



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Consultation Paper

Fees and Charges under the Australia New Zealand Therapeutic Products Regulatory Scheme

May 2006

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PURPOSE OF THE CONSULTATION

Prior to the establishment of the Australia New Zealand Therapeutic Products Authority (the Authority) the Joint Agency Establishment Group (JAEG) wishes to consult the therapeutic products industry in both Australia and New Zealand on the proposed approach to fees and charges under the joint regulatory scheme.

To inform this consultation, this paper contains information on:

- the Authority's cost recovery policy objectives and relevant Australian and New Zealand government cost recovery policy;
- the cost base that will need to be met by the Authority; and
- the details of the fee proposals that are currently being considered.

The purpose of this consultation is, therefore, to obtain feedback from the therapeutic products industry about:

- the proposed fee options and their potential impact on specific industry sectors in both Australia and New Zealand;
- features of existing fees and charges regimes that the industry wishes to see retained; and
- features of existing fees and charges regimes that the industry considers need to be changed.

HOW TO MAKE A SUBMISSION

You are invited to provide written comment on this consultation paper. Submissions can be sent by post or email and, where possible, should be structured to address the specific proposals set out in the consultation paper. In addition, we encourage you to provide other comments that will assist in developing the detail of the cost recovery arrangements and the schedule of fees and charges for the Authority.

Content of submissions

Your submission should include:

- name and full contact details (including email address), company name and designation of submitter, and industry sector. A form for providing this information can be found at www.anztpa.org/consult/submission-form.dot;
- comment on the proposals set out in the consultation paper;
- any other relevant information (for example, technical, economic or business information to support the view being expressed); and
- identification and discussion of any perceived omissions or alternative approaches not included in the consultation paper.

A **quick response form** has been prepared for those who wish to provide feedback, but may not have the time to prepare detailed submissions. The quick response form is available at: www.anztpa.org/consult/consdocs1.htm#fees

In addition, a **submission template** is available at www.anztpa.org/consult/consdocs1.htm#fees to assist those wishing to provide detailed comment on specific proposals.

Confidentiality of submissions

If you wish any information contained in a submission to be treated as confidential, please clearly identify the information and outline the reasons you wish it to be treated as confidential.

Address for submissions

Electronic submissions should be emailed to:

consultation@anztpa.org

Hard copy submissions should be sent to one of the following addresses:

ANZTPA Fees and Charges Consultation
c/- Joint Agency Establishment Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

ANZTPA Fees and Charges Consultation
c/- Joint Agency Establishment Group
Medsafe
Ministry of Health
PO Box 5013
Wellington
NEW ZEALAND

Questions relating to submissions

Any questions relating to submissions should be directed to the Project Officer, by email at:

consultation@anztpa.org

Deadline for submissions

The deadline for receipt of submission is **Tuesday 15 August 2006**

PART 1: CONTEXT AND BACKGROUND

Establishment of the Australia New Zealand Therapeutic Products Authority

1. In December 2003 the New Zealand and Australian Governments signed an Agreement¹ to establish a joint therapeutic products agency and regulatory scheme. The primary objective set out in the Agreement is to manage the risks to public health and safety from avoidable harm associated with the use of therapeutic products. The Australia New Zealand Therapeutic Products Authority (ANZTPA, the Authority) will be established to regulate the manufacture, supply, import, export and promotion of therapeutic products for Australia and New Zealand.
2. The Agreement provides for the establishment of a Ministerial Council (comprising the Australian Minister of Health and the New Zealand Minister of Health) to oversee implementation of the joint scheme, and an agency to administer the scheme. The Authority is to replace Medsafe in New Zealand and the Therapeutic Goods Administration (TGA) in Australia.
3. Both Governments have agreed that the costs of the regulatory scheme administered by the Authority will be fully funded through fees and charges paid by industry participants. The Agreement therefore provides for the Authority to set fees and charges in connection with the performance of its regulatory functions, with the approval of the Ministerial Council.
4. The legislative framework required to bring the joint regulatory scheme into existence and put the Agreement between the Australian and New Zealand governments into effect involves:
 - an Australian Bill and a New Zealand Bill, each to be considered through the respective country's Parliamentary process. Ratification of the Agreement will occur following passage of the legislation in both countries;
 - a single set of Ministerial Council Rules that will provide the detail of the regulatory framework. The Rules are legislative instruments and will only take effect following consideration by the Parliaments in both countries (that is, the Ministerial Council Rules may be "disallowed" in either Parliament); and
 - a set of Managing Director's Orders that define specific technical standards that will underpin the regulatory scheme.
5. The Authority's cost recovery arrangements will be set out in a Rule made by the Ministerial Council.

¹ *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.*
(<http://www.anztpa.org/about/treatytext.pdf>).

6. This consultation document sets out the proposals for cost recovery under the joint regulatory scheme and should be read in conjunction with the draft *Australia New Zealand Therapeutic Product Regulatory Scheme (Medicines) Rule* and the draft *Australia New Zealand Therapeutic Product Regulatory Scheme (Medical Devices) Rule* available at www.anztpa.org/consult/consdocs1.htm. It describes the policy framework in relation to cost recovery, the current Australian and New Zealand cost recovery mechanisms, and the issues to be considered in developing the cost recovery arrangements under the joint scheme.
7. The proposals in this paper are based on the proposed regulatory scheme detailed in draft Ministerial Council Rules. Any changes to the proposed regulatory scheme will impact on the proposals in this discussion paper.

Value of therapeutic product markets in Australia and New Zealand

8. The retail value of the therapeutic goods market in Australia in 2003-04 was estimated at around A\$11 billion², including A\$7.8 billion in pharmaceutical medicines, A\$1 billion in complementary medicines and more than A\$2 billion in medical devices. A further A\$3.6 billion of medicines and medical devices are sold overseas, representing Australia's third largest manufactured export. The sector has been estimated to employ around 17,000 people.
9. It is estimated that the New Zealand therapeutic products market is around NZ\$2 billion. This includes an estimated NZ\$900 million in pharmaceuticals and NZ\$700 to NZ\$800 million in medical devices.

Regulatory framework for therapeutic products

The current regulatory framework

10. Currently, therapeutic products are regulated in Australia under the Therapeutic Goods Act 1989 and, in New Zealand, under the Medicines Act 1981.
11. In both countries, the regulatory framework for prescription and over-the-counter (OTC) medicines is similar. Sponsors must obtain pre-market approval for products. In Australia, a product must (unless exempted) be entered on the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in, or exported from, Australia. In New Zealand, sponsors must (unless exempted) obtain consent for distribution of a product before it can be supplied in New Zealand, but consent is not required for products that are only for export.
12. Pre-market approval and entry on the ARTG is also required for medical devices and complementary medicines in Australia. Since 2003, medical device suppliers in New Zealand have been required to enter details of the medical devices they supply on an electronic database. There is, however, no current requirement for pre-market approval.

² Department of Industry, Tourism and Resources fact sheets and industry profiles; Industry association websites.

13. Most complementary medicines are currently sold in New Zealand as dietary supplements, which are regulated under food legislation administered by the New Zealand Food Safety Authority. There is no requirement for pre-market approval of these products.

The proposed regulatory framework

14. Under the proposed joint regulatory scheme, pre-market approval, in the form of a product licence, will be required for all therapeutic products (prescription and non-prescription medicines, complementary medicines and medical devices) supplied in or exported from Australia or New Zealand, unless the product or supplier is specifically exempted from this requirement. Therapeutic-type dietary supplements will be regulated as therapeutic products, with therapeutic claims able to be made for approved products.
15. The Authority will also be responsible for standard setting, auditing and licensing manufacturers of therapeutic products, post-marketing monitoring and enforcement activities in both countries, and for administering controls on advertising and access to unlicensed therapeutic products.
16. The Authority will not be responsible for administering controls relating to therapeutic products in the supply chain, such as controls on wholesaling, retailing, dispensing or prescribing medicines. These functions will remain the responsibility of the States and Territories in Australia, and the Ministry of Health in New Zealand.

Cost recovery under existing legislation

17. In Australia, the costs of regulating therapeutic products are fully recovered from industry. The TGA employs approximately 450 staff, mainly in Canberra. Costs of around A\$68 million are recovered through industry fees and charges each year.
18. Medsafe currently has approximately 50 staff, of which 35 are engaged in regulatory activities that will fall under the joint regulatory scheme and will therefore transfer to the Authority. The remainder are engaged in Medicines Control functions that will remain with the Ministry of Health.
19. Medsafe has a projected annual operating budget of approximately NZ\$6.6 million for those functions that will transfer to the Authority. Approximately NZ\$3.5 million is expected to be recovered through fees, with the New Zealand Government funding the balance. Although not implemented, full-cost recovery for the regulation of therapeutic products has been contemplated in New Zealand since the early 1990s.

Transitional arrangements

20. Transitional arrangements are proposed to allow products being lawfully supplied in Australia or New Zealand prior to commencement of the scheme to continue to be supplied during a defined transition period. At commencement of the joint scheme, the Authority will issue interim product licences authorising the continued supply of these products, in one country only, generally for a period

of three years. Where the same product was being supplied in both countries, two separate interim product licences will be issued – one to the Australian sponsor and one to the New Zealand sponsor.

21. During the transition period, sponsors will need to apply for an ANZTPA product licence and provide evidence that they meet all the requirements of the regulatory scheme. An ANZTPA product licence will authorise supply in both countries. Hence a sponsor supplying an identical product in both Australia and New Zealand may wish to seek an ANZTPA product licence at the earliest opportunity after the Authority commences operations. A fee may be payable for any evaluation work required to be undertaken by the Authority in granting ANZTPA product licences.
22. Similarly, manufacturers lawfully manufacturing products in either country prior to commencement will be able to continue manufacturing products during the transition period. Manufacturers will have two years to apply for a full ANZTPA manufacturing licence and will be required to show, before the end of the following year, that they meet Good Manufacturing Practice (GMP) requirements.
23. For applications made under existing legislation and still in progress when the Authority commences, the sponsor will be able to choose whether to have the application determined under that legislation (in which case a single-country interim product licence will be issued) or to resubmit the application under the joint regulatory scheme (in which case an ANZTPA product licence authorising supply in both countries will be issued). Where an application is resubmitted, it is expected that any fee already paid by the sponsor will be able to be applied against the fee payable to the Authority. Further details relating to transitional fees are set out in Section J in Part 4 of this document.

Other activities performed by the Authority

24. While the Authority will primarily regulate therapeutic products in both countries, either Government may request that the Authority perform additional functions in respect of one country or the other. The Authority may also undertake other activities, such as international training or laboratory services.
25. As these functions will not be part of the joint regulatory scheme, their costs will not be recovered through fees under the joint scheme. As they do not form part of the proposed joint scheme, such functions are not discussed further in this paper.

PART 2: COST RECOVERY

Section A: Policy Objectives

26. The Australian and New Zealand governments have determined that the Authority should recover the full cost of its activities through industry fees and charges³. In setting fees and charges, the Authority must take account of the cost recovery policies of both Governments, having regard to equity and efficiency in the cost recovery arrangements. Fees will, therefore, be based on the Authority's cost of performing assessment, evaluation and audit activities in respect of a particular sponsor or manufacturer. An annual charge will apply to licences held by both sponsors and manufacturers, to recover the cost of post-market activities (such as monitoring and enforcement of compliance with standards) that are not easily linked directly to individual products or companies.
27. Both the Australian and New Zealand governments have issued guidelines for Government agencies setting fees and charges. Although there are some differences between the New Zealand and Australian guidelines, such as differences in terminology, they are generally similar in substance.

Australian cost-recovery guidelines

28. The Australian Government has issued the *Financial Management Guidance No. 4 - Australian Government Cost Recovery Guidelines*⁴, which provide a framework to assist agencies to design and implement appropriate cost recovery arrangements. These guidelines are intended to ensure that agency arrangements improve economic efficiency and result in the users of regulated "products" bearing the costs of that regulation (the "user pays" principle). However, cost recovery is not warranted where it is not cost effective, or where it would be inconsistent with policy objectives or would stifle competition and industry innovation.
29. Key principles underpinning the Australian Government's guidelines for cost recovery are:
- Cost recovery arrangements should have clear legal authority and should not be vulnerable to challenge as amounting to taxation;
 - Cost recovery arrangements should be transparent, with cost recovery revenue clearly identified in agency financial statements and budget documentation;
 - Cost recovery arrangements should have sound economic underpinnings and should not be undertaken solely to raise revenue for government activities;

³ Article 15 of the *Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products* (<http://www.anztpa.org/about/treatytext.pdf>).

⁴ Available at www.finance.gov.au/publications/.

- Cost recovery should be undertaken on an activity basis, rather than applying to the agency as a whole or, where it is efficient to do so, applied to groups of activities with similar characteristics or objectives;
 - Where functions are undertaken for the Government which are directly linked to service and product delivery they should appropriately be included in agency charging;
 - Information that is provided for the 'public good' or that has substantial spill-over benefits should be taxpayer funded;
 - Administrative costs of regulation should be included in the charges recovered so that the regulated product includes the full cost of regulation;
 - Charges for products and services should, as closely as possible, reflect the costs of providing the products/service. Efficient costs should be used where possible;
 - Fees for services should be used wherever possible. Where this is not feasible or would be inconsistent with agency objectives, levies may be used; and
 - Significant cost recovery arrangements should have appropriate mechanisms to promote consultation with stakeholders.
30. Australian agencies are required to review their cost recovery arrangements periodically, and at least once every five years. As part of its review, each agency needs to consult with stakeholders and prepare a Cost Recovery Impact Statement (CRIS). The preparation of the CRIS should include the results of stakeholder consultations.

New Zealand cost-recovery guidelines

31. Principles for cost recovery by New Zealand government agencies are set out in *Guidelines for Setting Charges in the Public Sector* issued by the New Zealand Treasury in December 2002⁵.
32. The principles for the assessment of charging options are similar to those in Australia. In particular, the application of cost recovery should be consistent with agency objectives and should be both economically and cost efficient.
33. The New Zealand guidelines call for the options for user charges to be assessed against the following objectives:
- encouraging decisions on the volume and standard of services demanded and supplied that are consistent with the efficient allocation of resources generally, and the outcomes the Government is seeking for the service;
 - minimising the cost of supply in the short term;
 - keeping transaction costs low, and evasion at acceptable levels;
 - reducing reliance on funding from general taxation (with its associated costs);
 - dealing equitably with the taxpayer (industry), those who benefit from the output, and/or those whose actions give rise to it; and
 - looking for new ways to lower costs.

⁵ Available at www.treasury.govt.nz/publicsector/charges/.

34. As part of the assessment of cost recovery options, New Zealand agencies are required to assess whether the services provided by the agency have the characteristics of a public, club, private or merit good. In identifying who should pay the costs it is also necessary to identify who contributes towards the risks that are being addressed through regulation. The implication is that those contributing to the risks should contribute toward the cost of regulation.
35. The New Zealand guidelines recommend the use of 'Memorandum Accounts' to assess whether the level of fees is resulting in over- or under-recovery of regulatory costs. The objective is to adjust fees only where long-term trends emerge (i.e. over a five year period) and avoid frequent changes in fees, resulting from short-term volatility in agency costs.
36. It should also be noted that before assessing and applying cost recovery principles, New Zealand government agencies are required to explore whether the regulatory services should be provided by the agency, in full or part, or whether activities can be outsourced to other government agencies or to the private sector.

Capital user charges

37. Government cost recovery guidelines in both countries support the idea that efficient cost recovery charges should include provision for the opportunity cost of capital (sometimes called the user cost of capital). The opportunity cost of capital is an economic concept that represents the rate of return on an entity's capital required to justify the provision of that capital in the medium to long term. It is the equity equivalent of the interest rate charged on money borrowed and recognises that, in providing equity capital, the owner has foregone the opportunity to invest the capital elsewhere. The opportunity cost of capital is often made explicit by the imposition of a capital user charge. This document has been prepared on the assumption that capital user charges will not apply to the Authority, and consequently the fees and charges proposed in the document do not include provision for the opportunity cost of capital.

