the need for GMP for complementary medicines/healthcare products.

One consumer with a strong interest in these products supported the product notification approach to complementary healthcare products. This same person argued that any regulatory framework which raised compliance costs for the sector will encourage consumers to purchase products, which may be of lower quality than those available in either country, via the Internet exposing the consumer to increased levels of risk.

One consumer group in its response to the discussion paper supported the product notification approach to complementary healthcare products. This same group warned that any regulatory framework which raised compliance costs for the sector will encourage consumers to purchase products, which may be of lower quality than those available in either country, via the Internet exposing the consumer to increased levels of risk.

Governance

Transparency and accountability in all aspects of regulation are seen as vital components in a joint agency and all respondents support these principles. There was a desire for an open and transparent regulatory culture in a new agency and many respondents saw the creation of the single joint agency as a means to widen the role played by stakeholders and consumers on expert committees and in consultative forums on issues of medicines safety and regulation.

The governance framework for the agency is of considerable interest and in particular a number of New Zealand respondents generally sought an "equal voice" in regulatory policy and decision-making. The proposed mechanism that allows either country an 'opt

out' from decision-making, in exceptional circumstances, is acceptable to many respondents as long as the criteria for making this decision are clearly defined.

Particular questions raised concerning the proposed governance arrangements were :

- Whether closer economic relations (CER) obligations could be met while maintaining sovereignty of decision making for each country,
- Whether a joint agency would hinder either country establishing mutual recognition agreements (MRAs) with other parties; and
- Whether a single joint agency would undermine the continued implementation of the EU MRA for medical devices.

Project Team response

The proposed opt-out criteria would allow sovereignty to be maintained. It is not anticipated that mutual recognition processes would be hindered. These agreements take different forms. Sometimes they are negotiated on an agency to agency basis. Higher level agreements, such as the MRA with the European Union are negotiated on a government to government basis. Any current MRAs may have to be amended to reflect the single joint agency as the regulator. Australia's current negotiations on the implementation of the EU MRA for medical devices will be unaffected by the single joint agency project for the present time.

Trade and industry

The “encouragement of industry” principle caused a significant amount of comment. Interpretation of the principle was broad. Respondents suggested that it could encompass anything from “not down-grading” of industry outcomes to enhancement of industry through to policies that facilitate research, development and manufacturing.

Project Team Response

Encouragement of industry would be achieved by minimum, effective and appropriate regulation.

There is support for the principle regarding the encouragement of trade.

However, differences in pharmaceutical pricing and intellectual property are again identified as a concern as in the view of several sectors of the market they have the potential to undermine trade. Prohibition of parallel importing is supported across all therapeutic goods industry sectors.

New Zealand respondents doubt that “encouragement of trade” can be achieved in New Zealand due to Pharmac strategies. New Zealand respondents suggest that the facilitation of trans-Tasman trade in prescription medicines is likely to be in one direction (Australia to New Zealand) as there is very little manufacturing in New Zealand and little product is

being sold by multinationals from New Zealand into Australia. The New Zealand generic houses do see opportunities for themselves, as long as they can have the ability to ‘opt out’ of approval in both countries and seek approval in only one country (with a consequential reduction of fees).

The New Zealand medical device industry also doubts that trading opportunities would be enhanced under a joint agency given the requirement in Australia for companies to have at least one resident director.

Funding

The sector is generally accepting of fees, considering this is the nature of business, but would consequentially expect a high degree of formal accountability by the agency. However, all sectors are reluctant to pay for functions they regard as for the public good (e.g. functions such as compliance and enforcement activities, monitoring, taking regulatory action and international liaison.)

Australian respondents would not accept any increase in fees from current TGA levels and some sections of the New Zealand sector argue that fees set at the TGA level would be uneconomic for New Zealand industry.

The NZ medical devices sector argues that unilateral recognition is a cheaper and more appropriate option for New Zealand (noting that the government is the major consumer of their products). Similarly, New Zealand Government purchasing authority supports this position stating that the unilateral recognition model would offer greater cost savings for medicines purchasing and that less than full cost recovery would deliver greater influence for the New Zealand Government over regulatory outcomes.

