

*Regulation of Medicines
in Australia*

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C O N T E N T S

	<i>page</i>
Acknowledgements	
Executive Summary	
Part 1 - Introduction	1
Background	1
Objective of the Research	1
Methodology	1
Part 2 - Introduction	2
Terms and Definitions	2
<i>Therapeutic Good</i>	2
<i>Medicines</i>	4
<i>Listed Medicines</i>	5
<i>Registered Medicines</i>	5
<i>Complementary Medicines</i>	6
<i>Therapeutic Claims</i>	6
Part 3 - Country Background	7
Some Basic Facts	7
Part 4 - Legislative Framework of Medicines	9
Legislation Framework	9
<i>Therapeutic Goods Act 1989</i>	9
<i>Therapeutic Goods Regulations</i>	9
<i>Therapeutic Goods Advertising Code</i>	9
<i>Australian Code of Manufacturing Practice for Therapeutic Goods</i>	10
Authorities Involved in the Regulation of Medicines	10
<i>Therapeutic Goods Administration</i>	10
<i>Committees Involved in the Regulation of Medicines</i>	11
Part 5 - Regulation of Medicines	12
Pre-Market Assessment	12
Manufacturing Requirements	17
<i>Licensing of Manufacturers</i>	17
Post-Market Vigilance	19
<i>Adverse Drug Event Reporting</i>	19
<i>Recall of Medicines</i>	20
Regulation of Therapeutic Claims of Medicines	21

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Regulation of Advertisements	22
<i>Advertising of Non-Prescription (Low Risk) Registered Medicines and Listed Medicines</i>	22
<i>Advertising of Prescription (High Risk) Registered Medicines</i>	25
Regulation of Labelling	26
Control of Imports	27
<i>Good Manufacturing Practice for Medicines Manufactured Overseas</i>	27
<i>Imported Medicines Manufactured Overseas</i>	28
Patent Medicines	30
Infringement of Regulations	30
<i>Infringement</i>	31
<i>Counterfeit Medicines</i>	31
Dispensing of Medicines	32
<i>Dispensing Outlets</i>	32
<i>Pharmaceutical Benefits Scheme</i>	32
Regulation of Pharmacies	33
Fees and Charges	34
<i>Annual Charge</i>	34
<i>Evaluation Fee</i>	34
<i>Licence Fee</i>	35
Effectiveness of the Medicines Evaluation Process	35
Part 6 - Analysis	36
Introduction	36
Regulation of Medicines	36
<i>Mandatory Licensing of Manufacturers of Medicines</i>	36
<i>Mandatory Pre-Market Assessment and Regular, Responsive Post-Market Vigilance of Medicines</i>	36
<i>Mandatory Labelling</i>	37
<i>Mandatory Licensing of Importers of Medicines</i>	37
<i>Compulsory Registration of Pharmacists</i>	37
Acceptance of Evidence of Traditional Use for Substantiating Therapeutic Claims	38
Differentiated Control Over Advertising of Medicines Between Different Target Audience	38
Possible Extension of Patent Protection	39
Drawing Expertise to the Regulatory System	39
Adoption of a Risk Management Approach in the Pre-Market Assessment of Medicines for Flexibility	40
Appendices	41
References	57