Section B: Existing Cost Recovery Arrangements

Australia

38. Government policy has required the TGA to recover the full cost of activities within the scope of the *Therapeutic Goods Act 1989*. The TGA commenced partial cost recovery in 1990 and moved to full cost recovery in 1998-99.
39. Cost recovery is undertaken on an industry sector basis, with fees and charges paid by both sponsors and manufacturers of products. Different schedules of fees and charges apply to the following industry sectors:
 - Prescription medicines;
 - Non-prescription medicines that undergo pre-market evaluation by the regulator (mostly OTC medicines) – known as 'Registered' non-prescription medicines;
 - Non-prescription medicines that do not undergo pre-market evaluation by the regulator (including most complementary medicines) – known as 'Listed' non-prescription medicines;

- Medical devices; and
- Blood and blood products.

In addition fees are payable for the licensing of manufacturing facilities and the approval of advertisements for non-prescription medicines in certain types of media.

40. All TGA fees and charges are prescribed in regulations made under the *Therapeutic Goods Act 1989*, the *Therapeutic Goods (Charges) Act 1989* and the *Therapeutic Goods (Medical Devices) Act 2000*. The current fee schedule can be obtained from www.tga.gov.au/docs/html/fees05.htm.
41. **Pre-market fees** are paid by an applicant who wishes to:
 - Register or list a product on the Australian Register of Therapeutic Goods (ARTG) so that it can be marketed in Australia or exported;
 - Obtain a licence to manufacture therapeutic goods for supply in Australia; or
 - Vary an existing registration or licence.
42. The level of the pre-market fee is linked to the cost of the regulatory activity, which in turn is a function of the level of risk associated with the product. Accordingly, the 2005/06 fee for the evaluation of a new prescription medicine, which requires a high level of evaluation input, is A\$182,900 per submission (which can include multiple strengths and dose forms) whilst the fee for listing a non-prescription medicine, which involves no pre-market evaluation and is a largely automated process, is A\$500.
43. A number of fee reductions are available in relation to essential medicines that may otherwise be non-economic for marketing in Australia (for example, the Orphan Drugs Program). Abridged fees also apply where regulatory effort can be reduced through mutual recognition and information exchange with foreign regulators (for example, Conformity Assessments of medical devices and manufacturers).
44. **Annual charges** apply for each product registered or listed on the ARTG, and for each licensed manufacturer. The revenue from annual charges is used to fund post-market and regulatory scheme support activities (for example, adverse reactions monitoring, product testing, product recalls, complaints about advertising, auditing licensed manufacturers, providing regulatory advice). Annual charges vary depending on the product group, broadly reflecting the level of activity undertaken. For a high-risk biologic prescription medicine the annual charge is A\$3,630 whilst the annual charge for a lower-risk complementary medicine is A\$540. Exemptions from annual charges are available in specified circumstances.
45. A mandated review of the TGA's cost recovery arrangements was recently completed. A summary of the Cost Recovery Impact Statement (CRIS) outlining the TGA's cost recovery arrangements and incorporating the findings of the cost recovery review, including industry views, is available at www.tga.gov.au/about/cris0505.htm.

New Zealand

46. Medsafe is funded from a mixture of Crown funding and revenue from fees. Fees are charged for pre-market approval of prescription and non-prescription medicines and for auditing and licensing medicine manufacturers. The fees have not been increased since they were set in 1991 and most are set well below cost recovery levels. Medsafe has recently consulted with industry on a proposal to increase fees to cost recovery levels from 1 July 2006. The proposed schedule of fees can be found at www.medsafe.govt.nz.
47. While the fee to accompany an application for approval of a new innovative medicine is currently NZ\$15,300 (inc. GST), it is proposed to increase the fee to NZ\$122,625 from July 2006. The fee for a new generic or over-the-counter medicine is currently NZ\$7,800 (or approximately 50% of the current fee for a new innovative medicine). It is proposed that the fee for a new generic medicine will increase to NZ\$43,875, while the fee for a new over-the-counter medicine will decrease slightly to NZ\$7,650. The New Zealand legislation does not provide for the approval of lower-risk products without full evaluation by the regulator.
48. The Medicines Regulations 1984 provide for the Director-General of Health to waive or refund fees, having regard to the time taken to consider an application and the complexity of the application, and taking into account the interests of public health. Fee waivers in relation to applications for approval of new medicines (for example, for orphan or low turnover medicines) are considered on a case-by-case basis.
49. The fee to accompany a notification of a change to an already approved product made under Section 24 of the Medicines Act 1981 is currently set at NZ\$1,600. However, the Director-General of Health has approved a fee waiver for changed medicine notifications which reduces the fee to NZ\$400 for notifications of minor changes (where the evaluation workload is small) and NZ\$200 for self-assessable changes. It is proposed to increase the fee specified in the legislation to NZ\$3,200 from 1 July 2006, with the Director-General of Health granting fee waivers to NZ\$800 for minor changes and NZ\$400 for self-assessable changes.
50. Pre-market approval is not required for medical devices and there has been no fee for placing medical device details on the notifications database established by Medsafe. Similarly, there is no pre-market approval required for products sold as dietary supplements.
51. The fee for a licence to manufacture medicines is NZ\$3,800. This fee is intended to cover the cost of the auditing and licensing activity, but is currently set well below cost recovery. It is proposed to increase this fee to NZ\$13,750 from 1 July 2006.
52. There are no annual charges for approved products or manufacturers. The costs of post-market regulatory activities are met from funding provided by the New Zealand Government.

Section C: Cost Recovery under the Joint Regulatory Scheme

53. Both governments have agreed that the Authority is to be funded by fully recovering the costs of its regulatory activities through fees and charges (see paragraph 27). The Authority will be funded by fees for processing new licence applications and variations to existing licences, and through annual charges for maintaining a licence. Whilst fees should reflect the actual cost of providing the service, annual charges will be used to recover costs of regulatory and administrative activities that are unable to be linked to particular products or companies.
54. Full cost recovery from industry is already well established in Australia. However, regulatory costs for the New Zealand industry will rise, given that the complementary medicine and medical device sectors are not currently subject to any cost recovery, and that prescription and non-prescription medicine sectors are subject to partial cost recovery only.
55. Government cost recovery guidelines in both countries provide for full cost recovery of regulatory activities, including monitoring compliance, enforcement, industry information and education, and regulatory policy and parliamentary services related to maintaining the regulatory scheme. The Authority's cost recovery arrangements will need to take account of these principles.
56. The enabling legislation and Rules made by the Ministerial Council will provide the legal authority for fees and charges to be levied in both countries and will require cost recovery arrangements to:
- recover the full cost of the scheme in an efficient and equitable manner; and
 - provide incentives for the timely and efficient determination of applications by the Authority.
57. Given the requirements in the Agreement and the two governments' cost recovery guidelines, the Authority's cost recovery arrangements will incorporate the following features:

Cost reflective	The regulatory fees (particularly pre-market fees) should be linked to the cost of providing the service as closely as possible. Where charges or levies are imposed, the revenue generated should be consistent with the total cost of activities performed. The cost should reflect the risk presented by the product.
Equitable	The cost recovery arrangements should avoid cross subsidisation between industry sectors and individual companies to the extent that it remains efficient to do so.
Incentives for timely assessment	Incentives should be established to encourage timely assessment by the regulator. Incentives should not be confused with Priority Assessment, which will be determined by the Authority based on its assessment of public health benefit.

Incentives for compliance	There should be incentives in cost recovery arrangements that result in compliant companies incurring lower fees than those who are non-compliant or require a higher level of regulatory effort. The fees imposed will still reflect the actual regulatory cost/effort.
Cost-efficient	The cost recovery arrangements should be simple to understand and be administratively efficient for both the regulator and the regulated industry.
Predictability	The cost recovery arrangements should be predictable to assist the regulated industry with its business planning and avoid fluctuations in fees and charges from year to year (medium term approach).

58. The fees and charges framework should be transparent to stakeholders and be subject to ongoing consultation. It is intended that industry will be able to scrutinise the fees and charges applied by the Authority on an ongoing basis, building on existing consultative arrangements established with industry, such as the TGA's Industry Consultative Committee and Medsafe's Industry Liaison Group.
59. The fees and charges framework should also be subject to periodic review to assess continuing compliance with the cost recovery policies applying in both countries, and to validate pricing levels. Australian cost recovery guidelines recommend that such reviews be undertaken at least every five years, though persistent under or over-recovery of costs may give rise to earlier review. As noted later in this document, it is expected that detailed costing reviews will be undertaken for each major programme on a rolling basis, with such reviews involving industry consultation.

PART 3: JOINT REGULATORY SCHEME COST ESTIMATES

Section A: The Authority's Cost Base

60. The Authority needs to ensure that its fees and charges provide a sustainable financial base over the three-year transition period and beyond. Accordingly, a four-year financial forecast has been developed to estimate the Authority's costs over that period, taking into account the product numbers and activity levels predicted to occur as the result of the formation of a single trans-Tasman market for therapeutic products.
61. The cost of the joint scheme will largely be a function of the regulatory tasks performed and the expected activity volumes over the three-year transition period and beyond. A number of important assumptions need to be made in order to predict the likely impact of structural changes in the market following implementation of the joint scheme. Such changes could result from rationalisation (when two identical or similar product approvals are converted to a single product licence), and from the ability to in future lodge only one application to obtain an ANZTPA product licence authorising supply of a product in both countries.
62. The assumptions used in predicting costs for the Authority are set out below. While these assumptions have previously been 'tested' with industry representatives in both Australia and New Zealand, estimates for medical devices and complementary medicines are less certain because these products have not previously been subjected to pre-market approval in New Zealand. In the case of complementary medicines, there is no detailed information about the number of products on the market in New Zealand or the degree of product crossover between the existing Australian and New Zealand markets.

Licence and activity volumes

63. The assumptions compare the predicted number of approved products and activity levels for applications under the joint scheme with current product and activity levels in the Australian market, where all therapeutic products require pre-market approval and accurate figures are available. The estimates are deliberately conservative to avoid unrealistic revenue forecasts. The estimates will be closely monitored during the transition period.
64. The assumptions used are as follows:
 - The volumes of new applications and variations for **Prescription and OTC medicines** are expected to be **5% higher** than the current volumes in Australia alone. This reflects an estimated 65-70% product overlap between the Australian and New Zealand markets.
 - Activity volumes for **complementary medicines** are expected to **increase by 10%** compared with current volumes in Australia. This

increase is expected to come from two sources – new innovative products from New Zealand companies and new products from Australian manufacturers taking advantage of the wider range of substances able to be included in Class 1 medicines as a result of the expanded permitted ingredients list to be available under the joint scheme.

- Changes in application volumes for **medical devices** are more difficult to predict because a process of transition to a new regulatory scheme in Australia is already underway and may not be complete on commencement of the joint scheme. Volumes will be dependent on the rate at which Australian registered and listed devices transit to full licences (prior to October 2007) and the rate at which New Zealand device sponsors obtain full ANZTPA product licences during the first three years of the joint scheme. It is predicted that the introduction of regulatory costs for New Zealand device sponsors will mean that the total number of new applications received each year by the Authority after completion of the transition will be around **the same** as the number currently received in Australia.
- The number of **manufacturer inspections** is not initially expected to increase above current levels in both Australia and New Zealand, but will gradually **increase** as additional complementary medicine manufacturers in New Zealand obtain manufacturing licences. It is assumed that there will be **no increase** in overseas audit and pre-clearance activities.

65. The numbers of product licences and manufacturer licences, and thus the expected annual licence revenues, are influenced by:

- the extent of product cancellation as a result of the reduction of duplicate interim product licences or a decision to not obtain a full ANZTPA product licence;
- the rate of transition to ANZTPA product licences; and
- the net increase (decrease) in new product applications (as outlined above).

66. The assumptions used to build forecasts of product volumes and transition rates are substantially more complex and are set out in Appendix A. The resulting change in the number of licences (interim and full) is summarised below (using gross numbers of products before any exemptions for low value/low volume products). Comparisons are made to the current product numbers in Australia for illustrative purposes only.

No. of interim and full ANZTPA licences	Prescription medicine	OTC medicine	Complementary medicine	Medical devices	Manufacturer
Australia alone	5,570	4,908	17,788	13,484	350
ANZTPA Year 1	8,059	6,352	23,598	20,664	442
ANZTPA Year 4 (base)	6,751	5,169	19,289	16,922	369
Increase on current Australian numbers	21%	5%	8%	25%	5%

Cost base

67. The Authority's cost base over the transition period has been developed through a process of initially combining the current budgets of the TGA and Medsafe, then adjusting the total to take account of the changes in operations, efficiencies that are expected to be achieved, and changes in regulatory activity levels. The cost of implementing the regulation of in-vitro diagnostic devices has also been included in the forecasts.
68. Currency exchange forecasts will be a continuing feature of the Authority's budgeting process. The exchange rate between the two countries has narrowed since work on the cost recovery framework for the joint regulatory scheme commenced in 2003-04. The exchange rate has been relatively stable in recent times, but is once again widening. As a result of this variability, the budget forecasts used in this paper have taken a conservative view and are based on the narrower conversion of A\$1 = NZ\$1.07.
69. The budget for the first year following commencement of the scheme is forecast to be A\$79.8 million, reducing to A\$74.8 million (at 2005-06 prices) by the time 'steady state' is reached in Year 4. The following table summarises the projected cost for the first four years.

	Year 1 (A\$m)	Year 2 (A\$m)	Year 3 (A\$m)	Ongoing (A\$m)
Employee	50.0	50.0	48.0	48.6
Supplier	8.5	6.9	6.9	6.9
Corporate	21.3	21.0	19.3	19.3
Total Expenses	79.8	77.9	74.2	74.8
Transition Expenses (included in above)	2.1	1.3	2.6	-

70. The larger initial cost reflects the extra resources associated with the current transition for medical devices in Australia; the introduction of regulation for medical devices and complementary medicines and enhanced post market surveillance in New Zealand; and assessment costs involved in issuing ANZTPA product licences to replace interim product licences issued for existing Australian and New Zealand products. Over time, it is expected that the

Authority will reduce its fixed costs and realise efficiency savings despite some additional cost associated with operating in two countries and serving two governments.

71. The other major assumptions in the cost base include:

- Costs relating to current set-up and development activities will cease on or before commencement of the scheme;
- Following commencement of the scheme, the Authority will progressively increase its New Zealand-based staff numbers to around 60 to cover those activities not currently undertaken by Medsafe (for example, pre-market approval of medical devices and complementary medicines);
- Transitional work in assessing interim product and manufacturing licences for conversion to full ANZTPA licences will be performed from within Authority staffing levels;
- Transitional costs have been estimated on the basis of the predicted work effort required to assess applications for full ANZTPA licences;
- The Authority will replace corporate support currently supplied by the Ministry of Health and the Department of Health and Ageing;
- Some corporate costs, such as insurance and audit, will increase;
- The Authority will need to fund the Board and any new committees established (such as the medicines scheduling committee). The travel/communication costs for joint committees are expected to be around the same as the combined Medsafe and TGA budget cost;
- The Authority will reduce external evaluation and laboratory costs and source much of this work from within Authority staffing levels;
- Savings through market testing and target costing techniques will reduce other supplier costs such as IT, travel and amortisation on capital and software.

72. During the three year transition period the Authority will incur costs for processing and evaluating applications for ANZTPA product licences. Transitional costs are higher in Year 1 than in Year 2. This reflects the assumption that where a sponsor is supplying the same or very similar products in both countries and holds two interim licences, they will wish to convert to a single ANZTPA product licence in Year 1. Transition costs are highest in year 3, reflecting the assumption that many sponsors supplying products in one market only will delay submitting an application for an ANZTPA product licence until the end of the transition period.

