

CONSULTATION PAPER

**A POSSIBLE FRAMEWORK
FOR A JOINT TRANS-TASMAN AGENCY
TO REGULATE THERAPEUTIC GOODS
(INCLUDING NEW ZEALAND HEALTHCARE PRODUCTS)**

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**Medsafe (a regulatory unit of the Ministry of Health)
NEW ZEALAND**

and

the Regulatory Reform Taskforce in AUSTRALIA

Stakeholder Consultation Paper

Introduction

Australian and New Zealand Ministers agreed to explore the viability of establishing a joint agency to regulate healthcare products and therapeutic goods. Late last year, they called for the project to be given priority in the therapeutic goods co-operation programme under the Trans-Tasman Mutual Recognition Arrangement (TTMRA).

The purpose of this Paper is threefold:

- To brief interested parties on four possible joint agency models which were considered by the project group;
- To explain why one model was chosen as the preferred model for further development; and
- To seek comments on —
 - **the essential principles which should underpin any joint agency and**
 - **the preferred model.**

Stakeholders are also welcome to comment on the criteria the project team used to assess possible joint agency models.

A meeting of members of the Liaison Group for Trans-Tasman Co-operation on Therapeutic Goods is planned for 21 July 2000. This meeting will provide stakeholders with an opportunity to discuss their views with project officials.

The Regulatory Reform Taskforce in Australia¹ and Medsafe in New Zealand welcome any comments you may have. Please indicate in your submission if there are any aspects of your response you wish to be kept confidential.

The closing date for comments is **2 August 2000**.

Please send comments to:

For Australia:	For New Zealand:
Regulatory Reform Taskforce P O Box 9848, MDP 88 Canberra ACT 2601 Australia <u>Attention:</u> Graham Peachey e-mail graham.peachey@health.gov.au	Medsafe P O Box 5013 Wellington New Zealand <u>Attention:</u> Susan Martindale e-mail susan_martindale@moh.govt.nz

¹ Responsibility in Australia for exploration of options for a trans Tasman joint agency has been transferred from the Therapeutic Goods Administration to the Regulatory Reform Taskforce which has been charged by the Government to make recommendations on administrative arrangements for health regulation. The Taskforce is located within the Department of Health and Aged Care.

Background

Therapeutic goods (including New Zealand Healthcare Products) have a special exemption under the TTMRA until 1 May 2001. A condition of the exemption is that a trans-Tasman co-operation programme be conducted, where the TGA in Australia, and Medsafe in New Zealand, collaborate to resolve the Special Exemption. Under the provisions of the TTMRA, this can be achieved through mutual recognition, harmonisation or permanent exemption.

Australian and New Zealand Health Ministers have indicated that while no decision has been made on the final outcome of the Cooperation Programme, harmonisation of regulatory requirements is likely to be the preferred option.²

Ministers have agreed to explore the concept of a joint agency, as a way of achieving harmonisation and have established a project to explore the viability of establishing a joint trans-Tasman agency to regulate therapeutic goods (including NZ healthcare products). This project has been given priority on the TTMRA work programme.

This project only extends to regulatory decisions on the safety, quality, timely availability and efficacy of therapeutic goods (including New Zealand healthcare products) and to the implementation of these decisions in both countries.

It is noted that national priorities and approaches have resulted in different health and industry policy outcomes in the markets of both countries. Accordingly, consideration of a joint agency excludes New Zealand 's PHARMAC and the Australian Pharmaceuticals Benefit Scheme from the scope of the paper.

The focus of the project has been on:

- identifying principles which should underpin any joint agency;
- developing criteria for assessing the merits of possible joint agency models, and
- identifying the model that best meets the criteria.

A project team involving TGA and Medsafe staff has now developed options for achieving harmonised approaches.

An interdepartmental steering group, the Trans-Tasman Therapeutics Interdepartmental Committee was established to oversee the project. It is comprised of officials from:

- NZ Department of Prime Minister and Cabinet;
- NZ Ministry of Health;
- NZ Ministry of Economic Development;
- NZ Ministry of Foreign Affairs and Trade;
- Australian Department of Prime Minister and Cabinet;

² 1999 Therapeutic Goods Cooperation Program Report to the Council of Australian Governments including New Zealand (p. 29)."