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EXECUTIVE SUMMARY

1. In Australia, medicines can be classified as registered medicines or listed medicines, depending on their ingredients and claims made. Registered medicines can be further classified as non-prescription (low risk) registered medicines and as prescription (high risk) registered medicines. All medicines which are for export only are considered as listed medicines.
2. Registered medicines are of higher risk than listed medicines, therefore, the degree of control imposed on registered medicines is higher than that of listed medicines; registered medicines are evaluated for safety, quality and efficacy while listed medicines are evaluated for safety and quality only.
3. There are three levels of therapeutic claims - high, medium and general. High level therapeutic claims are the strongest claims which deal with treating, managing or preventing a disease. Medium level claims are lesser claims such as health enhancement claims. General level claims are the broadest claims such as health maintenance claims. Registered medicines are allowed to make all three levels of therapeutic claims but listed medicines can only make medium and general levels of therapeutic claims.
4. The main piece of legislation governing medicines in Australia is the Therapeutic Goods Act 1989 which establishes a national system of controls for medicines. The Therapeutic Goods Act 1989 is supported by the Therapeutic Goods Regulations and other state/territory legislation. The Therapeutic Goods Advertising Code and the Australian Code of Manufacturing Practice for Therapeutic Goods are the two main codes governing the advertising and manufacturing of medicines in Australia.
5. The Therapeutic Goods Administration is the main government agency responsible for enforcing the regulations of medicines in Australia. There are also a number of committees which play an equally important role as a government agency in the regulation of medicines. They are involved in the pre-market assessment of medicines, post-market vigilance, and regulation of advertisements of medicines, etc. These committees include members who are non-government officials such as healthcare practitioners, professionals, industry representatives and consumers.
6. It may be fair to say that rigid control has been placed on the supply of medicines in Australia. First, all medicines, registered or listed, must be submitted to a pre-market assessment before they can be supplied in Australia. The degree of control imposed over a medicine is directly related to the risk level of that medicine. Therefore, registered medicines are required to undergo a more rigorous assessment than listed medicines.
7. Secondly, all Australian manufacturers of medicines are required under the Therapeutic Goods Act to hold a licence which certifies compliance with the Code of Good Manufacturing Practice. Overseas manufacturers are also required to provide evidence to prove that they have met similar standards of Good Manufacturing Practice as the Australian manufacturers.
8. Thirdly, there are also post-market vigilance activities such as investigating problems, conducting inspections of manufacturing sites and testing samples of medicines, etc., carried out by the Therapeutic Goods Administration and relevant committees to ensure that medicines are of an acceptable standard.

9. Fourthly, both scientific evidence and evidence of traditional use are allowed to be used to support therapeutic claims. While scientific evidence can be used to support all three levels of therapeutic claims, evidence of traditional use is restricted to be used to support medium and general levels of therapeutic claims. There are also restrictions on the wordings of the claims which are solely supported by evidence of traditional use. In this way, consumers may not be denied some useful traditional medicines while at the same time they are alerted that these medicines have not undergone any scientific assessment or scrutiny.
10. Moreover, only non-prescription (low risk) registered medicines and listed medicines can be advertised publicly and the advertisements must comply with the Therapeutic Goods Advertising Code. They are also required to undergo a system of prior approval. It is illegal to advertise prescription (high risk) registered medicines publicly. Prescription (high risk) registered medicines are allowed to be advertised to health professionals only. However, there is no requirement that advertisements of prescription (high risk) registered medicines should seek approval prior to publishing. The means to ensure compliance with the relevant code is through an industry Monitoring Committee and a complaints mechanism.
11. Labelling of medicines is governed under the Therapeutic Goods Act 1989 and state/territory legislation. Apart from the general information such as name, quantity, and dosage of medicines, etc., which must be included in the labels, all medicines are required to carry either the "Aust R" or "Aust L" labels which indicate whether or not the efficacy of the products have been evaluated.
12. Sponsors who wish to import medicines for supply in Australia are required to obtain the appropriate licences/permits prior to importing. Import licences or permits for prescription medicines will only be issued to registered medical practitioners or pharmacists.
13. The standard patent protection for a new medicine is 20 years. This term of patent protection can be extended by a maximum of five years. While the Australian government is responsible for granting patents, it does not enforce patent rights. Enforcement is the responsibility of the patent right holder.
14. Pharmacies are subject to the control of state/territory legislation. In all states, the ownership of pharmacies is restricted to pharmacists only. In Northern Territory, pharmacies are required to be managed by pharmacists. The Australian Capital Territory legislation does not specifically restrict the ownership of pharmacies. All states and territories require the registration of pharmacists.
15. In 1996, the Australian National Audit Office carried out an audit to assess the efficiency, effectiveness and accountability of the evaluation and approval of prescription medicines conducted by the Therapeutic Goods Administration. The audit report made 14 recommendations and confirmed that "*the medicine evaluation process was efficient*". In 1999, a follow-up audit was conducted to review the extent to which the Therapeutic Goods Administration had implemented the recommendations. The follow-up audit report noted that there was "*a high level of industry confidence in the evaluation process of the Therapeutic Goods Administration*".

REGULATION OF MEDICINES IN AUSTRALIA

PART 1 - INTRODUCTION

1. Background

1.1 The Panel on Health Services at its meeting on 8 January 2001 requested the Research and Library Services Division to conduct a research on the regulation of medicines in Australia.

1.2 This request was made following our previous research report on "Regulation of Health Food in Australia" (RP04/00-01) and having regard to the initiative stated in "The 2000 Policy Address - Policy Objectives" that the Hong Kong Special Administrative Region Government planned to put in place a statutory framework for the regulation and control of Chinese medicines. This research paper aims to provide the Panel with information on how the Australian government regulates medicines.