Section B: Cost Recovery Across Industry Sectors

73. Prior to considering the level of fees and charges, it is necessary to allocate the Authority's regulatory costs to each of the product sectors, and then to activities and/or product groups. This process ensures that fees and charges are set as closely as possible on a cost-reflective basis in accordance with the regulatory work required in each product sector.
74. The TGA uses an activity-based costing (ABC) model to attribute costs across the industry sectors based on activities and the consumption of resources in each product group in Australia. This approach:
- allocates the TGA's corporate costs (personnel, finance, IT support, etc) to the regulatory branches based on how much of these services have been used (recruitment, accounts processed, desk-top computers, etc); then
 - attributes Branch regulatory costs to the activities undertaken (i.e. application entry, clinical evaluation, surveillance) and product groups (i.e. new chemical entity, conformity assessment, overseas manufacturing pre-clearance), based on estimates of time spent on these activities.
75. The TGA's ABC model was used to baseline the apportionment of costs in Australia. Regulatory costs in New Zealand have been attributed to regulatory sectors and product groups based on the proposed staffing profile for each industry sector and proportionally to product groups using the TGA's current activity as a guide. Adjustments to the current budgets to reflect changes in business operations and cost-savings were notionally attributed across affected sectors proportionately, having regard to the Australian ABC model. Finally, estimates for transitional activity were costed for each regulatory sector.
76. The following table summarises the result of cost attributions to industry sectors (all figures are in constant 2005-06 prices). These estimates represent the financial targets for the Authority in setting fees and charges.

All figures in A\$million	Prescription medicine	OTC medicine	Complementary medicine	Medical devices (incl IVD)	Manufacturer	Other
Year 1	39.8	7.7	7.9	15.5	6.6	4.7
Year 2	39.4	7.3	7.2	15.5	6.1	4.6
Year 3	38.3	6.9	6.9	12.9	6.2	4.7
Year 4	37.5	6.7	7.8	13.4	6.4	4.7

77. It is acknowledged that the allocations and attributions used in estimating regulatory costs will require validation (through activity costing) following commencement of the joint regulatory scheme.

Section C: Maintaining Operating Reserves

78. The Authority will be established as an independent body, with its Board accountable to a Ministerial Council controlled by the two Governments. As such, it will be a separate and distinct legal entity. Neither Government has any obligation to provide additional funding to the Authority. The implementing legislation and Rules will also limit the Authority's ability to make borrowings and require consent from the Ministerial Council. Accordingly, the Authority will need to take a range of appropriate measures to mitigate potential financial risks which may arise due to the variability and uncertainty in submission trends, or from large and unexpected regulatory events, such as a major recall or tampering incident.
79. While insurance is available for some adverse events, others will necessarily require the Authority to maintain an operating reserve as part of the capital base. An operating reserve could also be used to provide for additional investment in information technology to better support regulatory administration.
80. It is expected that the assets and liabilities of the TGA and Medsafe will be transferred to the Authority through transitional provisions in the implementing legislation. The combined net assets of the two agencies currently amount to some A\$15m. Both governments have appropriated funds for the establishment of the scheme and the Authority's infrastructure, with A\$10m to be repaid by the Authority following commencement of the scheme. As these obligations will crystallise into liabilities for the Authority, available operating reserves will fall to around A\$5m (or less than 7% of forecast turnover).

PART 4: PROPOSED COST RECOVERY FEE OPTIONS

Section A: General Cost Recovery Issues

Goods and Services Tax

81. Regulatory fees and charges applied by the Authority will be subject to the goods and services tax regimes that apply in each country. This is consistent with the concept that the Authority's employment and other operational activities should be subject to domestic laws to the extent that the Authority operates in either Australia or New Zealand. It is expected that:

- in Australia, the Treasurer's current Section 81 Determination to exempt TGA regulatory fees and charges from GST will be extended to the Authority; and
- in New Zealand, GST will continue to apply to regulatory fees at the rate of 12.5%, with companies able to claim input tax credits for the GST paid.

In this consultation document, all fees and charges are referenced GST-exclusive.

Pricing parity

82. To avoid the potential for arbitrage (where sponsors take advantage of currency differentials when submitting applications), the Authority's fee and charges will be determined using Australian currency and converted in New Zealand at the prevailing exchange rate. The fees schedule will be updated periodically to align fees chargeable in both countries.

83. Fees and charges collected from New Zealand residents will be subject to 12.5% GST. However, companies will be able to claim input tax credits in relation to the Authority's fees. Fees and charges collected from Australian residents are expected to continue to be exempt from GST. As a result, sponsors and manufacturers in both countries should pay the same net amount in fees and charges irrespective of the GST system.

Common pricing points

84. The Authority will aim to develop a fee schedule that is simple and, as far as is possible, applies the same business model across the different sectors of the regulated industry. It is recognised that the current fee schedule in Australia is large and contains a range of fees for relatively similar activities in different sectors. The approach used in regulating medicines and devices varies, with some involving separate application and evaluation/assessment fees and others having handling and screening costs included in evaluation fees.

PROPOSAL 1:

Application fees and processing fees for applications involving similar levels of work effort will be standardised around common pricing points.

PROPOSAL 2:

The Authority's business models will, as far as possible, avoid the use of separate application and evaluation/assessment fees.

Fee rounding

85. Fees in Australia have been subject to rounding in recent years to simplify fees and charges. Fees under A\$10,000 have been rounded up to the next A\$10 increment; whilst fees above A\$10,000 have been rounded up to the next A\$100 increment. Industry associations have accepted the principle of rounding, though concerns have been expressed regarding the size of the resulting increments in percentage terms for smaller fee items.
86. Maintaining pricing parity in fees and charges in both Australia and New Zealand will require periodic changes in fees and charges to reduce the differential that may arise due to currency fluctuation. As a result, larger rounding intervals may become counterproductive to maintaining parity.

PROPOSAL 3:

Rounding for fees and charges in both countries will be as follows:

- fees under \$100 will be rounded up to the next full dollar increment;
- fees from \$100 to \$1,000 will be rounded up to the next five dollar increment, and
- fees over \$1,000 will be rounded up to the next ten dollar increment.

Instalment payments

87. In both Australia and New Zealand, fees are generally payable at the time of lodgement of an application, or at the time the fee payable is notified to the applicant. In Australia, instalment payments can be made where evaluations are subject to a statutory performance timeframe, or in cases of assessed financial hardship.
88. In principle, payment prior to commencement of work minimises administrative costs and avoids the risks and additional costs associated with debt recovery and/or default – especially if product approval is declined. Nevertheless, the payment of large sums in advance of assessment, often many months prior to marketing approval, can place significant cash-flow burdens on businesses (particularly start-up companies).
89. Options for minimising this burden might include:
 - instalment payment plans based on stages of completion or regular intervals, with full payment due prior to approval; and/or

- a deferred payment scheme, involving settlement of the majority of the fee at the time of approval, or even over a longer period.
90. A deferred payment scheme would carry significant risks and place the Authority in a financing role that may be in conflict with its regulatory functions. It may be more appropriate for companies to independently finance their operations, and accordingly, a deferred payment scheme is not proposed.
91. There is a risk that using instalment payments for evaluations would increase the total evaluation time with the Authority, although the extra time would not count towards performance times. One way to reduce administrative costs and financial risks could be to require companies to enter into direct debit arrangements with the Authority and its banker.

PROPOSAL 4:

An instalment payment option will be developed for evaluations and assessments that usually involve periods of greater than three months duration, based on the principle that assessment work would cease if payment were not received as scheduled.

92. It is expected that the Managing Director would be authorised to agree to individual instalment payment plans in cases of serious financial hardship.
93. In relation to annual product licence charges, the Authority could provide an option to choose to make a single payment or to pay charges by quarterly instalments.

Performance-linked fees

94. Major evaluations and assessments undertaken by the Authority will be subject to performance targets for completion of evaluations. Where an application is subject to a performance target, the Authority would require only 75% of the fee to be paid on application. The remaining 25% of the fee would become payable if, and only if, the Authority completed the assessment within the performance time. Performance targets are intended to provide an incentive on the Authority to complete assessments in a reasonable timeframe. The balance of the fee would be required to be paid if the evaluation was completed in a timely manner, even where a licence was not granted or where a submission was withdrawn at a late stage.
95. Performance-linked fees can provide compensation to an affected company if the Authority takes more time to determine its application. However, since the Authority must recover the full costs of the regulatory scheme from the fee-paying industry, any shortfall in cost recovery must be made up from fees paid by other applicants. Nevertheless, as evaluation times are critical to industry and represent an important measure of the regulator's performance, there is sufficient incentive for the Authority to meet targets and thus avoid having to forego a portion of the fee.

PROPOSAL 5:

Fees for major evaluations and assessments that are subject to performance targets should be linked to meeting these targets, with 75% of the total fee payable on application and the remaining 25% payable only where the Authority completes work within the target period.

Access to unlicensed therapeutic products

96. Both countries presently have arrangements in place that permit the importation and personal use of unapproved medicines and medical devices under restricted conditions. Unapproved medicines and medical devices may also be used in clinical trials subject to approval and/or supervision by the regulator.
97. In Australia, a clinical trial sponsor must submit details of a proposed trial to the regulator and pay a notification fee or other fees associated with the conduct of the trial. In addition, a medical practitioner wishing to use an unapproved medicine must seek a permit from the regulator, though no fee is payable.
98. In New Zealand an application for approval of a clinical trial must be made to the regulator and an application fee paid. A medical practitioner does not currently require the approval of the regulator to use an unapproved medicine, but the supplier of an unapproved medicine is required to send monthly reports to Medsafe providing details of the supplies made.
99. It is proposed that the Authority would be responsible for issuing approvals and monitoring the use of unapproved products for personal use or use in clinical trials. The Australian arrangements for access to unapproved products were reviewed during 2004-05 having regard to the commencement of the joint scheme and with consultation undertaken in both countries. A number of recommendations that may expand the regulatory role for the Authority and add to the cost of monitoring clinical trials across the Tasman are being considered by Governments.

PROPOSAL 6:

Where the fees charged in relation to the use of unapproved therapeutic products do not recover the full cost, the shortfall will be recovered through annual licence charges.

100. This is consistent with Government policy objectives of ensuring access to medicines and encouraging innovation in both Australia and New Zealand.

Orphan therapeutic products

101. Orphan therapeutic products (usually prescription medicines or in vivo diagnostic agents) are used to diagnose, prevent or treat rare diseases. Because the number of patients is small, supply of the product may not be commercially viable if normal fees applied to product licence applications.

102. Australia currently operates an Orphan Drugs Program under which a sponsor can apply for a fee waiver provided the criteria for disease prevalence are met. New Zealand does not currently operate a specific orphan medicines programme, although there is provision in the legislation for fees to be waived in the interests of public health and this mechanism has been used to facilitate the approval of orphan medicines.

PROPOSAL 7:

The Authority will operate an orphan therapeutic products scheme similar to that currently operating in Australia.

103. Because the Authority will be required to recover the full costs of its activities through fees paid by industry, the costs of licensing products that meet the criteria set for orphan therapeutic products would need to be recovered from across all product licences.

Application fee refunds and screening fees

104. Application and processing fees are set to recover the costs of handling and processing, including attributions to recover corporate costs (such as IT systems and invoicing). These costs are usually incurred shortly after submission, with further handling required if a submission is withdrawn by a sponsor. Making application fees non-refundable can also act as an incentive for sponsors to ensure applications are correct and complete.
105. Prior to acceptance of a product licence application for a Class 2 medicine, the Authority would review the application to ensure it meets the relevant requirements for lodgement. The cost of screening is incurred regardless of whether an application is accepted or withdrawn by the applicant.

PROPOSAL 8:

Application processing fees will be non-refundable. A screening fee of up to 20% of the evaluation fee (based on the regulatory and administrative work performed) will apply if an application is withdrawn by the sponsor prior to acceptance for evaluation.

Assistance to small and medium enterprises (SMEs)

106. In accordance with Article 15 of the Agreement, fees and charges will be designed to recover the full cost of the Authority operating under the scheme in an efficient and equitable manner, providing incentives for the timely and efficient determination of applications.
107. A number of overseas therapeutic product regulators, including the US Food and Drug Administration and the European Medicines Agency, provide assistance to small and medium enterprises (as defined in those regions), which include special exemptions, fee concessions or waivers and specific administrative arrangements to assist smaller companies.

108. While the Authority will have much in common with other front line international regulators, it will be the only regulator that recovers the full cost of its activities from industry. In the absence of subsidies from government, proposals to provide fee concessions solely to small and medium enterprises would result in cross subsidisation of regulatory costs from other regulated companies and distort domestic competition.
109. While assistance for SMEs is a desirable policy objective for government, industry development is not considered to be a role for the regulator and may even conflict with its regulatory objectives.

PROPOSAL 9:

Initiatives adopted by the Authority to assist smaller companies will be designed, as far as is possible, to avoid cross-subsidisation from fees paid by other regulated companies.

110. The Authority's initiatives in this regard will be of the type already used by the TGA and Medsafe and similar to those available in Europe and can be expected to include:
- exemptions from annual product licence charges for products with low wholesale turnover/value;
 - reductions in annual licence charges for smaller manufacturers with low therapeutic product turnovers;
 - fee waivers for 'orphan' therapeutic products (small beneficiary groups);
 - instalment payment arrangements that can assist companies to manage cash flows prior to market authorisation;
 - mutual recognition and international information exchange agreements relating to equivalent device assessments and manufacturing certificates; and
 - access to regulatory and scientific advice at no charge (including the opportunity to discuss dossiers prior to submission).

Section B: Annual Licence Charges

111. Annual licence charges are used to recover the costs of post-market surveillance and regulatory management that can not be imposed on a fee for service basis. The level of recovery from annual charges should be reflective of the cost of the activities undertaken.
112. Annual charges for product licences will be calculated having regard to the risk profile of product groups (which affects the amount of regulatory effort and cost incurred) and the number of product licences on issue. Generally, the volume of a product supplied in the market will not have a significant bearing on the monitoring and surveillance undertaken.
113. In certain circumstances, different "versions" of a product would be able to be grouped under a single product licence. The circumstances in which grouping

can be used will vary according to the type and class of product. Where such grouping occurs, a single product licence annual charge will apply to the grouped products. (Refer to the description of the approach proposed for the draft Managing Director's Order on Grouping for further information).

114. While interim product licences will authorise supply of a product in one country only, it is not proposed to apply a reduced annual licence charge for interim product licences because this would reduce the incentive for sponsors to move to ANZTPA product licences. Further discussion of the fees applicable during the transition period can be found in Section J.
115. Where a sponsor elects to pay product licence charges by instalment, the company will remain liable for the full amount of the invoice. Where sponsors agree to transfer product licences, the initial sponsor will be required to discharge annual licence fees before the Authority updates the records to affect the transfer.
116. Once fees and charges are set in the Rules, the Authority will have no power to waive or reduce licence fees payable by sponsors or manufacturers. As the charge relates to product supply or manufacture in respect of a financial year, charges would not be reduced pro-rata if a product was withdrawn or manufacturing terminated prior to year-end.

PROPOSAL 10:

The annual charge payable by the sponsor for a product licence (which may cover a group of related products where such grouping is permitted) will reflect the cost of post-market surveillance and regulatory management activities.

117. Sponsors will be required to pay licence charges by 1 September each year in order to maintain their approvals. Companies will be able to pay these charges by quarterly instalment.
118. Annual licence charges will be non-refundable.