- Australian Therapeutic Goods Administration, Department of Health and Aged Care;
- The Regulatory Reform Taskforce, Australian Department of Health and Aged Care;
- Australian Department of Industry Science and Resources, and
- Australian Department of Foreign Affairs and Trade.

Closer trans-Tasman regulatory cooperation and the possible establishment of a joint agency have been under discussion with industry, professional and consumer groups for some time. Medsafe and the Australian Department of Health and Aged Care jointly convene a stakeholder forum, the Liaison Group for Closer Trans Tasman Cooperation on Therapeutic Goods. Earlier consultation has included consideration of *A Discussion Paper on Options for Closer Trans-Tasman Cooperation*, 1998.

This Paper presents the further development of thinking on these issues. Your comments will help guide the evolution of the project.

Essential principles which would underpin a joint agency

The purpose of a trans-Tasman agency is to deliver common regulatory outcomes for therapeutic goods including New Zealand healthcare products.

It is proposed that the following essential principles underpin any joint agency. The agency would have to:

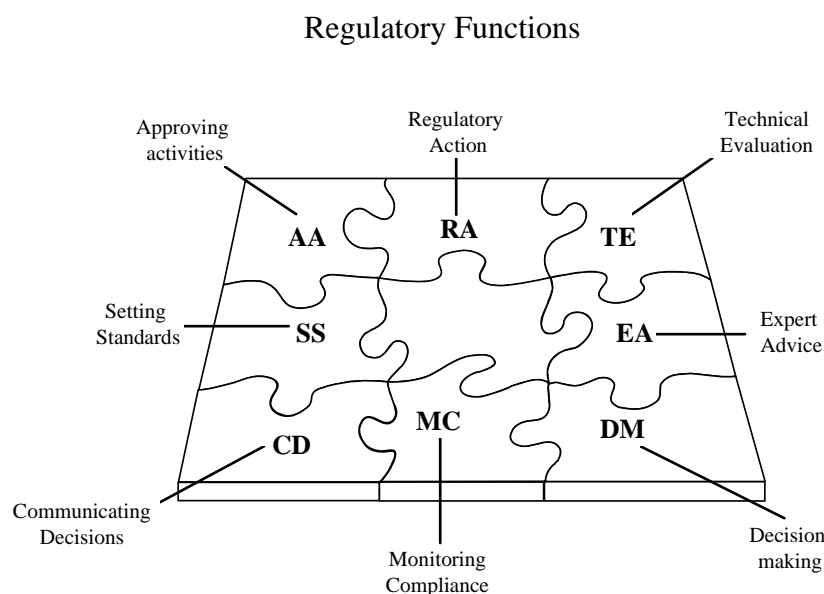
- enhance public health and safety;
- be responsive to the public health and safety needs of each country;
- deliver common regulatory outcomes while taking into account sovereignty issues;
- provide each country with an equitable input to decision-making;
- be directly accountable to both governments;
- facilitate stakeholder input to the development of regulatory policy;
- administer an evidence and risk-based approach to regulation and decision-making that is consistent with the Council of Australian Governments and the New Zealand Code of Good Regulatory Practice principles and is based on international best practice and principles of natural justice; and is transparent, timely and inclusive;
- be influential in global harmonisation decision-making;
- meet domestic and international treaty obligations;
- encourage the development of the therapeutic goods sector in Australia and New Zealand;
- support the export of therapeutic goods;
- facilitate trans-Tasman trade including examination of the scope for the operation of a single market, subject to the industry and health policies of both countries, and
- be fully funded through fees and charges paid by industry.

◆ You are invited to comment on the essential principles.

Derivation of the Models

When developing the models, the project team considered existing arrangements and categorised activities under broad functional groupings.

An overview of the range of functions undertaken by Medsafe and the TGA is shown in the following diagram:



The two agencies have many activities in common but there are some differences. For example, Medsafe is responsible for monitoring aberrant prescribers, auditing and licensing medicine wholesalers and for quality audits of pharmacies. These are activities performed by the States and Territories in Australia. An example of functions performed by the TGA but not Medsafe, is assessing and advising on agricultural and veterinary chemicals. TGA undertakes this work under contract to the National Registration Authority. Assessment in New Zealand is the responsibility of the Ministry of Agriculture and Forestry in conjunction with the Environmental Risk Management Authority.