2. Objective of the Research

2.1 The objective of this research paper is to analyze the regulation of medicines in Australia. The paper discusses the legislative framework, the control of the manufacture, advertising and labelling of medicines, the sale and distribution of medicines, the patent protection for medicines, and the enforcement of the relevant regulations.

3. Methodology

3.1 Information for this research report is obtained from the internet, government reports and relevant reference materials. Telephone interviews with Australian government officials were also conducted.

3.2 The average exchange rate in year 2000 between HK\$ and AUS\$ was HK\$4.53 = AUS\$1.¹

¹ Census and Statistics Department, *Hong Kong Monthly Digest of Statistics*, January 2001.

PART 2 - INTRODUCTION

4. Terms and Definitions

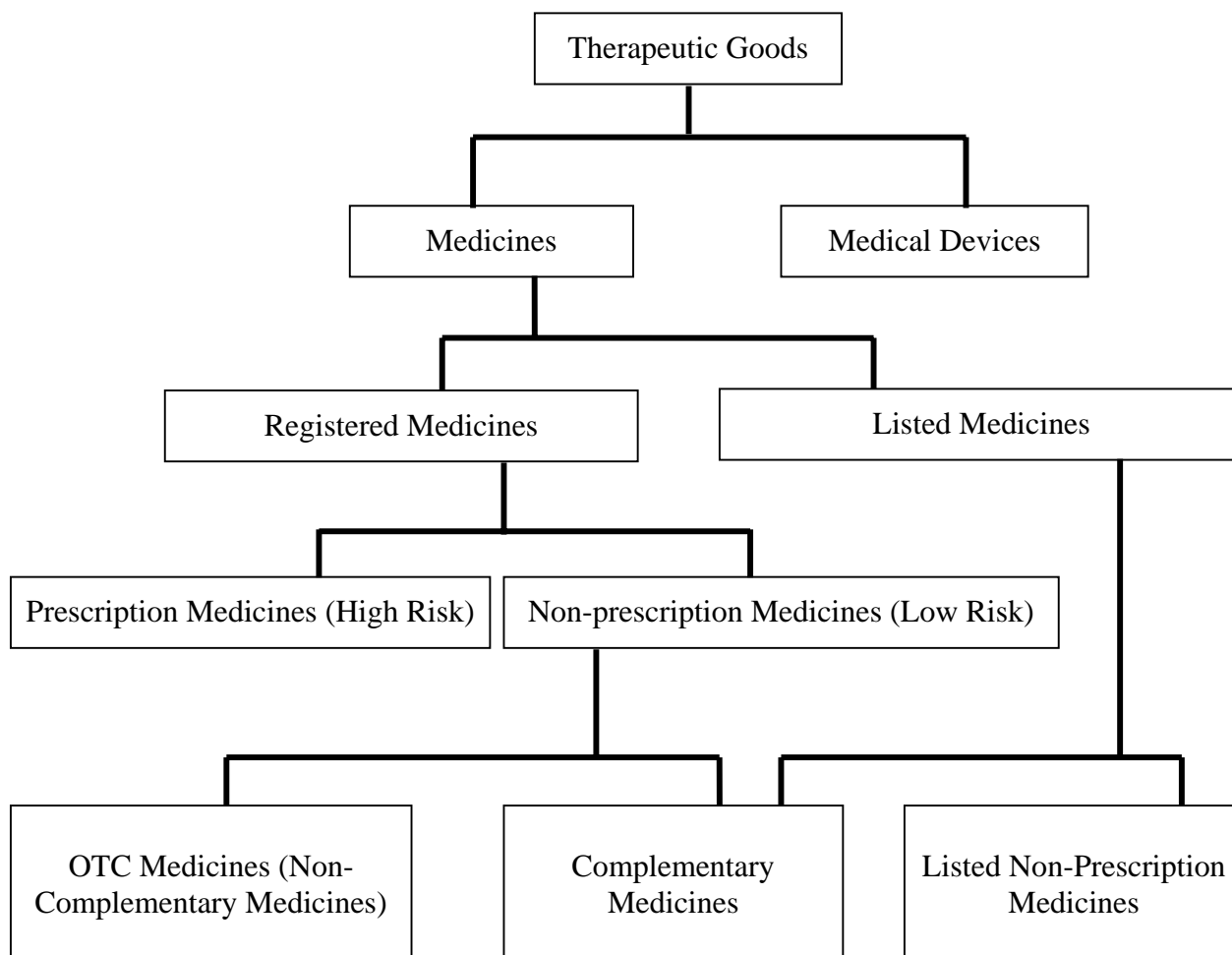
Therapeutic Good

4.1 A therapeutic good is broadly defined in the Therapeutic Goods Act 1989 as a good which can be represented in any form and which is for therapeutic use. It can be a medicine or a medical device. Please see Appendix I for the detailed definition of a therapeutic good. In general, a therapeutic good is used in or in connection with²:

1. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or
2. influencing, inhibiting or modifying a physiological process; or
3. testing the susceptibility of persons to a disease or ailment; or
4. influencing, controlling or preventing conception; or
5. testing for pregnancy; or
6. the replacement or modification of parts of the anatomy.

4.2 Diagram 1 shows the classification of therapeutic goods.

² Therapeutic Goods Administration, *Medicines Regulation and the TGA*, December 1999.

Diagram 1 - Classification of Therapeutic Goods

Remark:

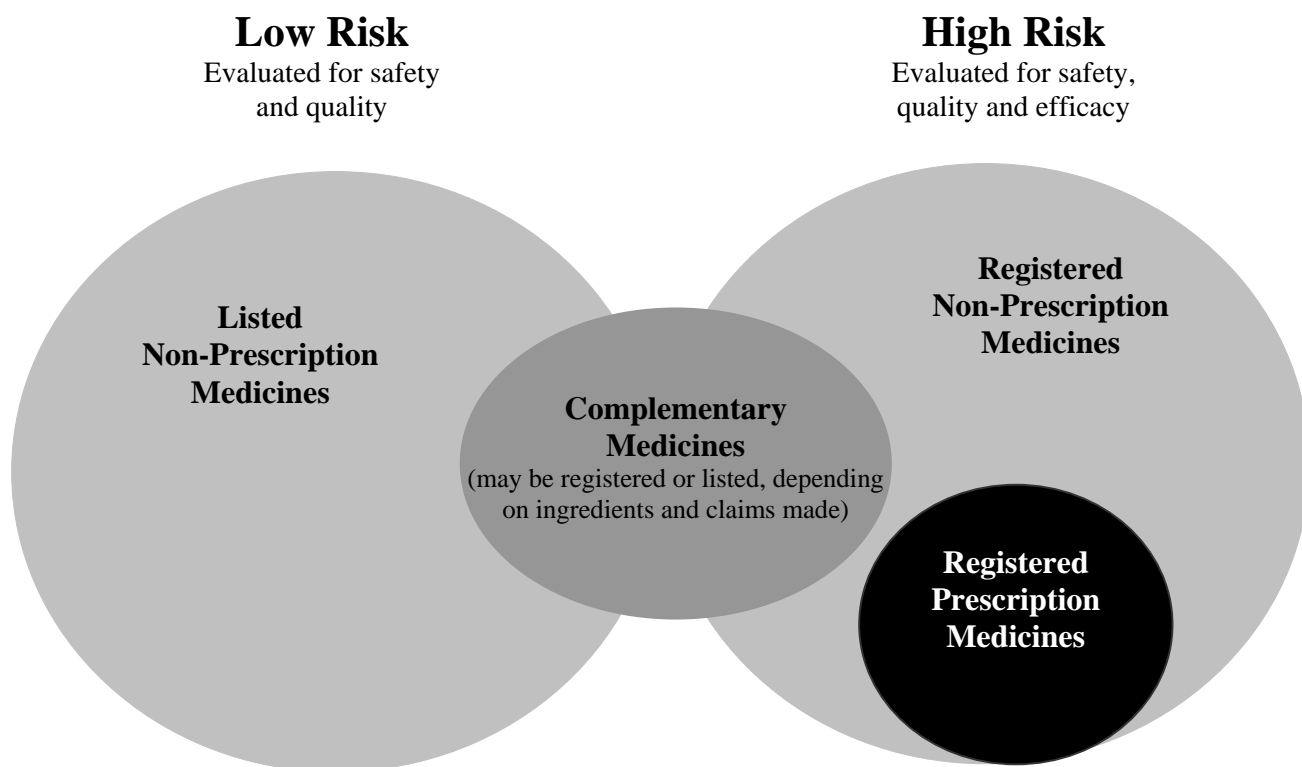
1. OTC Medicines - Over-The-Counter Medicines

Adapted from: Commonwealth Department of Health and Aged Care, *Overview of the Regulatory Requirements for the Manufacture and Supply of Medicines in Australia and for Export*, Nov. 1999.