Annual charges for older products

119. There may be an increased level of post-market scrutiny of a product containing a new substance during its early years in the market in order to identify problems that do not become apparent until the product is widely used. The regulator may impose additional reporting obligations on sponsors during this time.
120. Some stakeholders have suggested that this higher regulatory interest in newer products and substances should be reflected in differential annual charges, contending that older, more established products and generic/clone products have a lower incidence of adverse reactions and, thus, regulatory intervention. There is, however, little available evidence to confirm or quantify the differences in activity levels for new and more established products.

121. Whilst regulatory review may be enhanced for some newer products, the annual charge is also used to fund the cost of random and routine product testing, adverse events reporting and analysis, and a broad range of regulatory scheme support costs.

PROPOSAL 11:

The annual product licence charge for products in a particular risk category will be calculated by dividing the Authority's post-market surveillance and regulatory management cost for a risk category by the number of products in the risk category that have significant turnover.

122. Over time, older products will be withdrawn from supply and sponsors will arrange to cancel the relevant product licences. Lifecycles for therapeutic products continue to contract, with single season release of lower risk medicines not uncommon. However, with a shelf life of up to five years for medicines, products can remain in the supply chain and available for use long after a company has decided to discontinue supply. Implanted medical devices can remain in use for many years following cancellation of a licence, with manufacturers maintaining spare parts for older models long after they have been replaced in the market by new models.
123. The Authority will remain responsible for monitoring medicines and medical devices even after licence cancellation and may become responsible for recalls of these products down-stream. The Authority could retain annual licence charge obligations for products that are no longer being supplied by the sponsor but remain in use. However, the charge may not represent a fair apportionment of the post-market and regulatory management costs.

PROPOSAL 12:

The Ministerial Council Rules should permit the Authority to recover from the original product sponsor any costs associated with product recalls and investigations relating to a product for which the licence has been cancelled.

Low turnover products

124. An exemption from annual charges has been available in Australia for low turnover products. The annual charge is not payable where it exceeds 6.8% of the wholesale turnover for the product. The sponsor must apply for an exemption and pay a A\$100 application fee. Application fees are capped at A\$11,500 per year for a particular sponsor (i.e. the A\$100 fee applies only to the first 115 low turnover products for that sponsor). The application fee covers the cost of assessing eligibility for the exemption, so that no actual contribution is made to post-market or regulatory scheme maintenance costs.
125. It could be argued that granting exemptions from annual licence charges for some products effectively results in cross-subsidisation of post-market and regulatory support costs by product sponsors who do pay annual charges. Each year the TGA grants 13,600 exemptions for low turnover products with a total

value of A\$11.3 million. Ignoring product cancellation, had annual charges been paid for all approved products, the charge level could have been reduced by as much as 35%.

126. As annual charges are set to share post-market and scheme support costs equitably, it could be reasoned that an exemption from annual licence charges is an effective way of reducing regulatory costs where market supply is low. Such a mechanism would benefit sponsors of:
- large ranges of catalogue products, each sold only in small numbers;
 - unprofitable service products, where supply is maintained for small numbers of long-term consumers;
 - products in their first year of supply (where sales may only have reached nominal levels); and
 - products that are approved but are not yet intended for supply.
127. However, the current Australian system is administratively inefficient for both the TGA and sponsors, involving the submission of applications and processing of invoices and credit notes for annual charges. A large number of exemptions relate to products that have no sales volume at all, either because the product has yet to be marketed for commercial reasons, or because the product is newly-approved and production has yet to commence.
128. While there remains considerable uncertainty regarding the actual number of licences to be issued under the joint scheme (interim and full Authority licences) and the rate of transition, there is merit in retaining a low turnover exemption scheme that is similar to that currently in place in Australia. However, some modifications could be adopted to make the process more efficient.
129. A model has been identified that would reduce regulatory costs for sponsors of lower turnover products whilst achieving a level of contribution towards post-market and regulatory scheme costs in relation to many low turnover products. The model involves:
- Eliminating the annual charge in the year of approval, with a small handling cost being added to the product licence application fee. This could significantly reduce administration costs;
 - Establishing a new annual charge category for any class of product that is not marketed or supplied in either Australia or New Zealand. The lower annual charge (based on the same level as a low turnover exemption) would be payable each year, reverting to the original annual charge category should supply commence; and
 - Phasing out of the maximum application fee payable for low volume exemptions so that all products contribute to post-market and regulatory management costs.
130. Sponsors would be required to certify applications for low turnover exemptions, or to certify that a product is not in the supply chain and therefore qualifies for the reduced annual charge. The Authority would publish on its website a list of products certified as low turnover and not in the supply chain. There would be penalties and sanctions for making false and misleading statements.

PROPOSAL 13:

The low turnover assistance arrangements at commencement of the joint scheme will include:

- a low turnover exemption, obtained by applying to the Authority, where the product licence annual charge exceeds 6.8% of the wholesale turnover for the product (or cost of manufacture if the product is supplied at no charge);
- an application fee of A\$100 to apply for an assessment for a low turnover exemption;
- capping of the total amount paid by a sponsor for low turnover application fees at A\$11,500 per annum, with the cap phased out over the transition period;
- removal of first year annual charges, with applicable product application and evaluation fees being increased to cover some handling costs for initial licensing; and
- a low product licence annual charge category of A\$100 for products that a sponsor certifies are not in the supply chain (subject to penalties for incorrect certification).

131. The Authority would undertake a further review of the low turnover arrangements after the three-year transition period, when the total number of products on the market is known. The review would be undertaken with a view to removing the low value/low volume exemption scheme and adjusting annual product licence charges accordingly.

Section C: Manufacturing Standards

132. The Authority will apply the established principles of the Code of Good Manufacturing Practice (GMP) to ensure that therapeutic products are reliably manufactured to high standards of quality.

133. Manufacturers of therapeutic products in Australia and New Zealand will be required to hold an ANZTPA manufacturing licence and will be subject to periodic inspection. Manufacturers from other countries (overseas manufacturers) will be required to meet a standard of GMP comparable to that required of Australian and New Zealand manufacturers.

Pre-licensing activities

134. Prior to an Australian or New Zealand manufacturer being issued a licence, they will be subject to an on-site audit to ensure that they meet the required standard of GMP. During the audit the manufacturer will need to demonstrate compliance with manufacturing principles, including relevant codes of GMP and Quality Systems.

135. Sponsors wishing to supply products made by overseas manufacturers must provide acceptable evidence that the products are manufactured to a standard of GMP equivalent to that expected of Australian and New Zealand manufacturers. If acceptable evidence is not able to be provided (for example,

where the site has not been inspected by a recognised overseas regulator), the Authority would conduct an on-site audit.

Post-licensing activities

136. Manufacturers licensed by the Authority will be subject to scheduled audits to ensure that GMP standards are maintained. Scheduled audits will occur every two to three years for manufacturers demonstrating a high level of compliance, and more frequently where deficiencies have been identified during past audits.
137. In addition, unannounced audits will be undertaken when the regulator receives credible information of serious concern and a risk assessment indicates that regulatory action is required.
138. The Authority will also maintain the GMP regulatory framework.

Cost recovery issues

Compliance incentives

139. Both Australia and New Zealand currently charge fees for the audit and licensing of manufacturers. In New Zealand, all manufacturers are charged an annual fee, regardless of the level of compliance or number of audit inspections required. In Australia, the annual licence charge includes a set number of audit inspection hours – should additional inspection be required, the non-compliant manufacturer incurs additional costs.
140. However, given recent increases in the scope, scale and duration of manufacturing audits, the allowances for audit hours included in the Australian licence are not considered sufficient. As a result, most manufacturers incur unexpected additional inspection fees for which they may not have budgeted.

Audit costs

141. Many manufacturers perceive TGA audit inspection fees of A\$440 per hour (A\$910 for overseas audits) to be excessive. However, the fees are cost-reflective.
142. Unlike consulting fees, the TGA only levies manufacturers for the number of hours spent on-site (commonly less than a third of the total time spent on an audit). The hourly rate for domestic audits includes recovery of travel costs and travelling time, time spent planning and completing post-audit reporting and follow-up, as well as supervision, quality assurance and overhead costs.
143. The hourly rate for overseas audits is A\$910 and is higher than for domestic audits because more time is required to coordinate overseas audits and travel to manufacturing locations. The costs of airfares and travel allowances are recovered separately.

Unannounced Audits

144. Both Australian and New Zealand manufacturers are audited in accordance with a risk model, and an audit programme is prepared to ensure all manufacturing licences remain compliant with the Code of GMP. The programme is informed and updated based on the results of completed audits. The auditing

programme also allows for unannounced and additional (follow-up) audits, which are essential components of the auditing strategy.

145. Some manufacturers in Australia contend that it is not equitable to levy inspection fees on a manufacturer for an unannounced audit as the ensuing inspection may find no matter of non-compliance. However, unannounced audits are undertaken by the regulator based on credible evidence and a risk assessment. As a result, many such audits validate the issue of concern. However, if no issues of concern are identified, this will be taken into account in scheduling (deferring) the company's next planned audit, mitigating the extra audit hours and costs for affected companies.

Licence Consolidation

146. A number of Australian manufacturers have cancelled manufacturing licences and listed multiple manufacturing sites under a single licence (consolidation). While this has resulted in lower annual licence charges, the company only has a single allowance of audit hours and inevitably incurs higher inspection fees to cover the time spent auditing the additional sites.

PROPOSAL 14:

Manufacturers will be required to hold an ANZTPA manufacturing licence for each manufacturing site (location) in Australia and New Zealand.

Cost recovery options for manufacturer assessment and licensing

Fees for domestic audits

147. The Authority's cost recovery mechanism for manufacturer licensing should be cost-reflective, achieve equity in cost recovery by providing incentives for compliance, and provide predictability to assist industry budget planning. Two options have been identified for achieving these objectives.
148. The first option would be to apply annual licence charges that include a level of inspection hours that would generally result in compliant companies avoiding any subsequent charges for additional audit hours. TGA data on inspection times have been reviewed to estimate the required audit hours for high and low level manufacturing licences. Preliminary results show that to avoid additional inspection fees:
- High level manufacturing licences (sterile, multi-step manufacturing) would on average require an increase of 35 hours in the licence charge over three years.
 - Low level manufacturing licences would need on average an additional 21 hours in the licence charge over three years.
- The inclusion of these levels of audit hours would more than double the current TGA manufacturing licence charges.
149. This option has the advantage of providing good predictability of costs, thereby assisting companies in budget planning. However, companies that do not require the full allowance of audit hours (such as small, compliant

manufacturers) would be disadvantaged by having to pay the same annual charge as companies that did use the full allowance. Further, as the hourly rate includes overhead recovery, additional audit hours above Authority forecasts would lead to an over-recovery of costs.

150. The second option would be to adopt an approach used by some international regulators whereby a set fee is applied for the audit of different categories of manufacturer. The relevant fee would include all direct, indirect and overhead costs, and would apply to audits undertaken domestically as well as audits performed overseas. Features of this approach include:
- Multiple fee categories to ensure audits involving similar effort, having regard to the scale and complexity of operations, incur the same fee;
 - An additional hourly fee set to recover direct staffing and indirect costs only for audits that involve significant non-compliance, excess travelling time or other exceptional circumstances; and
 - Removal of annual manufacturing licence charges.
151. Categories of manufacturer would be determined on the basis of the type of manufacture undertaken and scale of manufacturing operations. Both factors have an impact on the manufacturing risk and therefore the level of audit effort and frequency. Accordingly, a matrix can be developed to group manufacturing sites based on the audit effort required. While details of the matrix would need to be finalised in consultation with industry associations, the matrix is expected to comprise the following:
- the type of manufacturing performed (i.e. sterile, non-sterile or both);
 - the number of steps in the manufacturing process (i.e. lab and quality testing; manufacture; labelling and release);
 - whether the audit is an initial audit (pre-manufacturing) or an ongoing review audit of manufacturing standards (routine or ad-hoc);
 - the scale of manufacturing undertaken (based on the number of different products manufactured as a proxy for volume and production line-changes); and
 - there would only be a small number of very large scale manufacturing sites, generally based overseas.
152. Licences for manufacturing sites would be linked to the categories developed from the matrix. However, to minimise fee structure complexity, audit fees would be standardised around audits of similar effort. This is illustrated in the following table:

Manufacturing licences and fee categories

		Sterile and Non-Sterile			Sterile Manufacture			Non-Sterile Manufacture		
Initial Audit	Very Large	E			E			D		
	All others	C			B			B		
		Sterile and Non-Sterile			Sterile Manufacture			Non-Sterile Manufacture		
		Steps			Steps			Steps		
		3	2	1	3	2	1	3	2	1
Production Audits	Very Large	E			E			E		
	Large	D	D	C	C	C	B	C	B	B
	Medium	C	C	B	B	B	A	B	B	A
	Small	B	B	A	B	A	A	A	A	A

Note: At present there are no Category E manufacturers in Australia or New Zealand

153. Initial audit fees would be set by type of manufacturer. Audit effort prior to the commencement of manufacture is very similar regardless of the planned scale of operations except in the case of the very largest manufacturing plants.
154. Five fee categories are proposed based on the preliminary analysis of manufacturing data and estimations of work effort performed by the TGA. These categories reflect the risk and audit effort required for recurring audits. The frequency of subsequent audits would be determined on the risk classifications and the extent to which GMP standards have been met during past audits. It is intended that a firm indication of the time for the re-audit would be advised to the manufacturer when reporting the audit results. As a general rule:
- manufacturers in categories D and E can expect re-audit in 12-24 months;
 - manufacturers in categories B and C can expect re-audit in 12-30 months;
 - manufacturers in category A can expect re-audit in 12-36 months.
- However, where GMP compliance is found to be unsatisfactory, an additional audit within 12 months may be scheduled.
155. Fees for domestic and international manufacturing audits would be the same. However, overseas audits would incur additional supplementary hourly charges relating to travelling time as well as reimbursement costs for travel expenses.
156. Predictability of costs for budget planning would be high, though audits may not be performed every year. Non-compliant companies would continue to pay additional audit fees, though at rates which would ensure the Authority avoided over-recovery of costs. The fee categories provide a simple model for understanding the audit fees to be paid.

PROPOSAL 15:

The Authority will set audit fees for manufacturing sites to reflect the average time taken to inspect a compliant manufacturer. Additional audit hours will be charged to manage non-compliance, excess travelling time associated with overseas audits, or other exceptional circumstances.

Fees for overseas manufacturers

157. While the Authority can set the same audit fee for domestic and overseas manufacturers, the fee cannot include travelling time and costs as this would result in cross-subsidisation with Australian and New Zealand manufacturers. Accordingly, the Authority would need to recover airfare, accommodation and subsistence costs from overseas manufacturers separately. Overseas manufacturers would also be liable for supplementary inspection hours associated with travelling time and factors which lengthen the time taken to conduct an audit (for example, the use of interpreters and the review of documents not available in English).
158. Ideally, cost recovery should be sought from the manufacturer directly, with commercial arrangements standing to recover these costs from product

sponsors. This would significantly reduce coordination and liaison costs for the Authority and result in lower fees.

159. A sponsor can avoid the cost of an audit where it provides evidence that a manufacturer has equivalent compliance with the Code of GMP from an overseas regulator accepted by the Authority. Alternatively, the Authority can seek evidence on behalf of a sponsor. The fees proposed reflect the increasing effort required to obtain and review overseas manufacturing evidence.