Project Team Response

Full cost recovery is current TGA policy and is proposed for New Zealand in the Healthcare and Therapeutic Products legislation. Reviews of cost recovery mechanisms and funding of “public good” activities are currently underway in both Australia and New Zealand.

Pricing and parallel importation

The medicines sector saw the establishment of the single joint agency, as it is proposed in the Consultation Paper, as creating the opportunity for the parallel importation of prescription medicines between the two countries.

Responses to the paper and discussions with representatives of the medicines industry in both countries indicate that they perceive that the motivation in recommending the single joint agency is to open the door for a Pharmac-like approach in Australia. Their rationale is that the exclusion of the 'Pharmac factor' in discussion on joint agency models ignores

an issue that has a significant potential impact on the sector. They believe this skewed the choice for a preferred model towards the single joint agency.

The medicines sector argued that the different pharmaceutical pricing policies in the two countries coupled with a single regulatory decision-making and product approval process would encourage third parties to exploit the price difference.

Should this scenario occur, innovator pharmaceutical companies have indicated that to prevent parallel importing they would protect their more profitable Australian market by withdrawing products from the small New Zealand market. In addition to reducing professional and consumer access to products, such actions would threaten the viability of the New Zealand industry and result in loss of expertise from the pharmaceutical and possible health sciences sectors. As New Zealand is also a significant market for Australian-based manufacturers, the medicines sector argues that the economic effects of parallel importation could affect both sides of the Tasman.

The sector clearly sees the prohibition of parallel importation in both countries as an essential requirement for the establishment of a single joint agency. Industry submissions and discussion at the Sydney consultative meeting indicated that if a mechanism could be found to address parallel importation then the prescription medicine industry would be more open to consider the Single Joint Agency Model.

Project Team Response

The project team has indicated at several meetings that the pharmaceutical pricing mechanisms and medicines industry policies of both countries will remain separate from the establishment of a joint therapeutic goods regulatory agency.

The project team has also noted that a range of current regulatory provisions interact to prevent parallel importation in both countries. These provisions currently operate to place controls over sponsors of therapeutic goods (the entity authorised to manufacture, import or export specific therapeutic goods), wholesalers and pharmacists to ensure that the quality, safety and efficacy of medicines are maintained throughout the distribution chain. The objective of these provisions, consistent with World Health Organisation standards, is to protect public health and to ensure effective monitoring and compliance of product safety.

Some sectors of the Australian and New Zealand Governments have also noted that a potential and unintended consequence of the establishment of a single market for therapeutic goods under a joint agency could be creation of the opportunity for parallel importation between the two countries, if the status quo regulatory provisions are removed. However, the therapeutic goods regulatory agencies in both countries are of the view that the status quo should be preserved in therapeutic goods regulatory arrangements underpinning the joint agency by the establishment of a sponsor licensing scheme.

Such a scheme would be established, consistent with World Health Organisation standards, to ensure that sponsors throughout the distribution chain have appropriate marketing authorisation for approved products to ensure that products are traceable, to prevent diversion and to facilitate product recall. As well as being devised to achieve public health objectives, this regulatory arrangement would continue the status quo arrangement of preventing parallel importation.

The medical device sector also has concerns regarding controls on parallel importation. With respect to medical devices, however, patents for most medical device products are not lodged in Australia or New Zealand. Therefore the issue of concern to the sector is not parallel importation but maintenance of “authorised distribution”. This is not provided for under current Australian legislation. The MIAA proposes the development of an “authorised representative” concept in legislation to ensure the accountability of the sponsor/distributor for the safety of the product.

Intellectual property

Linked with the discussions about parallel importation are the disparities in intellectual property rights and patent term between the two countries. The New Zealand patent protection period may be shorter than that given in Australia, as the Australian legislation allows an extension of the 20-year protection period to be granted in some circumstances. The sector proposes that this difference in patent protection could exacerbate parallel importation issues.