Medicines

4.3 Medicines can be classified as registered medicines or as listed medicines in the Australian Register of Therapeutic Goods. The Australian Register of Therapeutic Goods is a database of information about therapeutic goods which are approved for supply in or export from Australia. Registered medicines in the Australian Register of Therapeutic Goods are of higher risk than listed medicines. Therefore, the level of assessment and the degree of regulation which registered medicines undergo are also more rigorous and detailed: while sponsors³ of registered medicines are required to provide comprehensive safety, quality and efficacy data, sponsors of listed medicines are required to provide data on safety and quality only. Diagram 2 shows the risk relationship between the various types of medicines registered or listed in the Australian Register of Therapeutic Goods.

Diagram 2 - Risk Relationship Between the Various Types of Medicines



Source: Commonwealth Department of Health and Aged Care, *Overview of the Regulatory Requirements for the Manufacture and Supply of Medicines in Australia and for Export*, Nov. 1999.

³ A sponsor is someone who imports or manufactures therapeutic goods, or has therapeutic goods imported or manufactured on his behalf, or exports therapeutic goods from Australia. A sponsor must be a resident of Australia or carrying on a business in Australia. Source: Therapeutic Goods Administration, *Overview of the Regulatory Requirements for the Manufacture and Supply of Medicines in Australia and for Export*, 1999.

Listed Medicines

4.4 Listed medicines are low risk medicines and they may only contain ingredients which are listed in the Australian Register of Therapeutic Goods and such ingredients usually have a long history of use. Listed medicines do not contain substances which are scheduled in the Standard for Uniform Scheduling of Drugs and Poisons⁴. They are assessed by the Therapeutic Goods Administration for safety and quality but not efficacy. To expedite the evaluation process, sponsors are allowed to self-assess the products, i.e. the products are assessed by sponsors against standards defined by the Therapeutic Goods Administration. The assessment is then subject to a simple 'eligibility review' by the Therapeutic Goods Administration for compliance with certain basic safety and quality parameters. If the assessment passes the 'eligibility review', the sponsor receives a confirmation letter from the Therapeutic Goods Administration and the medicine can be listed in the Australian Register of Therapeutic Goods.

'For Export Only' Medicines

4.5 Medicines which are manufactured in Australia and *for export only* are required to be listed in the Australian Register of Therapeutic Goods. They need not be registered irrespective of ingredients and therapeutic claims made.

Registered Medicines

4.6 Registered medicines can be high risk products or low risk products which carry claims of efficacy. They can be classified either as non-prescription (low risk) registered medicines or as prescription (high risk) registered medicines. In assessing the level of 'risk', factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical condition for which the product is intended to be used are taken into account. Registered medicines are assessed by the Therapeutic Goods Administration for safety, quality and efficacy. They usually, but do not necessarily, contain substances scheduled in the Standard for Uniform Scheduling of Drugs and Poisons.

Non-Prescription (Low Risk) Registered Medicines

4.7 The purchase of non-prescription (low risk) registered medicines does not require a doctor's prescription. Examples of non-prescription (low risk) registered medicines are over-the-counter medicines such as analgesics, cough/cold preparations.

⁴ Some medicines contain substances which have restricted availability because of their toxicity, safety, risks and benefits associated with the use of them. These substances are listed in schedules contained in the Standard for the Uniform Scheduling of Drugs and Poisons.

Prescription (High Risk) Registered Medicines

4.8 Prescription (high risk) registered medicines are available on prescription only. Examples are all prescription medicines and, all injectables such as insulin for diabetics.

Complementary Medicines

4.9 Complementary medicines are low risk medicines which include herbal medicines, traditional medicines, vitamins, special purpose foods, nutritional supplements, homoeopathic and naturopathic products. They may either be registered or listed, depending on their ingredients and claims made. For details of the regulation of complementary medicines, please refer to our previous research paper entitled "Regulation of Health Food in Australia" (RP04/00-01).

Therapeutic Claims

4.10 Both registered and listed medicines can carry therapeutic claims. There are three levels of therapeutic claims - high, medium and general. High level claims are the strongest claims such as treating, curing, managing or preventing a disease or disorder, or treating vitamin or mineral deficiency diseases. Medium level claims are lesser claims such as health enhancement claims which apply to health enhancement of normal people, such as improving, promoting, enhancing or optimizing body organs or systems. General level claims are the broadest claims such as health maintenance claims which refer to an effect of a product or substance that may have in maintaining health. Appendix II summarizes the definitions of the different levels and types of therapeutic claims.