New Zealand's proposed Healthcare and Therapeutic Products legislation will introduce new controls on medical devices and healthcare products and align the food/therapeutics interface with Australia. This will close, but not eliminate, the legislative and functional differences between the two countries. The models have been developed on the premise that similar regulatory arrangements are in place in both countries.

The range of regulated products would therefore be medicines, medical devices and complementary medicines (healthcare products). This would include specialised medicinal products such as gene technology products and blood and blood products.

All of these products are currently under review in Australia. As a result, further work is required to determine the scope and nature of joint controls.

Using this “functional” approach, four models have been developed for analysis. They are:

Model 1: Single Joint Agency

Model 2: Licensing Authority

Model 3: Technical Advisory Committee

Model 4: Virtual Agency

The four models developed for consideration involve varying degrees of shared responsibility for regulatory functions.

Detailed descriptions of the four models are presented in this paper.

Analysis of Models

The following table summarises the analysis of the four models described overleaf. The single joint agency model performed consistently better than the other three models when it was assessed against the agreed criteria³. This is illustrated in the comparative analysis below.

Criteria	Models			
	Single Joint Agency	Licensing Authority	Technical Advisory	Virtual Agency
Regulatory Approach	Can deliver common regulatory outcomes with 'shared' governance and appropriate stakeholder input. Less complex regulatory interfaces.	Can deliver common regulatory outcomes with shared governance and appropriate stakeholder input. Residual agencies may cause slight confusion over roles, and additional interfaces increase administrative complexity/cost.	Can facilitate but cannot deliver common regulatory outcomes as the decision-making framework, has the capacity to result in different regulatory decisions with no direct stakeholder input. Multiple interfaces increase administrative complexity including separate registers.	Can deliver consistent regulatory approach so trans-Tasman trade is enhanced. However, has potential for confusion for stakeholders due to the piecemeal approach to regulatory activities and complex transitional arrangements Would have separate registers..
Regulatory outcome	Promotes timely and efficient decision-making that is responsive to national needs, and delivers common regulatory outcomes including communication of decisions and safety information.	Promotes timely, responsive decisions that can be communicated to consumers, but levels of service may not be improved.	Common regulatory outcomes may not be able to be communicated to consumers, thereby, unlikely to deliver improved service.	Transfer of information biased against timely decision-making, thereby unlikely to improve level of service and could create barriers to managing national variabilities.
Global Positioning	Strengthens influence on regional and global regulatory policy while meeting trade obligations and taking into account sovereignty issues.	Has the potential to influence global regulatory policy. Meets trade obligations while taking into account sovereignty issues.	Unable to influence regional and global regulatory policy and does not facilitate trans-Tasman trade.	Piecemeal approach cannot influence global regulatory policy. Does not resolve TTMRA obligations.
Cost	Efficient framework enables trade facilitation and improved service levels to fee-paying third parties. Likely to result in fees and charges increasing for New Zealand companies.	Division of functions between three agencies are likely to impose higher costs on fee-paying industry. Likely to result in fees and charges increasing for New Zealand companies.	Inefficient framework results in duplicating operating costs with no impact on trade Likely to result in fees and charges increasing for New Zealand companies.	Not cost-effective due to duplication of activities. Trade potential is reduced due to weakened international reputation. Likely to result in fees and charges increasing for New Zealand companies.

³ The criteria are described in Appendix 1

Communicating decisions Regulatory action

Examples of activities relating to these functions are:

- developing regulatory policy;
- approving products using a risk-based approach to assessment;
- auditing and licensing activities such as manufacturing and packing;
- approving clinical trials (subject to the approval of local ethics committees);
- setting product standards and issuing Codes of Practice;
- determining access restrictions for medicines (scheduling);
- administering regulatory controls on advertising;
- pharmacovigilance activities and safety monitoring of medical devices;
- product testing (all product types);
- export certification, including under the World Health Organisation (WHO) certification scheme;
- communicating regulatory decisions and safety information through written publications and electronic media;
- coordinating recalls (with local office involvement to liaise with local companies);
- administering border controls on narcotic and psychotropic substances and reporting to the International Narcotics Control Board (INCB). (The joint agency structure would also permit the “NZ office” to perform additional INCB functions currently performed by the States and Territories in Australia), and
- enforcement activities.

Once a joint agency was legally established, it would perform the full range of activities for new products seeking to enter the market. All decisions would be based on a unified set of guidelines. To facilitate the smooth operation of the new joint agency, the agency would also manage the phasing-in of products already approved in one or both markets. Phasing-in would take place over a three to five year transition period based on pre-agreed procedures.