Project Team Response

Discussions with the sector convened by DISR in Melbourne detailed in Appendix 2, concluded that there would be no real difference in the intellectual property protection under a single joint agency as:

- The data protection periods for new chemical entities under the Therapeutic Goods (TG) Act in Australia and the Medicines Act in New Zealand are the same. No change is proposed with the creation of a joint agency.
- An application for product approval under the Australian therapeutic goods legislation can be processed and granted as soon as the data protection period is over. Once the initial patent period has elapsed, intellectual property protection provisions allow the submission of an application for product approval (called springboarding). Where a patent extension is granted a company cannot manufacture in Australia until the end of that period. This restriction on manufacturing does not apply in other countries (e.g. New Zealand) where the patent is not in force, and companies can therefore manufacture products outside of Australia. They can also seek and be granted an Australian Certificate of Pharmaceutical Product (where they are manufacturing in an approved GMP establishment) while the Australian patent protection is still in force.

The proposed single joint agency, and any prohibitions on parallel importation, would not remove the existing right of New Zealand manufacturers to submit an application for approval of a generic product to the TGA, and manufacture that product in New Zealand during the Australian patent protection period.

Advertising

The differences in controls on advertising between the two countries are a concern raised by respondents on both sides of the Tasman. As a consequence of the New Zealand pharmaceutical pricing system the pharmaceutical sector state that the viability of their sector is determined largely by their ability to develop a secondary market outside of government funded pharmaceuticals through direct-to-consumer advertising (DTC). The issue of DTC is separately under consideration by the New Zealand Government, which has yet to indicate its view.

One company commented on consultation with Maori regarding sovereignty issues. It is normal government procedure to undertake consultation with Maori and this has been planned as part of the next round of wider stakeholder consultation if the project is supported.

6 THE NEXT STEPS

The Project Team will present this analysis as part of a report to both the Australian Minister for Health and Aged Care and the New Zealand Ministers of Health, Foreign Affairs and Trade, and Economic Development.

If the two Governments agree in principle to the creation of a single joint agency, a detailed work plan to progress the project and to develop new legislation for both countries will be prepared.

All aspects of regulation including governance and appeals mechanisms, stakeholder participation and the standards that will be applied to medicines, healthcare products and medical devices will be part of the work plan leading to new legislation. It is proposed that the stakeholders be invited to participate in discussions around the development of the new legislation required to establish the single joint agency. This would include involvement in working parties with officials from the regulatory agencies.

In keeping with normal government procedures for new legislation, further consultation with stakeholders including general public consultation would occur before final government approval of a single joint agency is sought and new legislation drafted.

Appendix 1

Respondents (written and oral)

New Zealand	Australia
<p>Researched Medicines Industry (RMI)</p> <p>Non-Prescription Medicines Association of New Zealand (NMA)</p> <p>Roche (NZ) Ltd</p> <p>Astra Zenica</p> <p>Aventis</p> <p>Novartis</p> <p>Pharmaco</p> <p>Douglas Pharmaceuticals</p>	<p>Australian Pharmaceutical Manufacturers Association (APMA)</p> <p>Australia Australian Self Medication Industry (ASMI)</p> <p>Cosmetic, Toiletry and Fragrances Association</p>
<p>Medical Industry Association of New Zealand (MIANZ)</p>	<p>Medical Industry Association of Australia (MIAA)</p>
<p>National Nutritional Foods Association (NNFA)</p> <p>Direct Selling Association</p> <p>International Nutritional Products Association (INPA)</p> <p>New Hope Nutrition (New Zealand importer)</p>	<p>Complementary Healthcare Council (CHC) Australia</p>
<p>The New Zealand Consumers Institute</p> <p>Citizens for Healthy Choice</p>	<p>Australian Consumers Health Forum</p>
<p>Pharmaceutical Society</p> <p>Pharmacy Guild</p>	<p>Pharmaceutical Society</p> <p>Pharmacy Guild</p>
<p>Pharmac</p>	<p>Pharmaceutical Benefits Branch, Dept of Health and Aged Care</p>

	Department of Industry, Science and Resources
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Outcomes Report

Meeting to discuss the impact of a Single Therapeutic Goods Agency for Australia and New Zealand on the medicinal products and medical devices sectors

Thursday 10 August 2000

6.1 Definition of parallel importing

Parallel importing is the importation of a product by a third party who is not the authorised agent of the manufacturer.