4.11 Registered medicines are allowed to carry all three levels of therapeutic claims. Listed medicines are allowed to carry medium or general levels of therapeutic claims.

PART 3 - COUNTRY BACKGROUND

5. Some Basic Facts

5.1 As at 1999, Australia has a population of 19 million.⁵ The Gross Domestic Products (GDP) of Australia in 1998-1999 amounted to AUS\$593 billion (or HK\$ 2.7 trillion).⁶

5.2 As at 1999, there were 4 954 approved pharmacies⁷ in Australia, representing a pharmacy to population ratio of one pharmacy to about 3 800 people. There were approximately 182.7 million prescriptions dispensed through pharmacies in 1997-1998.⁸

5.3 Between July 1998 and June 1999, Australian households spent an average of AUS\$699 (or HK\$3,166.5) each week on goods and services. Of which, AUS\$8 (or HK\$36.2) were spent on medicines, pharmaceutical products and therapeutic appliances.⁹

5.4 According to a National Health Survey conducted by the Australian Bureau of Statistics in 1995, about 69% of the Australian population had used some form of medicines in any two weeks during 1995. The National Health Survey also found that 59% of the population had used prescription or non-prescription medicines, 26% used vitamins and minerals and 9% used herbal or natural preparations for health related purposes.

5.5 Expenditure on medicines by both government and private sector represented 12% of the recurrent health expenditure in Australia in 1994-1995, reaching a total of AUS\$4,200 million (or HK\$19,026 million).¹⁰ Over half of this expenditure (51%) was incurred by the private sector and the remaining by the government, largely through the Pharmaceutical Benefits Scheme (to be detailed in paragraphs 17.3 - 17.4)

⁵ Australian Bureau of Statistics, *2001 Year Book Australia*, 2001, p. 131.

⁶ Australian Bureau of Statistics, *2001 Year Book Australia*, 2001, p. 973.

⁷ Commonwealth Department of Health and Aged Care, *Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation*, 1999.

⁸ Commonwealth Department of Health and Aged Care, *Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation*, 1999.

⁹ Australian Bureau of Statistics, *Household Expenditure Survey, Australia: Detailed Expenditure Items*, at <http://www.abs.gov.au/>.

¹⁰ Australian Bureau of Statistics, *Australian Social Trends 1998: Health - Health Related Actions: The Use of Medication*, at <http://www.abs.gov.au/>.

5.6 In 1999-2000, the value of imports of human use pharmaceuticals was AUS\$3.33 billion (or HK\$15.1 billion) whereas the value of exports of human use pharmaceuticals was AUS\$1.62 billion (or HK\$7.3 billion).¹¹

5.7 The pharmaceutical industry is the largest funder of medical research and the second most innovative manufacturing industry in Australia.¹² It generally takes on average 15 years to research and develop a new medicine; and only three in 10 approved medicines may produce sales that match or exceed the average R&D (research and development) costs.¹³

¹¹ Australian Pharmaceutical Manufacturers Association, *At A Glance: Pharmaceutical Fact Sheet*, at <http://www.apma.com.au/>.

¹² Australian Pharmaceutical Manufacturers Association, *1999-2000 APMA Facts Book: Pharmaceutical and Health Industry Information*, at <http://www.apma.com.au/>.

¹³ Australian Pharmaceutical Manufacturers Association, *1999-2000 APMA Facts Book: Pharmaceutical and Health Industry Information*, at <http://www.apma.com.au/>.

PART 4 - LEGISLATIVE FRAMEWORK OF MEDICINES

6. Legislative Framework

6.1 The main legislation governing medicines in Australia is the Therapeutic Goods Act 1989. The Therapeutic Goods Act is supported by the Therapeutic Goods Regulations, and various Orders and Determinations made pursuant to the Therapeutic Goods Act. Other Commonwealth, State and Territory legislation may also apply to certain medicines. The Therapeutic Goods Advertising Code and the Australian Code of Manufacturing Practice for Therapeutic Goods are the two main codes governing the advertising and manufacturing of medicines in Australia. Appendix III gives a list of legislation relating to the regulation of medicines in Australia.

Therapeutic Goods Act 1989

6.2 The objective of the Therapeutic Goods Act is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods including medicines in Australia.