Organisational risk management processes would be used to balance competing budget demands. In an environment which would otherwise have an in-built bias towards improving levels of service to industry, risk management would ensure that post market functions were given adequate attention. Examples of post-marketing functions include reporting adverse reactions to medicines and medical device incident monitoring.

The joint agency would be responsive to national needs by ensuring that approval mechanisms include a conditional approval in defined circumstances. Specifically, this would allow conditions to be placed on a medicine approval to meet the needs of one country

Similarly, scheduling decisions would continue to allow jurisdictions to vary access where this is necessary to meet local needs.

Organisational form and governance

The joint agency would be responsible for the full range of regulatory functions in both countries including the implementation and enforcement of decisions. It would replace the TGA in Australia and Medsafe in New Zealand. It would be established as an entity which would be given legal recognition by both countries, possibly through a Treaty, in order to ensure that there was a binding obligation on both parties.

Offices would be established and maintained in each country to provide a local point of contact with the joint agency. This would facilitate the handling of media enquiries, Ministerial correspondence and technical and regulatory enquiries from local stakeholders.

Personnel based in each country would be directly employed by the agency on the same terms.

Each country would have shared input to decision-making, regulatory policy development, and operation of the joint agency through an executive committee comprising the Minister of Health of each country, or a nominated delegate, and a statutory office holder). The statutory office holder would be the Chief Executive of the Joint Agency. The statutory office holder would be accountable to the Ministers of both countries for the day to day running of the Agency and for its performance and functions. The Chief Executive would provide an annual written report to Ministers. The Executive Committee would be accountable for the outcomes of the Joint Agency decisions.

Stakeholders, including industry and consumers, would have input to decision-making, as appropriate, and regulatory and administrative policy development through stakeholders consultative fora.

Monitoring of the joint agency would be the responsibility of the Ministers of Health through their respective departments or Ministries.

The agency would be fully funded through fees and charges from industry (third party revenue) linked to negotiated agency performance standards. Financial arrangements would operate on an accrual and trust account basis. This would include contestable arrangements to improve cost efficiency and accountability through service level agreements with internal and external service providers.

Decision-making

The joint agency would deliver common regulatory outcomes through transparent decision-making processes. These processes would be required to meet statutory timeframes and would be underpinned by quality assurance mechanisms such as peer review, use of standard operating procedures and International Standards Organisation accreditation.

The agency would utilise expert advisory committees with experience of the health system in each country. These advisory committees would consider technical reports prepared by agency staff or external evaluators and make recommendations to the statutory office holder. The statutory office holder would be the decision-maker.

Market authorisation decisions would be notified in the Australian and New Zealand Government Gazettes. Twenty-eight (28) days would be allowed for either country to opt out of the regulatory decision in extra-ordinary and pre-agreed circumstances according to criteria to be established. The “opt out” provision would recognise that there may be public health and safety issues relevant to one but not both countries.

Developing and implementing a subsequent (different) decision for one country could be undertaken by the joint agency by agreement between the relevant Minister and the Chief Executive Officer.

In the event of an “opt out”, the relevant Minister will publish a statement of reasons for the decision.

Time-lines would be established to resolve the resultant variation between the Australian and New Zealand approaches.

Applicants would have access to common appeal and review arrangements as the initial mechanism for dealing with appeals against technical decisions. Reviewable decisions would be set out in the enabling legislation and agreement reached on a higher appeal authority. There are precedents - in the TTMRA and in the *Treaty between Australia and New Zealand Establishing a System for the Development of Joint Food Standards* - for recognising the Australian Administrative Appeals Tribunal.

Transitional Issues

Transitional arrangements would be required to deal with a range of issues including:

- Standards setting;
- Changes to existing products;
- Policy for the nomenclature of pharmaceutical substances;
- Evaluations in progress and applications received by Medsafe and TGA before the commencement date of the joint system;
- Harmonising approved particulars such as indications and dosage for medicines already on the market;
- Setting access standards (scheduling) in both countries;
- Appeals against decisions made prior to the commencement date;
- Committee membership and processes;
- Development of a common policy framework for the release of official information;
- Application of advertising codes in both countries;
- Commitment to existing Treaties and Agreements;
- Representation or acting as agent of both Governments, at international fora, or for the purposes of interactions with other agencies (e.g.; WHO, INCB) or bilateral or multilateral arrangements with other countries;
- Development of agency procedures;
- Data conversion to create a common database;
- Staffing and staff training, and
- Fees and charges, banking and GST.