Purpose, scope and output of the meeting

The purpose of the meeting was to identify problems which could be created by the formation of single therapeutic agency and ascertain whether they could be resolved. Detailed examination of the problems and appropriate solutions will be the subject of further consultation between industry and regulatory authorities.

Sectoral interests

Representatives from the over the counter medicines (OTC), complementary health care and medical devices sectors expressed broad support for the idea of a joint agency and indicated a preference for a single market.

Representatives from the prescription medicines sector outlined their concerns about any move to a joint agency as detailed in their response to Government. Of the models presented in the discussion paper, they expressed a preference for a joint agency conducting some functions such as evaluation of new medicines (model 3) but were concerned that the formation of any new body would lead to a single market for their products.

The meeting noted the different interests of the industry sectors and agreed that a solution that meets the needs of all sectors will require further exploration.

Single Agency - what are the issues?

- creation of opportunities for parallel importing
- effect on intellectual property rights
- impact on provisions for direct to consumer advertising in both countries

Parallel Imports

How might parallel importing occur under the proposed model?

The formation of a joint therapeutic register may create legal opportunities for parallel importing. Currently, the operations of the Therapeutic Goods Act provide the sponsor of a product exclusive marketing rights in Australia, but under a single system of registration this may not be the case. This may be overcome by altering the registration process to separate evaluation and approval for market, thereby achieving a common regulatory outcome for both countries as well as separate licensing regimes. One method to achieve this goal might be to evaluate and approve products jointly and grant separate licenses to place the product on the market in either country. In any event, the meeting agreed that the role of the sponsor in any joint agency needs to be clarified before proceeding further.

There may also be the potential for parties in the supply chain such as wholesalers and pharmacists to engage in parallel importing with the creation of a single agency. Australian wholesalers and pharmacists cannot engage in re-exportation of products except as an agent of the sponsor for the product. In New Zealand, new legislation will effectively prevent pharmacists from engaging in third party trading but there is nothing to prevent wholesalers from doing so. The meeting agreed this loophole should be closed as soon as possible to prevent wholesalers and/or other third parties from engaging in Trans Tasman re-exportation of prescription medicines. One method suggested to achieve this was to make the wholesaler the agent of the distributor or manufacturer. In view of the ease with which this regulatory change could be implemented, it was suggested that that this issue should be resolved before a final decision is made on a joint agency.

Concerns were raised about the extent to which Australian intellectual property legislation would prevent parallel importation. It was stated that IP laws would not provide a sufficient guarantee against the development of a third party trade in pharmaceutical products. However, given the availability of regulatory mechanisms to prevent this trade it does not appear that it will be necessary to rely on this legislation, provided that these regulations are in place before a final decision is made on a joint agency.

Enforcement issues

It was identified that appropriate enforcement mechanisms are required to ensure parallel importation does not occur under any form of joint agency. Suggestions were presented such as different packaging for Australia or New Zealand or different country registration numbers. However, there was not universal agreement that these were acceptable solutions. Further discussion is required on this issue, including the need for adequately resourced surveillance mechanisms.

Intellectual property rights (IPR's)

Concerns were expressed that the formation of a joint agency might adversely affect the intellectual property rights of pharmaceutical companies in Australia. However, further examination revealed that both Australia and New Zealand intellectual property legislation had similar provisions dealing with generics. The major difference between the two systems was the additional patent term for pharmaceutical products in Australia. Thus, the creation of a joint agency would not change the current situation with regard to the entry of generic pharmaceuticals. However, this remains an issue for further discussion.

DTC and other issues

Differences in regulatory approaches to direct to consumer advertising and clinical trials were identified as potential issues in the formation of a single therapeutic agency. It was agreed that as the process moved forward, consideration would be given to those areas of regulation that would be harmonised and those that could differ. DTC and clinical trials were regarded as areas where each country could continue to maintain separate regulations.