Proposed fees for manufacturing assessments

160. The proposed fees and charges for the first year of the joint scheme are set out below.

Indicative Fees and Charges <small>(Note 1)</small>	Fee A\$	Basis of Charge
Manufacturing Audit		
Manufacturing Licence Application Fee	800	Per application
GMP audit Category A	11,000	Per audit
GMP audit Category B	13,600	Per audit
GMP audit Category C	21,900	Per audit
GMP audit Category D	29,500	Per audit
GMP audit Category E	35,000	Per audit
Supplementary inspection fee (incl. overseas travel time)	270	Per hour
Overseas Travel Costs	At cost	
Certificate of GMP Compliance	360	Per certificate
Quality Systems Certificate	360	Per certificate
Mutual Recognition Agreement Certificate	360	Per certificate
Certified Copy of a Certificate	360	Per submission
Overseas Pre-Clearance		
Assessment of GMP evidence	500	Per manufacturer, site, or sponsor
Obtaining evidence from overseas regulatory agency	500	Per manufacturer, site, or sponsor
Reinstatement of expired GMP clearance approval	800	Per manufacturer, site, or sponsor

Note 1: All fees and charges expressed in 2005-06 prices

Comparison with fees charged internationally

161. Cost recovery arrangements amongst overseas regulators vary, but in all cases it appears that the costs of manufacturer assessment are subsidised by the government. Most charge annual licence fees for domestic manufacturers, though often the licence will be sufficient for supply to other countries (such as in Europe).
162. The MHRA in the UK applies a system of fees per audit performed, with fees based on the size of the facility. The fee was recently supplemented with an additional hourly rate fee in recognition of the additional cost arising where there is significant non-compliance.

Section D: Class 2 Prescription Medicines

163. The costs of pre- and post-market regulation of Class 2 prescription medicines, which includes innovative and generic medicines, will be fully recovered from the prescription medicines industry sector through a combination of product licence application fees and annual product licence charges.

Pre-market assessment of product licence applications

164. Class 2 prescription medicines are high-risk medicines for which, in order to obtain a product licence, sponsors will be required to submit an application to the Authority providing comprehensive data on the safety, quality and efficacy of the product.

165. The Authority will undertake a rigorous and comprehensive assessment of a product licence application involving the following key steps:

- Product licence application receipt and acceptance;
- Evaluation of the application;
- Preparation of an evaluation report;
- Joint Expert Advisory Committee consideration; and
- Decision to grant/refuse to grant a product licence.

166. Product licence variations will follow a similar path, although the level of detail would vary depending on the nature of the change(s) being made to the product.

167. Generally, it could be expected that the applicant would benefit from holding the product licence and would be expected to meet the full cost of pre-market evaluation through the payment of a fee for service.

Post-market activities

168. The Authority will implement a multi-faceted scheme for monitoring the safety of licensed products that are on the market in Australia and/or New Zealand. This scheme, which is common to all medicine types, will include:

- Monitoring scientific developments and international trends that may provide new information or give rise to concerns relating to particular substances or products;
- Requiring sponsor companies to provide regular post-market safety reports for their products and to inform the regulator of any international concerns related to the safety or effectiveness of a product;
- Undertaking random and targeted laboratory testing of licensed products to ensure continued compliance with standards;
- Maintaining a problem reporting system, including analysing local and international information on adverse reactions to medicines and

providing regular medicines safety information to prescribers and pharmacists; and

- Taking appropriate action where problems are identified through post-market monitoring and surveillance (for example, suspending or cancelling a product licence or administering a product recall).

169. The Authority will also be responsible for maintaining the integrity of the regulatory framework, which will include:

- Maintaining and enforcing standards for product packaging, labelling and advertising;
- Providing information and guidelines to industry participants and consumers of prescription medicines;
- Investigating potential breaches of the regulatory framework, including investigations of counterfeit manufacture or supply; and
- Providing the New Zealand and Australian Governments with advice, through the Ministerial Council, in relation to the operation of the regulatory scheme.

170. The cost of post-market surveillance and regulatory management in relation to Class 2 prescription medicine is related to that sector of the regulated industry, and would be recovered from the participants in that sector. However, it is not possible to allocate the costs of post-market activities directly to individual products or sponsors. As a result, a simple and equitable system of cost allocation would be used to recoup costs on a per-product licence basis with a higher fee for biologics (blood, human cellular and tissue therapies and vaccines) to reflect the higher risk and increased level of laboratory testing and monitoring associated with these products.

Cost recovery issues

171. Previous consultations on cost recovery arrangements in both Australia and New Zealand have identified a number of issues that impact on the cost recovery model and the level of fees and charges for Class 2 prescription medicines. These issues are considered below.

Aligning pre-market and post-market fees

172. The TGA has previously estimated that 60% of the cost of regulating prescription medicines relates to pre-market approval activities and 40% to post-market and regulatory support activities. Past feedback from pharmaceutical companies has indicated that some would prefer to see pre-market fees set below cost to promote market access, with the remaining cost recovered through increased annual charges on products. Other companies consider pre-market costs are less of an issue because they are built into Head Office budgets, but would prefer to see lower post-market costs and hence lower ongoing break-even costs.

173. In Australia, prior to 30 June 2003, approximately 80% of the total revenue from the prescription medicines sector came from pre-market fees, although pre-

market activities accounted for only about 60% of the total regulatory cost. Since that time, the fee structure has been progressively altered, with reductions in pre-market approval fees offset by increases in annual product charges for biological and non-biological medicines. It was planned that the transition would be completed by June 2008.

PROPOSAL 16:

Product licence application fees and product licence annual charges should be cost reflective.

Fee rider/spill-over effects for generic medicines evaluation

174. Prescription medicines include both innovative pharmaceuticals and generic medicines. Whilst both medicine categories are subject to the same post-market surveillance and manufacturing requirements, a pre-market generic medicine evaluation is concerned with determining whether the generic product meets quality requirements and is equivalent to the innovator's product (bioequivalence). A recurring issue faced by regulators internationally is whether the fee paid for the evaluation of a generic medicine should reflect the actual cost of completing the required evaluation work, or should include a 'premium' to take account of the benefit the sponsor of a generic medicine derives from the regulator's earlier evaluation of the innovator's data package.
175. In a number of overseas jurisdictions the fee for evaluation of a generic medicine is linked to the cost of a full evaluation for a new innovative medicine, with the fee for a generic medicine varying from 30% to 97% of the fee for a new innovative medicine. In the US, the fee for evaluation of a generic medicine is set at over A\$400,000, which is 50% of the fee for a new innovative medicine, whereas the EMEA fee for a generic evaluation is 30% of the fee for a new innovative medicine.
176. In Australia and New Zealand, intellectual property rights exist to enable the innovator to recoup the cost of bringing products to market. Further, both countries comply with the TRIPS agreement which provides a five-year protection to data provided by companies. This means that the regulator is not able to use information provided by the innovator in evaluating a generic medicine application until after the 'protected period' of five years has expired, regardless of the current patent expiry period.
177. Given that the innovator has market exclusivity through the patent process, it can be argued that it has an opportunity to realise a commercial benefit and that fair compensation for the higher cost of evaluation has already been provided. Increasing the fee for evaluation of generic medicines to a level significantly above cost recovery (with a compensating reduction in fees for innovator products) could not then be justified.
178. In addition, the magnitude of the benefit derived by the sponsor of the generic medicine is very difficult to quantify, as evidenced by the large variation in

outcomes when regulators overseas have attempted to link generic medicine fees to innovative medicine fees.

PROPOSAL 17:

The fee for an evaluation of a product licence application for a new generic medicine will be cost reflective and will not be set as a percentage of the evaluation fee for a new innovative prescription medicine.

Minor variations and changes

179. It is common for a submission (a group of applications involving the same active ingredient or combination of active ingredients from the same company submitted at the same time) seeking approval for a minor variation or change to affect multiple product licences. There is generally minimal, if any, evaluation work required for each additional product licence and the fee is set to reflect the administrative cost of updating each product file. Several options can be considered:

- A fee per application (i.e. for each product licence affected). This would average out costs, though sponsors varying a range of related products are likely to pay more.
- A fee per submission, regardless of the number of licences affected. This approach would be administratively simple, though would arguably have the opposite impact to option A.
- A fee per submission for the evaluation, plus a fee for each licence affected. Although adding some complexity in setting the fee payable, this approach would best align fees with underlying costs.

180. Australian data shows that more than 98% of submissions affected fewer than 5 products, with the remaining handful of submissions affecting up to 30 products.

PROPOSAL 18:

Fees for product licence variations will be set to recover the cost of evaluation and handling and will be charged on a “per submission” basis.

Proposed Fees for Class 2 Prescription Medicines

181. The proposed fee structure for class 2 prescription medicines would target a ratio for pre-market fees and post-market fees and charges of 60:40. Pre-market fees would be on a fee for service basis in accordance with the following structure:

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
Product licence application involving a new chemical entity <small>(Notes 2,3 and 5)</small>	161,700	Submission
Product licence application for a new generic medicine	62,600	Submission
Product licence application for an additional trade name	10,100	Submission

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
Product licence variation seeking extension of indications	96,100	Submission
Product licence variation - major variation (new strength, dosage form, route of administration, change in patient group, change in dosage)	65,000	Submission
Product licence variation - minor variation (involving evaluation of chemistry, quality control and manufacturing information, and/or clinical, pre-clinical and bio-equivalence data.	3,700	Submission
Product licence variation - minor variation where no evaluation is required (changes in formulation, composition, specifications or containers)	1,150	Submission
Product licence variation – self assessable and corrections	1,150	Submission
Changes to product information involving the evaluation of data	3,700	Submission
Changes to product information or consumer medicine information where no evaluation is required	1,150	Submission
Safety Related Notifications	1,150	Submission
Annual Product Licence Charges		
Biologics	4,710	Per product licence
Non-biologics	2,810	Per product licence
Other fees		
Clinical Trial notification	250	Per Trial
Clinical Trial to be reviewed by the Authority	15,300	Per Trial
Advice for listing on the Australian Pharmaceutical Benefits Listing Program ^(Note 4)	1,500	Per application

Note 1: All fees and charges are expressed in 2005-06 prices

Note 2: Applicable fees apply for the evaluation of the quality (chemical, quality control and manufacturing information) and/or the non-clinical (animal toxicology) data of a new chemical entity incorporated as an ancillary component of a medical device.

Note 3: Product licence variations involving the evaluation of only chemistry, quality control and manufacturing information would have proportionately reduced fees.

Note 4: This non-regulatory fee is subject to Australian GST

Note 5: This fee includes any scheduling related activities for the new chemical entity

Comparison with fees charged internationally

182. The costs of pre-market evaluation of new prescription medicines are recovered, through fees charged to applicants, by all the major regulators internationally. With the exception of Health Canada, the major regulators also charge annual fees for approved products. Recent pre-market and post-market fees, expressed in Australian dollars, are shown in the following table.

183. Fee comparisons are indicative only, as there are variations in the way fees are applied, what the stated fee covers (for example, whether it covers additional dose forms and strengths) and the level of cost recovery that applies in a particular country.

REGULATOR	FEE (A\$)		ANNUAL FEE PER PRODUCT (A\$)
	Medicine containing a new chemical entity	Generic medicine (no clinical evaluation)	
FDA	861,538	430,769	53,474
EMA	380,328*	113,934	123,934
MHRA	191,871	74,062	35,162
Proposed ANZTPA	161,700	62,800	Biologic 4,710 Non-biologic 2,810
Health Canada ⁶	125,806*	-	-

* Single strength and presentation only

184. While the Health Canada fees appear to be lower than those for all the other regulators, it should be noted that the fees shown in the table cover a single dose form for a single route of administration with only one indication. Additional fees apply for evaluation of chemistry and manufacturing data relating to other dose forms or routes of administration, and there is a fee of A\$56,881 for clinical evaluation for each additional indication.

185. The fee for evaluation of a generic medicine varies from 50% of the fee for a new innovative medicine for the FDA, to 30% for the EMA. It should be noted that for the Authority, the proposed fee shown for a pre-market evaluation of a new generic medicine is cost-reflective and is not pegged to the cost for a new innovative medicine.

Section E: Class 2 Non-Prescription Medicines

186. Class 2 non-prescription medicines are predominantly 'over the counter' medicines but also include some complementary medicines. Products in this category are considered to be lower risk than prescription medicines but present significantly greater risks than Class 1 products. However, pre-market assessment and post-market monitoring by the regulator are still required to ensure product safety and appropriate use.

Pre-market assessment of product licence applications

187. The Authority will undertake an assessment of a product licence application involving the following key steps:

- Product licence application receipt and acceptance;
- Evaluation of the application;

⁶ Fee is for one indication for a single dose form and route of administration only.

- Preparation of an evaluation report;
 - Expert Advisory Committee consideration; and
 - Decision to grant/refuse to grant a product licence.
188. Product licence variations would follow a similar path, although the level of detail would vary depending on the nature of the change(s) being made to the product.
189. Generally, it would be expected that the applicant would benefit from holding the product licence and would be expected to meet the full cost of pre-market evaluation through the payment of a fee for service.
190. Consistent with the Authority's cost-recovery principles, the costs of pre-market evaluation would be recovered on a fee for service basis.

Post-market activities

191. The Authority will implement a multi-faceted scheme for the ongoing safety and compliance of therapeutic products with applicable standards that are available for supply in either Australia or New Zealand. This scheme, which is common to all medicine types, will include:
- Monitoring scientific developments and international trends that may provide new information or give rise to concerns relating to particular substances, products and manufacturing processes;
 - Undertaking random and targeted laboratory testing of licensed products to ensure continued compliance with standards;
 - Maintaining a problem reporting system, including the analysis of local and international adverse reactions to medicines.
 - Taking appropriate action where problems are identified through post-market monitoring and enforcement` (for example, suspending or cancelling the product licence or administering a product recall).
192. The Authority will also be responsible for maintaining the integrity of the regulatory framework, which would include:
- Maintaining and enforcing standards for product packaging, labelling and advertising;
 - Providing information and guidelines to industry participants and consumers of prescription medicines;
 - Investigating potential breaches of the regulatory framework, including investigations of counterfeit manufacture or supply; and
 - Providing the New Zealand and Australia Governments with advice, through the Ministerial Council, in relation to the operation of the regulatory scheme.
193. The cost of post-market surveillance and regulatory management in relation to Class 2 non-prescription medicines is related to that sector of the regulated industry, and would be recovered from the participants in that sector. However,

it is not possible to allocate the costs of post-market activities directly to individual products or sponsors. As a result, cost recovery through an annual charge based on the number of products regulated in the sector would be simple and equitable.

Cost recovery issues

194. Both Australia and New Zealand currently charge fees for Class 2 non-prescription medicines. Feedback from stakeholders during related consultations has given rise to several issues which are considered in the following paragraphs.

Structure of pre-market fees

195. In New Zealand, a flat fee applies to all applications for approval of OTC medicines. In Australia, the fee is based on the page-count of an application. The page count approach was developed several years ago as a proxy for the work-effort involved. Over time, however, the fee basis has caused delays in application acceptance (confirming the fee payable), disputes in fee assessments (determining what constitutes a 'page' of evaluation information/data), and has resulted in stoppages in evaluation to request further information (incurring an additional cost). Page-counts are also not considered to be a good proxy for the regulatory effort required, which results in the fees not being cost reflective. The TGA has observed that over the past two years, the sector has not achieved full cost recovery.

196. In developing fee options for the Authority, consideration has been given to achieving, as far as is possible, consistency in fee arrangements for different types of medicines. The page count approach is not used for assessments of other types of medicines and it is not therefore intended that the Authority would adopt this approach.

PROPOSAL 19:

Product licence application fees for Class 2 non-prescription medicines will be based on a fee for service model.

Application categories

197. Product licence applications for new Class 2 non-prescription medicines will be divided into broad categories for the purpose of determining fees as follows:

- New product - contains a new active ingredient, excipient or combination of active ingredients not currently included in any other licensed product;
- Generic product - has the same quantitative composition of active substances and pharmaceutical form, the same safety and efficacy properties, and is bioequivalent to an existing licensed product;
- New Substance/Excipient – New substance or excipient not currently contained in an existing Class 2 Non-Prescription Medicine;
- Clone product - identical in all respects (except for the name) to an existing licensed product.