Managing the transition

All expert advisory committees would be in position from the agency's commencement date and be ready to handle applications. The agency would also manage a transition programme to phase-in the regulation of products already on the market in one or both countries. It would also phase-in applications submitted to national agencies before the commencement date. For most regulatory functions, the transition phase would be short. Activities such as surveillance and monitoring could commence immediately although it may be necessary for the agency to apply the old "national rules" during the transition phase.

The most complex issue to be resolved would be harmonisation of approved particulars for medicines already on the market. The planned introduction in New Zealand of a five-year product licensing regime for medicines would, however, facilitate harmonisation of details such as indications and dosage regimes. The regime would enable a phased implementation. Australia is also considering the introduction of a periodic review of approved products. Harmonised particulars would continue to be phased in through the changed medicine evaluation process. In addition to considering the requested change, the sponsor would be expected to deliver a harmonised set of product particulars. These activities would need to be adequately resourced to ensure that pre-agreed service levels to industry were maintained.

The treatment of applications already submitted to national agencies before the commencement date would be facilitated by harmonisation of guidelines in the run up to inception of the joint agency. They will also have the legislation underpinning the establishment of the joint agency deem those applications to be received by the joint agency.

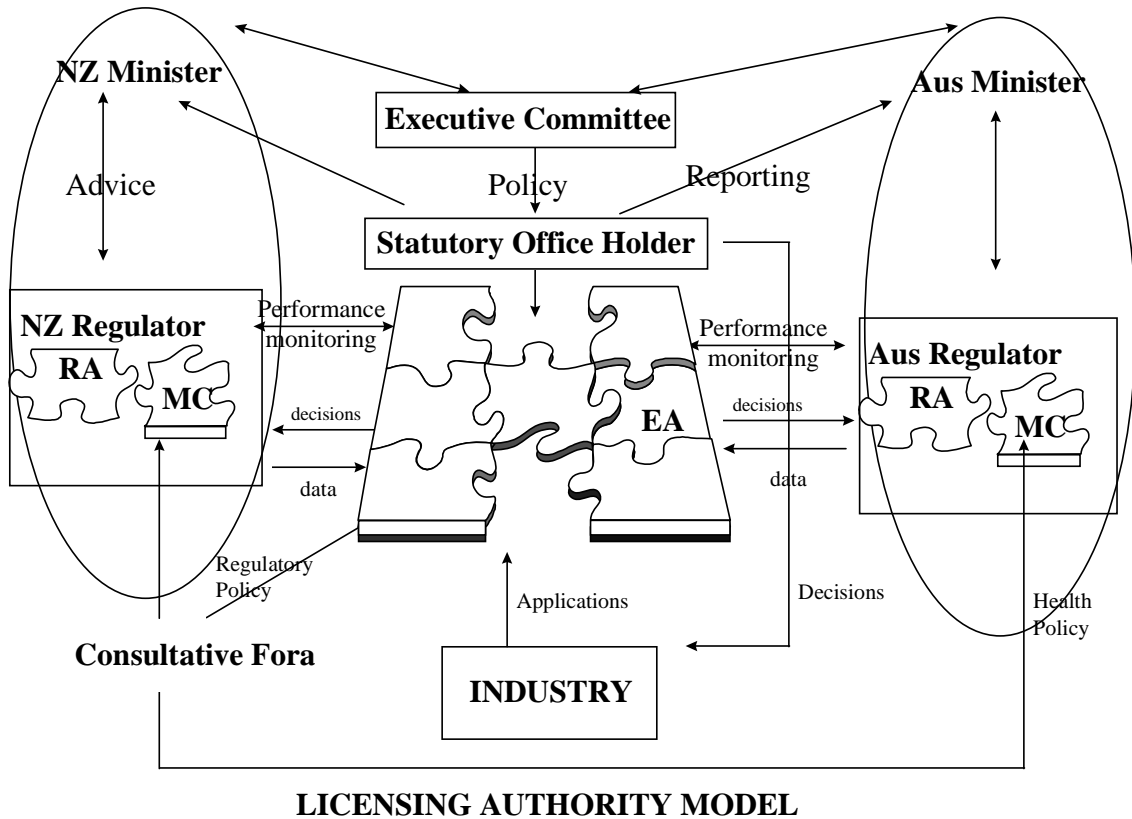
Applications would then be processed under the joint agency transitional procedures. The procedures would need to specify how applications entering the system at different stages of completion should be treated from both a technical and timeframe perspective.