6.3 The Therapeutic Goods Act sets out requirements for manufacturing, supplying, advertising and labelling medicines in Australia. It also details the requirements for listing or registering medicines in the Australian Register of Therapeutic Goods.

6.4 The Therapeutic Goods Act applies to all parties who supply medicines or manufacture medicines for supply in Australia, and all parties who import or export medicines.

Therapeutic Goods Regulations

6.5 The objective of the Therapeutic Goods Regulations is to prescribe matters in respect of the manufacture, supply, advertising, registering or listing of medicines in Australia so as to make it necessary or convenient to carry out or give effect to the Therapeutic Goods Act.

Therapeutic Goods Advertising Code

6.6 The objective of the Therapeutic Goods Advertising Code is to ensure that the marketing and advertising of medicines to consumers is conducted in a manner that promotes the quality use of medicines, is socially responsible and does not mislead or deceive consumers.

6.7 The Therapeutic Goods Regulations require that all advertising about therapeutic goods including medicines must comply with the Therapeutic Goods Advertising Code.

Australian Code of Manufacturing Practice for Therapeutic Goods

6.8 The Australian Code of Good Manufacturing Practice is a set of principles and procedures which are necessary to follow in order to provide assurance that each medicine product is safe and of the required quality. It comprises requirements relating to premises, equipment, personnel, documentation and quality control. These requirements are enforced through systems of factory audits and mandatory licensing of factories which manufacture medicines.

6.9 The Therapeutic Goods Act 1989 requires Australian manufacturers of medicines to hold a licence. Licence holders are required to comply with the Australian Code of Good Manufacturing Practice under the Therapeutic Goods Act 1989.

6.10 Overseas manufacturers of medicines supplied to Australia must provide evidence that the goods are manufactured to a standard of Good Manufacturing Practice equivalent to that expected of Australian manufacturers of the same goods.

7. Authorities Involved in the Regulation of Medicines

Therapeutic Goods Administration

7.1 The Therapeutic Goods Administration is a division of the Commonwealth Department of Health and Aged Care and is responsible for administering the Therapeutic Goods Act.

7.2 The Therapeutic Goods Administration's overall control of the supply of medicines in Australia is exercised through five main processes:

1. pre-market evaluation and approval of medicines intended for supply in Australia;
2. licensing of manufacturers in accordance with international standards under Good Manufacturing Practice;
3. post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries;
4. development, maintenance and monitoring of the systems for registering and listing of medicines; and
5. the assessment of medicines for export.

Committees Involved in the Regulation of Medicines

7.3 There are a number of committees which make recommendations in relation to medicines, or monitor the regulatory framework of medicines. They play an equally important role as a government agency in the regulation of medicine. For example, the Medicines Evaluation Committee is a statutory committee which provides advice to the Therapeutic Goods Administration on whether a new substance or a new medicine should be permitted on the Australian Register of Therapeutic Goods as a listed or a registered product. The Therapeutic Goods Committee is an expert committee which is responsible for advising the Australian Minister for Health and Aged Care on adoption of therapeutic standards, requirements for labelling/packaging and the manufacturing principles. The Therapeutic Goods Advertising Code Council is responsible for the review and maintenance of the Therapeutic Goods Advertising Code. There are 14 such committees participating in the regulatory framework of medicines in Australia.

7.4 Some of these committees operate within the Therapeutic Goods Administration. Others are composed of people from industry, healthcare practitioners, professionals, and consumers. For details of the functions and membership of the committees, please refer to Appendix IV.