Separate categories are also proposed for applications to vary a product licence where the application requires:

- evaluation of clinical or pharmacokinetic data;
- evaluation of chemistry, quality control or manufacturing information but not clinical or pharmacokinetic data; or
- assessment of labelling, product or consumer information only.

Submissions versus applications

198. An application relates to a single product licence, whilst a submission consists of one or more applications relating to variants (for example, different dose forms or strengths) of a product. To be included in the submission, each of the variants must contain the same active ingredient or combination of active ingredients and be submitted by the same sponsor at the same time.
199. Submissions for non-prescription medicines commonly only involve a single application. Charging fees on a “per submission” basis would therefore result in single application submissions cross subsidising the few multi-application submissions.

PROPOSAL 20:

Product licence application fees for Class 2 non-prescription medicines will be applied on a “per application” basis.

Consolidation of application fee and evaluation fee

200. The total cost for a licence application is made up of the cost of evaluation work (which may include external advice and review) and the cost of the various processing tasks related to handling an application from receipt through to decision. New Zealand has a single, standard fee, whereas in Australia, there is an application fee (required to be paid at the time the application is lodged) which covers the cost of initial handling and calculation of the separate page-count based fee required to be paid before evaluation commences.
201. In light of the proposal that the Authority adopt a fee for service, rather than a page count-based fee, consideration has been given to having a single application fee that covers handling and evaluation costs. This approach has the advantages that it:
- keeps the fee schedule simple, with only a single price to pay for a new licence or variation;
 - avoids delays associated with processing separate (and unnecessary) application fees;
 - reduces administrative costs for the Authority and sponsors; and
 - standardises Class 2 prescription and non-prescription medicine fee payment arrangements.
202. Under this proposal, a refund of the evaluation fee would be returned to the sponsor in the event that the licence application is rejected by the Authority or

withdrawn by the sponsor prior to evaluation. In such cases, the Authority would retain a screening fee of up to 20% of the evaluation fee.

PROPOSAL 21:

There will be no separate application and evaluation fees for product licence applications for Class 2 non-prescription medicines. A single product licence application fee will be required to be lodged at the time of submission, with a screening fee of up to 20% to be applied if an application is rejected or withdrawn by the sponsor prior to acceptance.

Proposed fees for Class 2 Non-Prescription Medicines

203. An indicative fee structure for Class 2 non-prescription medicines is set out in the following table.

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
Licence Applications ^(Note 2)		
New product with <ul style="list-style-type: none"> • a new active ingredient; • a new excipient; or • a new combination of active ingredients 	20,100	Per licence application
New generic product with bioequivalence, clinical or toxicological data	23,200	Per licence application
New generic product without bioequivalence, clinical or toxicological data	10,400	Per licence application
New 'clone' product	700	Per licence application
New active substance (not included in registered product)	27,100	Per licence application
New excipient (not included in registered product)	8,700	Per licence application
Product licence variations		
Involving new indications, directions for use, dose or patient population and involving evaluation of clinical pharmacokinetic data	18,100	Per licence application
Involving the evaluation of chemistry, quality control or manufacturing information	3,100	Per licence application
Involving the evaluation of labelling, product information or consumer medicine information	3,100	Per licence application
Notifications not involving evaluation	300	Per licence application
Approval for exemption from Standards	2,650	Per licence application
Product licence annual charge	850	Per product licence

Note 1: All fees and charges are expressed in 2005-06 prices

Note 2: This fee includes any scheduling related activities for a new active ingredient

Comparison with fees charged internationally

204. The Australian, New Zealand, UK and Canadian regulators charge fees for the pre-market approval of over-the-counter medicines. Variations in the level of cost recovery required by governments and the business rules that determine the way in which fees are applied make comparisons difficult. The fees charged by other regulators are shown in the following table:

Regulator	Fee for pre-market approval
MHRA	£ 8,160
Proposed ANZTPA	A\$10,400 (NZ\$12,480)
Health Canada	From CAD\$ 2,200

205. The FDA and EMEA do not have an equivalent application type, since over-the-counter medicines that require pre-market approval are regulated in the same way as prescription medicines (see Section D). FDA approval is not required for over-the-counter products that comply with a monograph. Fees for pre-market approval of products that do not comply with a monograph are charged on the same basis as for prescription medicines.

Section F: Class 1 Medicines

206. Class 1 medicines are lower-risk medicines that will not undergo pre-market evaluation by the Authority. This group includes most complementary medicines and some other OTC medicines. Product licences for Class 1 medicines would be granted on the basis of self-assessment and declarations by the sponsor using an electronic lodgement facility, and would be subject to post-market review. The lower level of regulatory management required for Class 1 medicines would be reflected in the product licence fee and annual charge.

Pre-market assessment of product licence applications

207. The sponsor of a Class 1 medicine will be required to obtain a product licence before placing a new product on the market. This will involve electronic submission of key details about
- the sponsor;
 - the product's ingredients, intended uses/claims, the dose(s) and form(s) of delivery;
 - the product's manufacturer(s); and
 - details of the product's packaging and labelling.
208. Sponsors must certify that the information supplied is true and correct and that they hold all relevant information and certifications required. Licence variations may similarly be lodged electronically.
209. The Authority's electronic lodgement systems would usually complete mandatory checks and produce a new/varied licence within 24-48 hours of submission and payment.

Pre-market assessment of new substances

210. The Authority will maintain a list of ingredients permitted to be included in Class 1 medicines. New substances for use in Class 1 medicines will be evaluated for safety and quality before being placed on the permitted ingredients list. Applications for inclusion of new substances on the list of permitted ingredients will be reviewed by a joint expert advisory committee with a role similar to the Australian Complementary Medicines Evaluation Committee.

Post-market activities

211. The Authority will carry out both random and targeted reviews of information that supports the grant of a product licence for complementary and other low-risk medicines. These activities include:

- Random reviews of around 20% of electronically-submitted product licence applications;
- Investigation, including risk analysis, of products where a potential problem has been identified from either internal sources (such as manufacturing audits) or external sources (consumers, overseas regulators);
- Safety and efficacy reviews of products or product groups; and
- Risk assessment and determination of regulatory action, such as product warnings or recalls.

212. Information used in post-market monitoring and surveillance will be drawn from across the Authority and will include laboratory testing (both random and targeted samples), manufacturing audits, adverse event reports and investigation reports.

213. In addition, the Authority will be responsible for maintaining the integrity of the regulatory framework, which will include:

- Maintaining and enforcing standards for product packaging, labelling and advertising;
- Providing information and guidelines to industry participants and consumers;
- Investigating potential breaches of the regulatory framework, including investigations of counterfeit manufacture or supply; and
- Providing the New Zealand and Australian Governments with advice, through the Ministerial Council, in relation to the operation of the regulatory scheme.

214. The level (and therefore cost) of post-market surveillance and regulatory management in relation to Class 1 medicines would be recovered from the participants in that sector. However, it is not possible to allocate the costs of post-market activities directly to individual products or sponsors. As a result, cost recovery through an annual charge based on the number of products regulated in the sector would be simple and equitable.

Cost recovery issues

Balance between pre- and post-market fees

215. One of the Authority's key cost recovery principles is that fees should reflect costs and that cross subsidisations should be avoided wherever possible. A recurring issue with fees for low risk complementary medicines in Australia has been the balance between pre- and post-market fees. It has been suggested that the pre-market application fee should be reduced or eliminated because it may present a barrier to new and innovative products being introduced. In order to cover costs, there would be a commensurate increase in annual charges. This would not be consistent with the Authority's cost recovery principles.

PROPOSAL 22:

Product licence application fees and product licence annual charges for Class 1 medicines will be cost-reflective.

New substances

216. A sponsor who pays for the evaluation of a new substance for use in Class 1 medicines does not obtain exclusive use of that substance because it is rarely covered by intellectual property rights (patents). As a result, other sponsors can immediately start using the substance without having contributed to the costs of the evaluation. Whilst the initial applicant can realise commercial benefits by being 'first to market', the short lead times for the approval of new Class 1 medicines rapidly reduces the advantage.
217. The inability to restrict benefits to only the applicant is referred to as a "free-rider" effect. As a result, it would not be fair to levy the full cost of the evaluation of a substance on the initial applicant alone.
218. To address this problem, the Authority could consider introducing data protection/privilege arrangements to provide the initial applicant with reasonable opportunity to recoup their investment. Alternatively, the Authority could develop arrangements such that all beneficiaries bear a share of the cost of substance evaluations. In either event, it would be necessary to charge an application fee to avoid Authority resources being wasted evaluating frivolous applications or applications for substances for which the commercial returns would be questionable.
219. As the Authority is not proposed to have a role in setting policy for market exclusivity, it is proposed that application fees for substance evaluations be set at a level that is reasonable for companies, but would not unduly restrict product innovation. The excess cost of substance evaluation would then be recovered through product licence annual charges.

PROPOSAL 23:

The fee for the evaluation of new substances will be set below the total regulatory cost to recognise that benefits from the evaluation of new substances are not

exclusive to the applicant. The remaining cost of evaluation will be recovered through annual product licence charges for all Class 1 medicines.

Proposed fees for Class 1 Medicines

220. The proposed fee structure for Class 1 medicines is shown in the following table:

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
Product licence application - new product ^(Note 2)	880	Per application
Product licence variations	250	Per application
Evaluation of a new substance for use in Class 1 medicines	5,270	Per substance
Evaluation of documents as part of a product safety review	4,910	Per product
Product licence annual charge	690	Per product licence

Note 1: All fees and charges expressed in 2005-06 prices

Note 2: Application fee includes processing of first year licensing (see Section A)

Section G: Medical Devices

221. A 'medical device' is generally any instrument, apparatus, appliance, material or other article (or accessory) intended to be used for human beings to diagnose, prevent, monitor or treat a disease or an injury/disability; to investigate, replace or modify human anatomy or a physiological processes; or to control conception. Medical devices include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, X-ray equipment, heart rate monitors, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves.

222. Regulation of medical devices has arisen world-wide in response to community concerns about the number of medical devices coming onto the market as a result of technological advances and the increasing role of devices in health care. Medical devices are not consumer goods, and they are mainly used through necessity. Consumers and industry alike should have confidence in the medical devices being used in Australia and New Zealand.

223. Arrangements for the regulation of medical devices under the joint scheme would closely mirror the framework introduced in Australia in October 2002 which is modelled on the Global Harmonisation Task Force (GHTF) framework.

224. The Australian medical devices sector is currently in transition to the new regulatory framework, though the transition process will not be completed until October 2007. The New Zealand medical devices sector would transit from a regulatory environment where no pre-market approval is required.

Pre-market activities

225. The regulatory model proposed for the joint regulatory scheme is based on the new Australian regulatory scheme which is based on recommendations from the GHTF.
226. Devices will be required to comply with a set of essential principles for safety and performance which would be prescribed in the Rules for the joint scheme. A medical device must be classified by its manufacturer according to risk classification rules. The device must then be subject to conformity assessment procedures, appropriate to the risk class, to demonstrate compliance with the essential principles and the application of quality management systems for manufacture. Evidence that the device has been subjected to the appropriate conformity assessment procedures must be available before a product licence is issued.
227. Devices would be categorised by manufacturers into one of five classes (seven sub classes) by means of risk-based rules that are based on the level of invasiveness, duration and the location of use of the device and whether it acts by converting energy. The level of regulation would depend on the risk class of the device. Product licences are issued on the basis of 'kinds of medical devices' – referring to devices which have identical characteristics of sponsor, manufacturer, classification, and Global Medical Device Nomenclature (GMDN) code (and Unique Product Identifier in some higher risk classes).
228. Applications for all devices would be able to be lodged with the Authority electronically, providing details of the devices classification and manufacture. Applications for higher risk devices would be subject to random and targeted application audits, which are desk audits of the certifications and technical documents of overseas manufacturers that have been declared as conforming to joint scheme requirements. In addition, the Rules would specify any high risk devices for which the Authority must always conduct the conformity assessment.
229. Prior to approval for supply, a medical device sponsor will need to ensure that evidence is available to demonstrate that the appropriate conformity assessment procedure has been applied to the device. "Conformity assessment" is the term used to describe the manner in which a manufacturer can demonstrate compliance with the essential principles and regulatory requirements. Manufacturers can choose the path by which conformity can be demonstrated, whilst the level of regulation increases with the risk category of the device. Higher risk devices may require full quality management system certification and/or a product design examination. An abridged assessment may be performed where a manufacturer holds equivalent conformity assessment certification from another regulator recognised by the Authority.

Post-market activities

230. Following market approval, a device manufacturer must continue to hold a current declaration of conformity for the device and keep the records relevant to the manufacture of the device for at least five years from the date of manufacture of the last medical device to which the declaration applies. The

sponsor must retain distribution records that can assist the Authority in responding to serious health threats and recalls.

231. Manufacturers will be required to ensure ongoing compliance, quality, safety and performance of their devices, maintain records that demonstrate compliance with the essential principles and importantly, maintain a post-market surveillance, reporting and corrective action system for problems or complaints associated with a device. Manufacturers will also be subject to periodic surveillance audits of their quality systems.
232. Sponsors and manufacturers would be required to report adverse events involving their devices within specified timeframes to be set out in the joint scheme Rules in accordance with the seriousness of the event. In addition, the regulator would undertake:
- targeted and random testing of devices in the laboratory;
 - product surveys involving technical file audits;
 - general market oversight and surveillance;
 - monitoring of scientific developments and international trends; and
 - imposing conditions on conformity assessment certificates and product licences or recalling devices.
233. The regulator would also be responsible for maintaining the integrity of the regulatory framework, which would include:
- maintaining and enforcing requirements for labelling and advertising;
 - providing information and guidelines to industry participants and users of medical devices;
 - investigating potential breaches of the regulatory framework, including investigations of counterfeit manufacture or supply; and
 - providing the New Zealand and Australian Governments with advice, through the Ministerial Council, in relation to the operation of the regulatory scheme.

Cost recovery issues

234. Previous consultations in both Australia and New Zealand on cost recovery arrangements have identified a number of issues that impact on the design and level of fees and charges. These issues are considered below.

Complexity of the fee structure

235. Industry has previously expressed concern about the complexity of the current Australian fee structure for medical devices. While it is recognised that the fee structure includes many fee items, this reflects the complexities of regulating medical devices under a framework that applies the GHTF approach.

PROPOSAL 24:

The Authority's fee structure for medical devices will be substantially the same as that being used for the new Australian regulatory framework (i.e. for included devices).

Australian fees for Registered and Listed devices

236. Australia has regulated medical devices since 1987 and as noted above, introduced a new regulatory framework for devices in October 2002. Sponsors of medical devices were allowed five years (until October 2007) to transit these devices to the new scheme. In 2003, the TGA significantly increased annual charges applicable to 'registered' and 'listed' therapeutic devices (under TGA's previous regulatory scheme) both to make up for past under-recovery of funds and to act as an incentive to transit these devices to the new regulatory system.
237. All medical devices in New Zealand will need to similarly undertake a transition process to comply with the essential principles and regulatory requirements and will be given three years following commencement of the scheme to comply. Devices notified on the 'WAND' database at the time of the commencement of the scheme will be issued an interim licence based on the notified class and will pay the applicable licence charge

PROPOSAL 25:

To avoid disadvantage during the transition period, annual charges for interim product licences will be the same in both countries.

Cost of conformity assessments

238. A recurring issue raised by the medical device industry has been the cost of conformity assessments. The new Australian regulatory framework has been in place since October 2002 and remains in a transition phase until 2007. When the transition phase has been completed it is intended that a review of the fees would be undertaken to ensure that they are cost-reflective.

PROPOSAL 26:

The fees for conformity assessment will be the same as those applying under the new Australian medical devices regulatory framework until a review is undertaken at the end of the transition period.