The joint agency would use a single product register and database from commencement date. This would require the adoption of agreed common nomenclature and data conversion of the two national sets of data currently in use. Australia is currently developing software for a comprehensive regulatory database which could be populated with the common data set. As product registration dates will vary between the two countries, data protection periods will also vary over the first five years of the operation of the joint agency. Management processes will need to be put in place to manage data protection issues. Trade implications such as parallel importation also need to be managed.

Any appeal against decisions made by TGA or Medsafe would need to be resolved with that organisation. The establishment legislation would specify that the appeal mechanisms in both countries prior to joint agency inception would remain in place

until the appeal period had expired and would then be replaced by the new joint agency appeals system.

Model 2: Licensing Authority Model



Functions and characteristics

The agency would be responsible for the regulatory functions associated with market authorisation:

- Technical evaluation
- Expert advice
- Decision-making
- Setting standards
- Approving activities
- Communicating decisions

Examples of activities which relate to these functions are:

- approving products using a risk-based approach to evaluation
- revoking marketing authorisation for products
- administering expert advisory committees providing advice on medicines, medical devices and complementary medicines and healthcare products
- determining access restrictions for medicines
- setting standards for products and issuing Codes of Practice

TGA and Medsafe would retain the regulatory functions:

- monitoring and compliance;
- regulatory action; and
- enforcement.

They would also collect and analyse local pharmacovigilance and safety monitoring of medical devices data. TGA and Medsafe would also monitor the performance of the Licensing Authority.

Organisational form and governance

The Licensing Authority would be established as an entity which would be given legal recognition by both countries but would not replace the national agencies TGA and Medsafe. It would be responsible for a more limited range of functions than the Single Joint Agency Model described as Model 1. The Authority would undertake most pre-marketing approval processes with post marketing activities remaining with the national agencies.

Personnel based in each country would be directly employed by the Licensing Authority on the same terms.

Each country would have shared input to decision-making, regulatory policy development and the operation of the Licensing Authority for those functions that are shared. Decision-making would be through an executive committee comprising the Minister of Health of each country, or a nominated delegate, and a statutory office holder. The statutory office holder would be the Chief Executive of the Licensing Authority. The statutory office holder would be accountable to the Ministers of each country for the day to day running of the Authority and for its performance and outputs. The Chief Executive would provide an annual written report to Ministers. The Executive Committee would be accountable for the outcomes of the Authority's decisions.

Stakeholders, including industry and consumers, would have input to regulatory decisions, and as appropriate, regulatory and administrative policy development through stakeholder consultative fora.

Monitoring the Licensing Authority would be the responsibility of the Ministers of Health through the national agencies. National agencies would have only indirect access to, and very limited influence over, the licensing authority.

The Licensing Authority has an in-built bias towards jointly regulated activities. Therefore organisational risk management processes would be required to ensure the rigorous implementation of post marketing functions (such as medicines adverse reactions and device incident reporting) that remain with the residual national agencies to support the monitoring and review of Authority decisions.

The agency would be fully funded through fees and charges from industry (third party revenue) linked to negotiated agency performance standards. Financial arrangements would operate on an accrual and trust account basis. This would include contestable arrangements to improve cost efficiency and accountability through service level agreements with internal and external service providers.

Decision-making

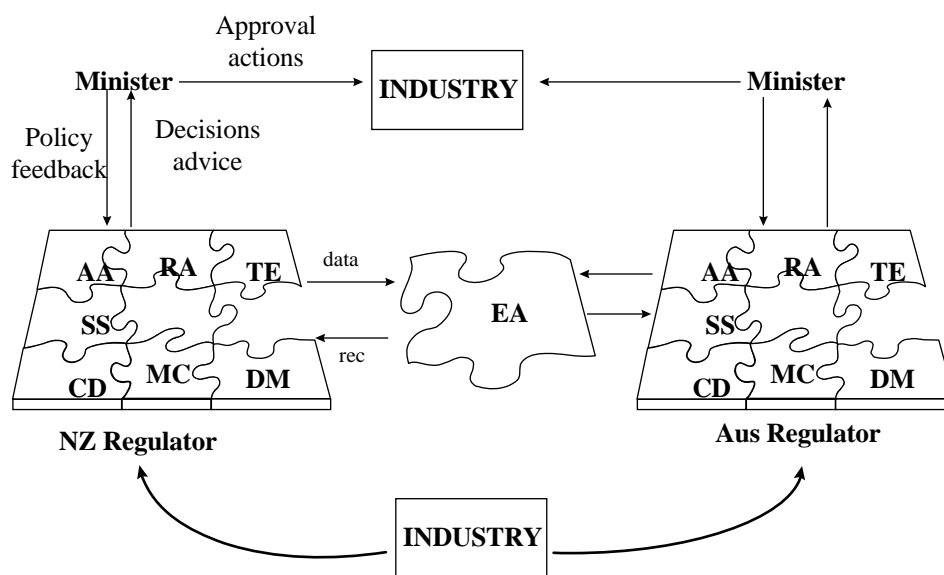
The process for decision-making would follow that described for the Single Joint Agency Model except that the national agencies would be consulted about decisions on market authorisations for products, the licensing of activities and access restrictions (scheduling) of medicines. National agencies would input local monitoring data into the decision-making process.

Transitional issues

The Licensing Authority would need to be established by formal agreement between each country and underpinned by national legislation to provide a mandate for the Authority to perform its regulatory functions.

There would be a similar range of transitional issues to be managed as for the Single Joint Agency model with the added complication of how to apportion funding derived from industry fees and charges between the Licensing Authority and the residual national agencies.

Model 3: Joint Technical Advisory Model



JOINT TECHNICAL ADVISORY MODEL

Functions and characteristics

Under this model the only joint functions would be “expert advice”.

A joint technical advisory model would provide expert advice on regulatory activities such as:

- assessing the safety, efficacy and quality of medicines and medical devices based on evaluation reports received from national agencies;
- assessing the safety of complementary medicines and healthcare products;
- setting standards for products;
- determining access restrictions for medicines (scheduling), and
- monitoring adverse reactions to medicines and medical devices.

The joint technical advisory model would consist of a joint secretariat supporting a number of expert technical committees. The committees would comprise of Australian and New Zealand members appointed for their technical expertise or, where appropriate, their ability to provide a consumer or industry perspective to the committee deliberations.

Organisational form and governance

Under this model, the national regulators, the TGA and Medsafe, would retain responsibility for all other regulatory functions. This includes decision-making,

technical evaluation, monitoring and compliance, setting standards, approving activities, communicating decisions and regulatory actions.

To manage the interface between the national agencies and the joint technical advisory Secretariat, each national agency would need to:

- prioritise applications;
- employ a small pool of evaluators to provide expert input into initial assessment and prioritisation of applications;
- retain sufficient technical expertise to peer review the recommendations of the joint technical advisory committees and provide advice on whether they should be accepted or rejected;
- process appeals against the decisions of an expert committee or that the regulatory body, and
- establish a central secretariat to provide administrative support for the expert committees.

The key role of the joint technical advisory committees would be to provide expert advice based on technical evaluation reports provided by national agencies and to issue recommendations to accept or decline the application.

This model facilitates, but does not deliver, common regulatory outcomes because both countries retain independence of decision-making powers (which reside with the national regulator) and could therefore accept or overrule the recommendations of the committees.