Fees for abridged conformity assessments

239. Consistent with arrangements in both countries, it is intended that where a sponsor is able to demonstrate evidence of conformity from an overseas regulator that is accepted by the Authority (eg. a memorandum of understanding or mutual recognition agreement is in place), the conformity assessment can be abridged and a reduced fee would apply.

240. Examples of where fees may be reduced include:

- Application audit fees where evidence of conformity is applicable to several devices submitted at the same time by the same sponsor and the devices are sourced from the same manufacturer and are similar in nature;
- Manufacturers holding a GMP licence that includes the manufacture of the product(s) subject to conformity assessment and includes the same elements required for certification of the quality management system;
- Manufacturers holding acceptable current EC certification (93/42/EEC or 90/385/EEC) with the same elements required for certification of the quality management system or certification for type examination or an examination design;
- A manufacturer holding a relevant Type Test certificate performed against a Medical Device Standard where testing was performed by a NATA-accredited testing laboratory for the purpose of Type Examination certification;
- An examination of design certification for kinds of devices that are sufficiently similar, where one of the devices is subject to full conformity assessment.

241. Although the fee reduction would be considered on a case-by-case basis, business rules have been developed that would provide reduced fees for reduced regulatory effort. These rules will be published to provide increased transparency and assist in business planning for industry.

Regulation of in-vitro diagnostic devices

242. Australian has recently finalised the development of regulatory arrangements to bring previously excluded in-vitro diagnostic devices (IVDs) within the regulatory framework following consultation with industry and anticipates commencement from July 2006. Following consideration of the proposed regulations planned for Australia and consultation with New Zealand stakeholders, the New Zealand Government has agreed to the inclusion of the regulation of IVDs within the joint scheme.

243. IVDs would be regulated as a subset of medical devices. Four classes of IVDs have been developed based on their risk to public and personal health – the extent of regulatory oversight would depend on the risk posed by the particular IVD.

244. IVDs must conform to a set of essential principles defining quality, safety and performance, and manufacturers must have quality systems in place to ensure that the product meets its design specifications and complies with the essential principles. Manufacturers must also have systems to review experience from the use of the IVD once it is approved for use, implement appropriate corrective actions, and notify the regulator of serious adverse incidents within specified timeframes.

245. In Australia, the regulatory framework will include in-house (assembled) assays, although implementation for these IVDs will be undertaken after the date of implementation for commercially-supplied IVDs. The New Zealand Government is yet to determine whether the joint scheme will include in-house assays as

part of the IVD regulatory scheme. Hence the regulation of these may be an Australia-only function.

Proposed fees for Medical Devices

246. The proposed fees and charges for product licences and variations to licences are set out below. The annual licence fees are payable in relation to a product or grouping of products.

Indicative Fees ^(Note 1)	Fee A\$	Basis of Charge
Product Licence Application Fees		
Class I ^(Note 2)	60	Per kind of medical device
Class Im and Is, Class Ila and I Ib	680	
Class III and AIMD	890	
In-vitro diagnostic devices - all classes	800	
Variation to amend a product licence that contains incomplete or incorrect information	300	Per licence
Variation - transfer of licence sponsor	680	Per application
Application Audits		
Level 1 - verify a sponsor's application and evidence of conformity	2,590	Per audit
Level 2 - verify a sponsor's application and assess evidence of conformity	4,740	Per audit
Annual Licence Charges		
Class I	60	Per kind of medical device
Class Im and Is, Class Ila and I Ib	680	
Class III and Class AIMD	890	
In-vitro diagnostic devices - all classes ^(Note 3)	550	

Note 1: All fees and charges are expressed in 2005-06 prices

Note 2: Application fees for this class would not apply for the transition period of the scheme

Note 3: IVD annual charges would not be applied until the end of the transition period

247. Additional fees are payable in relation to conformity assessment for certain classes of device. Fees apply for different pathways to attain conformity, and sponsors and manufacturers are referred to explanatory material made available by the TGA and Medsafe to determine the most appropriate assessment arrangements. As appropriate, the Authority would reduce conformity assessment fees where abridgement of assessment activity is possible.

Conformity Assessments ^(Note 1)	Fee A\$	Basis of Charge
Application Fee (other than IVDs) – all procedures and changes	680	Per application
Application Fee for IVDs– all procedures and changes	300	Per application
Full quality management system	19,900	Per assessment

Conformity Assessments ^(Note 1)	Fee A\$	Basis of Charge
Examination of product design	39,400	Per assessment
Type examination	27,400	Per assessment
Assessment of verification procedures	19,200	Per assessment
Production quality assurance	17,500	Per assessment
Product quality assurance	15,000	Per assessment
Abridged assessments -immunohaematology reagents	12,000	Per assessment
Surveillance audits of manufacturer's quality management system	5,810	Per audit
Supplementary assessment time, including assessor preparation/travel time associated with assessments conducted outside of Australia and New Zealand	290	Per hour
Reasonable travel, accommodation and allowance costs	At cost	
1. Reassessment of conformity assessment of manufacturer's management and quality system and examinations of product design attract the full initial fee		
2. Changes to conformity assessments would be charged at 60% of the initial fee.		

Note 1: All fees and charges are expressed in 2005-06 prices

248. The Authority would recover the cost of producing certifications for sponsors as requested and performing other activities. The fees related to these services are set out below:

Other Fees ^(Note 1)	Fee A\$	Basis of Charge
Considering submissions in relation to a proposed suspension of a medical device licence	4,740	Per submission
Notification of intention to sponsor a clinical trial of a medical device to be used solely for experimental purposes in humans	250	Per trial
Application for approval to use a specified kind of medical device solely for experimental purposes in humans	15,300	Per trial
Authority certification of CA for CE marking	Contracted rates apply	
Reproduction of device certificates etc	250	Per certificate

Note 1: All fees and charges are expressed in 2005-06 prices

Comparison with fees charged internationally

249. Arrangements for the regulation of medical devices in Europe and Canada are broadly similar to the GHTF model being adopted for the joint scheme. That is, medical devices are required to demonstrate compliance with essential principles through a conformity assessment process and are subject to ongoing post market reporting arrangements. However, unlike the model proposed for the joint scheme, both Europe and Canada allow conformity assessments and surveillance audits (to maintain certification) to be completed by notified bodies that have been accredited by the regulator. Health Canada retains authority for approving the supply of a device and issues a licence. Licence application, variation and reinstatement fees apply based on the type of device involved. Annual renewal processing fees of CAN\$50-100 per device also apply.
250. Direct comparisons of fees in Europe and Canada are difficult to make due to the unavailability of fee structures of notified bodies and the scope and purpose of contributions made by governments to post-market monitoring and surveillance programs. Further, the Authority's fees would be reduced where abridged assessments can be performed (where medical device sponsors can provide equivalent certification accepted by the regulator).
251. The US approach to regulation of medical devices is significantly different and is based on pre-market evaluation of the device. In October 2002 the Medical Device User Fee and Modernization Act became law and authorised the Food and Drug Administration to charge fees for certain medical device products. A medical device is subject to a full pre-market application and evaluation fee (US\$239,237 in 2005), although a much lower notification fee of US\$3,502 can be paid where a sponsor can demonstrate substantial equivalence to an existing submission (monograph). The FDA's budget is supplemented by the US Government to resource its post market surveillance and monitoring programs and provide concessions for small business.

Section H: Blood and Tissues

252. Blood, blood components and plasma derivatives will be regulated as therapeutic products under the joint scheme. Blood and blood components include whole blood extracted from human donors and therapeutic components that have been manufactured from human blood, including red cells, white cells, platelets and plasma for transfusion. Plasma for fractionation and plasma derivatives would be subject to regulation as Class 2 prescription medicines. The scope of regulation for blood, blood components and plasma derivatives is currently similar in both Australia and New Zealand.
253. Human tissue for implantation in the human body that is obtained, stored and supplied without any deliberate alteration to its biological and mechanical properties will also be regulated under the joint scheme. This includes most banked tissue, such as dura matter, heart valves, skin, corneas and bone as well as haematopoietic progenitor cells. Currently, Australian manufacturers of

these tissues are required to be licensed and comply with the Code of Good Manufacturing Practice for Human Blood and Tissues. In New Zealand, with the exception of haematopoietic progenitor cells, tissue-based therapies are not regulated, with providers instead operating under voluntary codes of practice.

254. Human tissue extracts, cell extracts and cells, whose principal therapeutic purposes are achieved through chemical, pharmacological or metabolic actions that are generally able to be batch released, are regulated as medicines, whilst other human tissues and cells subjected to deliberate alteration are regulated as therapeutic devices.
255. Therapeutic products regulation in both countries currently excludes blood and blood components that are provided as autologous and directed donations under the supervision of a medical practitioner where the blood or blood components are immediately supplied for a named patient on a predetermined basis. However, where storage occurs and supervision of that storage by the same medical practitioner can not be guaranteed, the blood or blood components may not be exempt from regulation under the joint scheme.

Regulatory activities

Regulation of blood and blood components

256. The regulation of blood and blood components is largely concerned with
- Post-market licensing and inspection;
 - evaluation and approval of technical master files and variations to the files;
 - monitoring of blood and blood components processed and supplied;
 - analysis, advice and oversight of donor-initiated and other recalls; and
 - monitoring developments domestically and internationally affecting the safety and quality of the collection, storage, testing, processing and supply of blood and blood products.
257. A manufacturer of blood, blood components or haematopoietic progenitor cells must, unless exempted, obtain a licence from the Authority. Blood or blood components must be manufactured in compliance with the standards to be established by the Authority under the Rules and Guidelines, the Code of Good Manufacturing Practice for Human Blood and Tissues and in a manner consistent with the relevant Technical Master File lodged by the manufacturer.
258. 'Technical Master Files' are compilations of scientific data provided by the manufacturer which includes a description of the steps in manufacture. The detailed technical information must satisfy the Authority that the blood, blood components or haematopoietic progenitor cells are manufactured according to the standards described in the Rules and Guidelines.
259. The laboratories that carry out viral and serological testing associated with the collection of blood and blood components are also required to comply with the Code of Good Manufacturing Practice for Human Blood and Tissues.

Regulation of human cell and tissue therapies

260. In July 2002, the Australian Health Ministers' Conference recommended that the TGA develop regulatory proposals for a new regulatory framework for human cell and tissues (HCT's) and other emerging biological therapies. Development of the new framework in Australia is well advanced following consultations with stakeholders and State and Territory jurisdictions. Development of cost recovery proposals are currently being developed by the TGA and will be subject to public consultation after consideration by the Australian Health Ministers Advisory Council.
261. Following consideration of the new framework proposed for Australia and consultation with New Zealand stakeholders, the New Zealand Government has agreed to the inclusion of the regulation of HCTs within the joint scheme and would cover all articles containing or consisting of or derived from, human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient. The joint scheme would include four classes of HCT, based on the risks posed by these therapies. The approach would involve evaluation of standards files/product dossiers and manufacturing quality systems prior to licensing of manufacture or product supply.

Cost recovery issues

Human cell and tissue therapies framework

262. The development of the HCT framework is continuing and will include further engagement with New Zealand stakeholders. As a result, separate consultation on fees and charges associated with the framework will be undertaken at a later date.

Exemptions from fees and charges

263. In Australia, manufacturers (mostly tissue banks and testing laboratories) that are determined to be 'not-for-profit hospital supply units' are able to gain exemption from regulatory fees and charges. These facilities largely comprise hospital-based units and research institutions that are financed from public health systems, grants and donations. However, a number also recover costs from patients, private health insurance funds and other organisations.
264. The effect of the exemption in a full cost recovery context is to shift costs onto other regulated parties, including some non-exempted facilities that compete with those that qualify for exemption. The proposed new regulatory framework for human cellular and tissue therapies would include many of these previously exempted facilities.

PROPOSAL 27:

No exemptions from fees and charges will be available under the joint scheme for not-for-profit hospital supply units.

Basis for licence charges

265. In Australia, licence charges relating to the collection and supply of blood by the Australian Red Cross Blood Service (ARCBS) are tiered, with one Primary licences held in each State/Territory, and secondary licences held for all fixed blood collection centres in each jurisdiction. The licence charges are set to recover the cost of regulation on an equal amount per licence for each tier – the charges do not reflect the actual volume of blood collected and processed in each jurisdiction or site.
266. The ARCBS has suggested that licence charges could be linked to the volume of blood collection in each jurisdiction. While linking the licence fee to blood collection may not ultimately be appropriate, further consideration of this approach will be undertaken in light of the inclusion of regulation of blood collected in New Zealand within the joint scheme.

PROPOSAL 28:

A primary licence will be issued for each jurisdiction (i.e. one for each Australian State and Territory and one for New Zealand). Each primary licence will attract an annual charge to simplify the method of recovering costs for the sector. Secondary blood collection sites, including mobile collection units, will be separately licensed but will not incur an annual charge.

Page-count based evaluation fees

267. In Australia, the fees for technical master file evaluations and variations have been based on page-counts of the data submitted. Increasingly, these page-counts have little bearing on the level of work required to perform the evaluation.

PROPOSAL 29:

A fee for service, based on the average cost of performing a master file evaluation, will be established to simplify the fee structure and add predictability of cost recovery.

Proposed fees for human blood, cells and tissues

268. The proposed fees for blood and blood components are provided in the following table. Fees are not set out for haematopoietic cells and tissues due to the planned development of the new HCT framework.

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
New licence application fee	680	Per application
Manufacturing licence (ARCBS, NZBS)	120,000	Per jurisdiction
Other manufacturer audits	See Section C	
Technical Master File evaluation – initial	22,000	Per evaluation
Technical Master File variation application fee (including notifications)	300	Per variation
Technical Master File evaluation – variation involving evaluation	4,500	Per variation

Note 1: All fees and charges are expressed in 2005-06 prices

Section I: Other Cost Recovery Arrangements

Other therapeutic products

269. In Australia, certain other products (such as hospital grade disinfectants for which therapeutic claims are made and sanitary tampons) are regulated by the TGA. It is planned that the Authority will regulate these products for Australia only. Applicable fees and charges for the pre-market evaluation and post-market monitoring of these products are based on the cost of performing these activities. Details of the current fees are available at www.tga.gov.au/docs/html/fees05.htm

Exports

270. The sponsor of a medicine or medical device intended only for export from Australia or New Zealand to a third country would be required to hold an export-only product licence, unless specifically exempted. The sponsor would apply for an export-only product licence by completing an electronic application and making certain declarations about the product. In some cases the Authority may conduct an initial audit of the application.

271. An exporter may request the Authority to provide a "Certificate of Pharmaceutical Product" (CPP) or an "Export Certificate for a Medical Device" for a product that is the subject of a product licence authorising supply in Australia/New Zealand or an export-only product licence. Certification may also be sought for additional documents, such as the consumer medicine information or labelling details. In such cases, the Authority's costs would include checking multiple documents and a higher fee is proposed.

PROPOSAL 30:

A higher processing fee will apply where a request for an export certificate includes a request for certification of additional documents.

272. In Australia, the TGA recovers around 50% of the cost of administering the export listings and certifications.
273. Alternatives to under-recovery would be to increase fees to achieve full cost recovery and/or introduce an annual licence charge for products being exported. The inclusion of an annual licence charge would ensure that applicants monitor their licences and cancel those for products which are no longer being supplied. In this way, the Authority would have a better understanding of products actively being exported overseas. The charge would need to be less than or equal to the application fee, as otherwise companies would simply lapse licences and apply for new licences.
274. Industry associations have indicated a preference for keeping barriers to trade to a minimum to maintain competitiveness, and have agreed in the past to meet the shortfall in cost recovery through the levy imposed on all products.

PROPOSAL 31:

The Authority will set fees for exported products at a low level with the shortfall recovered through product licence annual charges across all sectors.