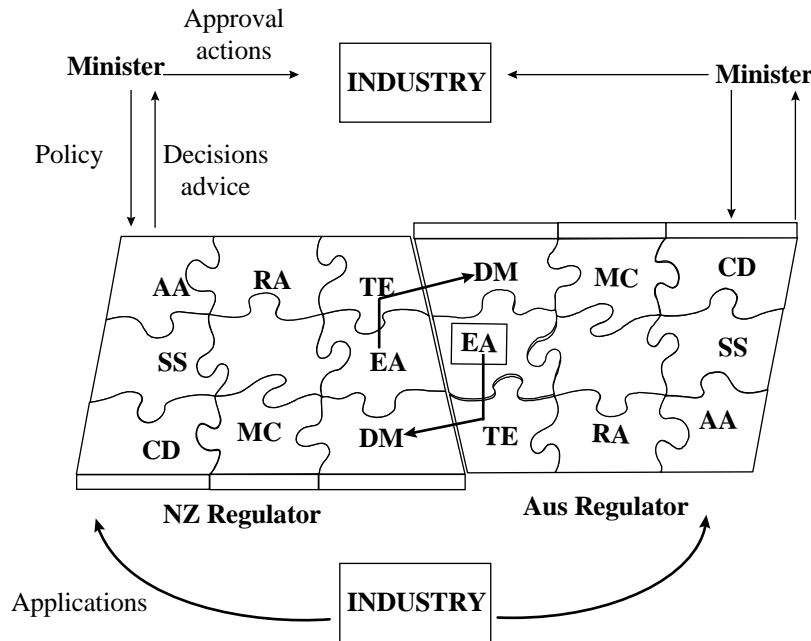
The role of monitoring joint technical advisory Secretariat and committees could be performed by either the national regulators or another external agency.

Transitional Issues

The joint technical advisory Secretariat would be established to handle both incoming new applications and those already received but not evaluated from commencement date. Applications which had been partly or completely evaluated by national agencies or their expert committees, before commencement date, would continue to be handled by those agencies and committees during the transition phase.

The establishment of an efficient data matching system and a database within the joint technical advisory Secretariat would be necessary to ensure that national agencies and the Secretariat could share information about products and processing times.

Model 4: Virtual Joint Agency



VIRTUAL AGENCY MODEL

Functions and characteristics

The virtual agency would be responsible for a broad range of functions:

- Technical evaluation
- Expert advice
- Decision-making
- Monitoring and compliance
- Setting standards
- Approving activities
- Communicating decisions
- Regulatory action

Organisational form and governance

Rather than the establishing a new agency, this model is based on the concept of reallocating functions between the current national regulators, Medsafe and the TGA. Reallocating functions would mean that each national agency would lose some functions to the other and that specialist functional units would be created in each agency.

Each country would retain sovereignty over decision-making but with an enhanced probability of reaching the same decision. This is because each national agency would base its decision on the technical and conformity assessments performed by the other agency. The model would therefore deliver a limited form of mutual recognition.

Transitional Issues

The virtual agency model would need to be underpinned by legislation in each country to authorise the reallocation of functions. Transition issues to be managed would include:

- re-assignment of staff within or across agencies to match the allocation of functions;
- financial management processes to identify the costs attached to particular functions and allocate the appropriate revenue to functional units within each agency; and
- inter-agency arrangements for monitoring the performance of the functional units.

◆ You are invited to comment on the preferred model (Model 1: single joint agency).

Commentary

A report on the progress of the project and the views of stakeholders will be presented to the Australian and New Zealand Ministers of Health at the end of the consultation period and following analysis of the submissions.

TGA and Medsafe will continue to liaise with industry and professional organisations, consumers and other interested parties to facilitate open discussions on these issues.

The following criteria have been used to assess the merits of possible models for a joint agency.

Regulatory Approach

The proposed model has the capacity to:

- utilise an optimal regulatory model;
- influence international regulatory policy e.g. ICH, CIOMS;
- facilitate trans-Tasman trade including examination of the scope for the operation of a single market, subject to the industry policies of both countries;
- maintain public and professional confidence in medicines regulation;
- develop and maintain national competencies and expertise in therapeutics regulation;
- enable orderly transition from existing regulatory arrangements to those established under the new agency;
- be underpinned by appropriate legislative arrangements;
- allow transparent decision-making procedures that enable sufficient public input to decisions; and
- be responsive to the Governments of both countries.

Regulatory Outcomes

The model has the capacity to:

- enhance public health and safety;
- make decisions within an acceptable timeframe;
- maintain, or improve, the level of service to the sector;
- provide useful and appropriate information for consumers;
- facilitate trans-Tasman trade; and
- identify and manage national variability in drug use or disease distribution.

Global Positioning

The model allows each country to meet its requirements with respect to:

- Closer Economic Relations;
- multilateral trade obligations; and
- maintaining sovereignty of decision-making.

The model allows the agency to be recognised in the international arena as a leading regulatory agency with a role to play in determining global policy in medicines regulation.

Cost

Impact of the model on:

- international trade;
- the pharmaceutical sector;
- domestic and Trans-Tasman markets;
- on export potential;
- fiscal impact on Government; and
- cost-effectiveness.