275. The proposed fees for export-only product licences and certificates are as follows:

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
New licence application fee	500	Per application
Variation processing fee	250	Per variation
Certificate of Pharmaceutical Product or Export Certificate for a Medical Device ^(Note 2)		
Certificate only	100	Per product licence
Certificate and additional documents	300	

Note 1: All fees and charges are expressed in 2005-06 prices

Note 2: Certificates are provided as a service and would be subject to GST in Australia

Therapeutic product advertising

276. The advertising of therapeutic products is currently regulated in both Australia and New Zealand. Under Australia's co-regulatory system, pre-approval of advertisements directed to consumers in certain specified media is delegated to two industry associations, while advertisements directed to healthcare

practitioners are subject to industry self-regulation. In New Zealand, the advertising and media industries have developed a self-regulatory system that includes pre-vetting of advertisements. Complaints handling mechanisms operate in both countries.

277. The joint regulatory scheme would cover the advertising of all therapeutic products (medicines and medical devices) directed both to consumers and healthcare practitioners and would be underpinned by a Trans-Tasman Therapeutic Products Advertising Code. Key aspects of this scheme include the pre-approval of certain advertisements for therapeutic products, dependent on the media in which the advertisement is placed (in the case of medicines) or the type of medical device being advertised, and a mechanism for handling complaints resulting from the advertising of therapeutic products.
278. An Interim Advertising Council (IAC) (comprising broad stakeholder membership from both countries) was appointed by the two governments to develop proposals for the regulation of therapeutic products advertising across the Tasman. The joint advertising scheme is substantially based on the model recommended by the IAC. Under this scheme, New Zealand will essentially retain a self-regulatory framework administered through the advertising and media industries within a co-regulatory legislative framework which includes the Trans Tasman Therapeutic Products Advertising Code. Australia will also retain its co-regulatory framework with the role of the TGA being replaced by the Authority. The Authority would also approve and maintain 'Delegated Authorities' who would be able to approve advertisements in line with the Code. The Authority would be guided by advice from the Advertising Council (as the expert committee to be established on advertising matters) on the effectiveness of regulating the advertising of therapeutic products in both countries.
279. The IAC also reviewed options for cost recovery arrangements and completed a study to collect details of current costs in both countries and estimated the ongoing cost of necessary regulatory activities at A\$1.83 million. A number of cost recovery options were considered by the IAC before it made its recommendations to the two governments on advertising regulation. Further detail on the regulation of advertising under the joint scheme can be found at <http://www.anztpa.org/advert/index.htm>.
280. The following fees are proposed to apply for advertising clearance by the Authority and under the co-regulatory arrangements. Other costs of the Authority relating to complaints handling arrangements, monitoring and evaluation, maintenance of standards, education and enforcement would be recovered through product licence annual charges.
281. These fees have been set to cover the direct costs of the approvals process based on the time required to approve an advertisement. The difference in the proposed approvals fees between Australia and New Zealand recognises that the complaints handling system in New Zealand is funded through contributions by the advertising and media bodies as members of the New Zealand Advertising Standards Authority. During the stakeholder consultation process, stakeholders in New Zealand emphasised that it was important to take into

account the self-funded component of the New Zealand complaints system in developing fees and charges.

Indicative Fees and Charges ^(Note 1)	Amount A\$
Pre-approval of an advertisement for a therapeutic product	105/15 min (NZ\$ 99/15 min in NZ)
Application for Delegated Authority (DA) accreditation.	550

Note 1: All fees and charges are expressed in 2005-06 prices

Scheduling of medicines

282. The Authority will be responsible for the scheduling of substances used in the manufacture of medicines and other therapeutic products. This will involve initial scheduling of substances and the ongoing review and rescheduling of substances. This regulatory model advances the recommendations arising from the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (the 'Galbally Review') in Australia.
283. Initial scheduling of a new chemical entity included in a product will be determined as part of the evaluation of the product's licence application. The cost of initial assessment would form part of the cost of evaluation of the medicine and would be included in product licence application fees.
284. Reviews of current scheduled substances may be sought by a product sponsor seeking to have products rescheduled to a lower risk level, or by the Authority or a member of the expert committee on the scheduling of medicines based on public submissions or scientific developments.
285. Where an application is made by a sponsor, the cost of the review is triggered by the actions of the sponsor and cost recovery should be considered. However, the substances listed in the schedule may be used in a wide range of medicines, and, as the process of review involves a level of public scrutiny, the initiating sponsor may not capture an exclusive market benefit (that is to say, other companies may also benefit from the rescheduling decision). As a result, it would not be appropriate to charge the applicant the full cost of the review. Nevertheless, the application fee should be set at a level that would avoid frivolous applications.

PROPOSAL 32:

The fee for an application for rescheduling of a medicine will be set below the cost of performing the review in recognition of the fact that the applicant does not obtain an exclusive benefit. Any residual cost will be met from annual licence charges on all products.

286. Where a review of scheduling is undertaken other than at the instigation of the sponsor (for example, at the instigation of the Authority or as the result of a

submission from a member of the public or other stakeholder) the cost of the activity will be recovered through product licence annual charges.

287. The proposed fees for scheduling are as follows:

Indicative Fees and Charges ^(Note 1)	Fee A\$	Basis of Charge
Application for rescheduling of a medicine	5,270	Per application

Note 1: All fees and charges are expressed in 2005-06 prices

288. The Australian Pesticides and Veterinary Medicines Authority charges A\$3,380 for the scheduling of an agricultural or veterinary chemical. This is understood to be around 40% of the cost of evaluation. The UK Medicines and Health Regulatory Agency charges £6,480 for scheduling a complex application (i.e. one which needs public consultation) and £3,240 for a "standard" application.

Section J: Transitional Fees

Medicines approved in both countries prior to commencement

289. At commencement of the joint scheme there may be many products on the market that have been approved for supply in both Australia and New Zealand. These would be prescription and non-prescription medicine products that are on the ARTG and also have consent for distribution in New Zealand. There will be no medical devices or complementary medicines in this situation because New Zealand does not currently grant approvals for these products.
290. Initially, two separate interim product licences will be issued to the sponsor/s in the two countries – one authorising continued supply in Australia and the other authorising continued supply in New Zealand for the duration of the transition period. Both interim licences will be subject to annual product licence charges from the commencement of the scheme.
291. During the transition period, sponsors will need to apply for a full ANZTPA product licence. Sponsors marketing the same (or similar) products in the two countries under separate interim product licences will be able to obtain a single ANZTPA licence for their products. However, separate ANZTPA licences may be required where different sponsors hold interim product licences for the same or similar products (which may be the result of commercial or contractual considerations that limit supply to one or other country).
292. Medsafe and the TGA are developing business rules for the assessment of applications to convert from an interim to a full ANZTPA product licence in circumstances where the product has been supplied in both countries prior to commencement of the scheme. The level of review required to be undertaken by the Authority will depend on a range of factors including the extent to which the approved details of the two products match, and the nature of any differences. In some cases, evaluation may be required.

293. Annual charges for interim and full ANZTPA product licences have been set at the same charge levels for comparable products. The charge levels have been set to ensure that, when the transition period is complete, the Authority recovers the cost of its post-market and regulatory management activities. Having regard to the rate of transfer of licences, estimates show that there would be some over-recovery from annual charges over the first two years of the scheme while there were two interim product licences in effect for the same product. This surplus could be used to finance the cost of assessing applications to convert from interim to full ANZTPA product licences where the applications do not require evaluation, thus removing any financial hurdle for the regulator from assessing and processing these licence applications.

PROPOSAL 33:

The Authority will not charge a fee for an application to convert from an interim product licence to a full ANZTPA product licence, provided the application does not require an evaluation to be undertaken.

Therapeutic products supplied in both countries but only approved in Australia

294. At commencement of the joint scheme there may be many complementary medicines and medical devices that are supplied in both countries, but are only approved in Australia because there has been no requirement for approval in New Zealand. In these instances, the actual product being supplied may be identical, but there may be different sponsors in the two countries.
295. Provided the product in New Zealand is lawfully supplied prior to the scheme and has been notified to Medsafe, an interim product licence will be issued allowing continued supply in New Zealand. Transitional requirements for these products are the same as for products that have been approved in both countries.

Complementary medicines supplied in New Zealand only

296. At commencement of the joint scheme there will be many complementary medicines that are supplied in New Zealand but have not been required to be approved, and are not supplied in Australia. An interim product licence will be issued authorising the continued supply of these products in New Zealand only for the duration of the transition period. There will be no fee for obtaining an interim product licence.
297. During the transition period, sponsors will need to apply for a full ANZTPA product licence. This will involve submitting an application to the Authority, which will be assessed or evaluated in the same way as an application for a new product would be under the joint regulatory scheme.
298. An application for a full ANZTPA licence for a Class 2 complementary medicine that has not previously been approved will require lodgement of a data package for evaluation by the Authority, together with the payment of the requisite evaluation fee.

299. For Class 1 complementary (and other low risk) medicines the sponsor will enter the product details in the Authority's electronic lodgement system to validate the product's ingredients and manufacture prior to the automated issue a full ANZTPA licence. While product licence annual charges will apply to all Class 1 medicines from commencement of the scheme, there will be no fee for an application to convert to a full ANZTPA product licence.

Medical devices supplied in New Zealand only

300. At commencement of the joint scheme there will be many medical devices that are supplied in New Zealand but have not been required to be approved, and are not supplied in Australia. An interim product licence will be issued authorising the continued supply of these products in New Zealand only for the duration of the transition period. Annual product licence charges will apply from commencement of the joint scheme.
301. During the transition period, the sponsor will be required to apply for an ANZTPA product licence and, for all except Class I medical devices, pay the applicable fees (i.e. application fee, conformity assessment fees where required and any application audit fees). There will be no application fee for converting from an interim to an ANZTPA product licence for a Class I medical device, where the application involves electronic lodgement and self certification.

Medical devices currently in transition in Australia

302. For included devices, an interim product licence will be issued at the commencement of the scheme and annual product licence charges would apply. The sponsor will be required to apply for a full ANZTPA licence during the transition period, but there would no fee for this application.
303. Interim product licences will also be issued for registered and listed devices that have not completed transition to the included regulatory scheme in Australia. The sponsor will then need to convert the interim licence for a registered or listed device to an ANZTPA licence for an included device by 4 October 2007, in accordance with the existing transition arrangements applying in Australia. The sponsor will be required to pay the fee applicable to an application for inclusion on the register (i.e. application fee, conformity assessment fees and application audit fees), though there will no additional fee for obtaining a full ANZTPA product licence.

GLOSSARY

Agreement	<i>The Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint regulatory scheme for therapeutic products</i> signed by the two governments in December 2003.
ANZTPA Product Licence	A product licence issued by the ANZTPA, for a product that meets the requirements of the joint regulatory scheme.
Australia New Zealand Therapeutic Products Authority (ANZTPA)	The name given to the proposed agency to be established to administer the joint regulatory scheme. Also referred to as “the Authority”.
Australian Register of Therapeutic Goods (ARTG)	The register of therapeutic goods that have been approved for supply in, or export from, Australia.
Enabling legislation	The Australian Bill and the New Zealand Bill required to enable the establishment and implementation of the ANZTPA and the joint regulatory scheme.
Global Harmonisation Task Force (GHTF)	A group of representatives from national medical device regulatory authorities and the regulated industry established to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices.
Interim product licence	A transitional approval available for each therapeutic product lawfully on the market in Australia or New Zealand at commencement of the joint regulatory scheme, authorising supply of the product in one country only for the duration of the transition period.
Joint regulatory scheme	The regulatory scheme for therapeutic products to be administered by the ANZTPA.
Managing Director’s Order (MDO)	An Order made by the Managing Director of the ANZTPA, specifying the technical detail in relation to requirements under the joint regulatory scheme (e.g. the Labelling Order).

Medsafe	The New Zealand Medicines and Medical Devices Safety Authority – the current therapeutic products regulator for New Zealand.
Ministerial Council	The Therapeutic Products Ministerial Council comprising two members – the Australian Minister of Health and the New Zealand Minister of Health.
Ministerial Council Rule	A Rule relating to the requirements under the joint regulatory scheme, made by the Therapeutic Products Ministerial Council.
Orphan therapeutic product	A therapeutic product that is used to diagnose, prevent or treat a rare disease, and, because sales volumes are low, is unlikely to be commercially viable if normal product licensing fees are applied.
Product licence	A marketing authorisation for a therapeutic product. See also “ANZTPA product licence” and “Interim product licence”.
Sponsor	The person or company responsible for a product in the Australian/New Zealand market. In the case of a licensed product, the sponsor is the product licence holder.
Therapeutic Goods Administration (TGA)	The current therapeutic products regulator for Australia

APPENDIX A

LICENCE ASSUMPTIONS

Prescription Medicines

- All current products will obtain interim product licences.
- 65% of products are considered to be the same or similar in both markets. 60% will rationalise/convert to full ANZTPA licences in Year 1 and 20% in each of Years 2 and 3.
- 100% of products available in Australia-only will obtain a full ANZTPA product licence, but only 90% of products available in New Zealand-only will obtain a full ANZTPA licence. The remaining 10% will cancel their interim product licence.
- Products available in only one country will transfer to full licences more slowly, with 70% unlikely to convert until Year 3.

OTC medicines

- All products currently supplied will obtain interim product licences.
- 70% of products are considered to be the same or similar in both markets. 60% will rationalise/convert to full ANZTPA licences in Year 1 and 20% in Years 2 and 3.
- 90% of products available in either Australia-only or New Zealand only will obtain a full ANZTPA licence.
- Products available in only one country will transfer to full ANZTPA licences more slowly, with 70% unlikely to convert until Year 3.

Complementary Medicines

- There are estimated to be 12,200 complementary medicine products and sunscreens in New Zealand, with 11,400 not requiring pre-market evaluation.
- All current products available in Australia will obtain interim product licences, and will obtain full ANZTPA product licences.
- 35% of products are considered to be the same or similar in both markets. 60% will rationalise/convert to full licences in Year 1 and 20% in Years 2 and 3.
- 100% of NZ products supplied to or sourced from Australia will obtain an interim product licence – only 60% of remaining products will obtain an interim product licence.
- Between 35 and 40% of products available in New Zealand-only will obtain a full ANZTPA product licence (due to GMP requirements).
- 80% of product cancellations will occur in Year 2 (GMP transition period is 2 years).
- Products available in only one country will transfer to full ANZTPA product licences slowly, with 80% unlikely to convert until Year 3.

Medical Devices

- Australian devices will continue to transition according to existing modelling assumptions by October 2007.
- NZ only supplied products will need to undergo pre market assessment, consistent with current Australian transition requirements.
- Many products are imported to both countries.
- There are currently as many products in New Zealand as there are in Australia.
- 80% of products are the same and available in both countries (based on the interim WAND database).
- Products obtaining interim product licences in both countries use the same manufacturers (no new manufacturers).
- 54% of products in New Zealand-only will not obtain a full ANZTPA product licence, with 60% cancelling in Year 1.
- 46% of products in New Zealand-only will proceed to assessment for a full ANZTPA product licence, with 70% waiting until Year 3.

GMP

- 100% of Australian manufacturers will obtain an interim licence and a full ANZTPA manufacturing licence, with 80% waiting until Year 2 to obtain a full licence;
- NZ has some 100 manufacturers (90 being small businesses and not licensed). Of the 19 licensed manufacturers, 10 currently supply to Australia;
- 100% of large and medium manufacturers in NZ will obtain an interim licence and a full ANZTPA manufacturing licence. 80% of manufacturers will obtain an ANZTPA licence in Year 1; and
- 70% of the small manufacturers in NZ will obtain an interim licence and only 10% will obtain a full ANZTPA manufacturing licence. 80% of withdrawals will occur at the end of Year 2.