PART 5 - REGULATION OF MEDICINES

8. Pre-Market Assessment

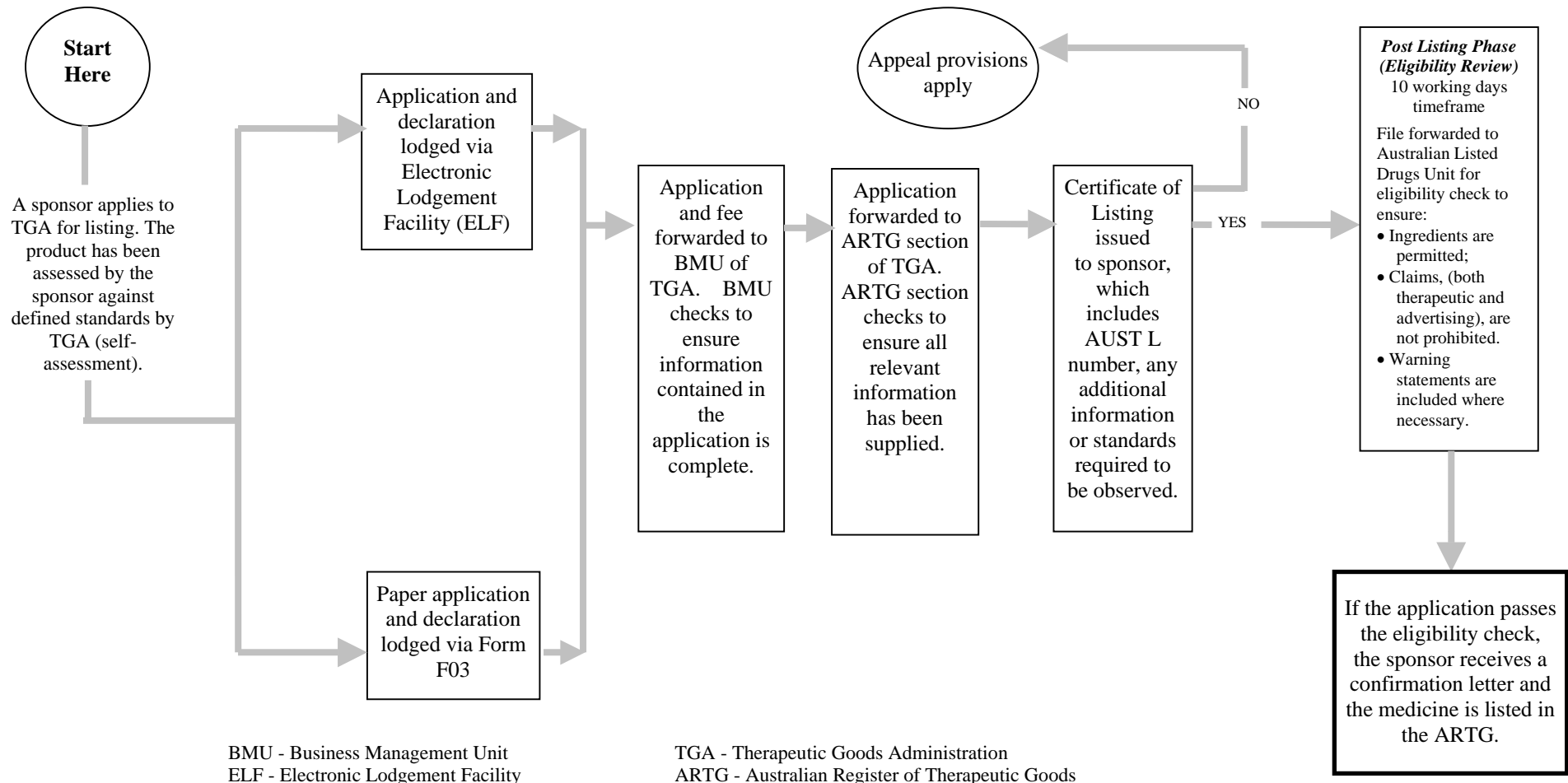
8.1 All medicines must be either listed or registered in the Australian Register of Therapeutic Goods before they can be supplied in Australia. They are also required to undergo an assessment before they can be listed or registered. The assessments of listed and registered medicines are different in terms of the complexity of the procedures undergone and the standard of requirements to be met. However, there are a few procedures which are common to both listed and registered medicines.

1. A sponsor submits an application to the Therapeutic Goods Administration for listing or registering a medicine in the Australian Register of Therapeutic Goods. He may refer to Schedules 4 and 5 of the Therapeutic Goods Regulations 1990 to determine whether the medicine is listable or registrable. (Please see Appendix V for details). A fee is required when the application is accepted for evaluation.
2. The Therapeutic Goods Administration evaluates the application or it refers the application to an external committee for evaluation.
3. If the application is accepted, an AUST L or AUST R number will be issued for the medicine and the medicine can be listed or registered in the Australian Register of Therapeutic Goods.
4. If the application is rejected, the sponsor may appeal.
5. The appeal is handled by the Therapeutic Goods Administration. During the appeal, the sponsor may submit additional information to the Therapeutic Goods Administration for evaluation. If the application is rejected, the sponsor may further appeal to the Secretary of the Department of Health and Aged Care, and ultimately, to the Administrative Appeals Tribunal¹⁴.

8.2 For details of the process of listing or registering medicines in the Australian Register of Therapeutic Goods, please refer to diagrams 3, 4 and 5.

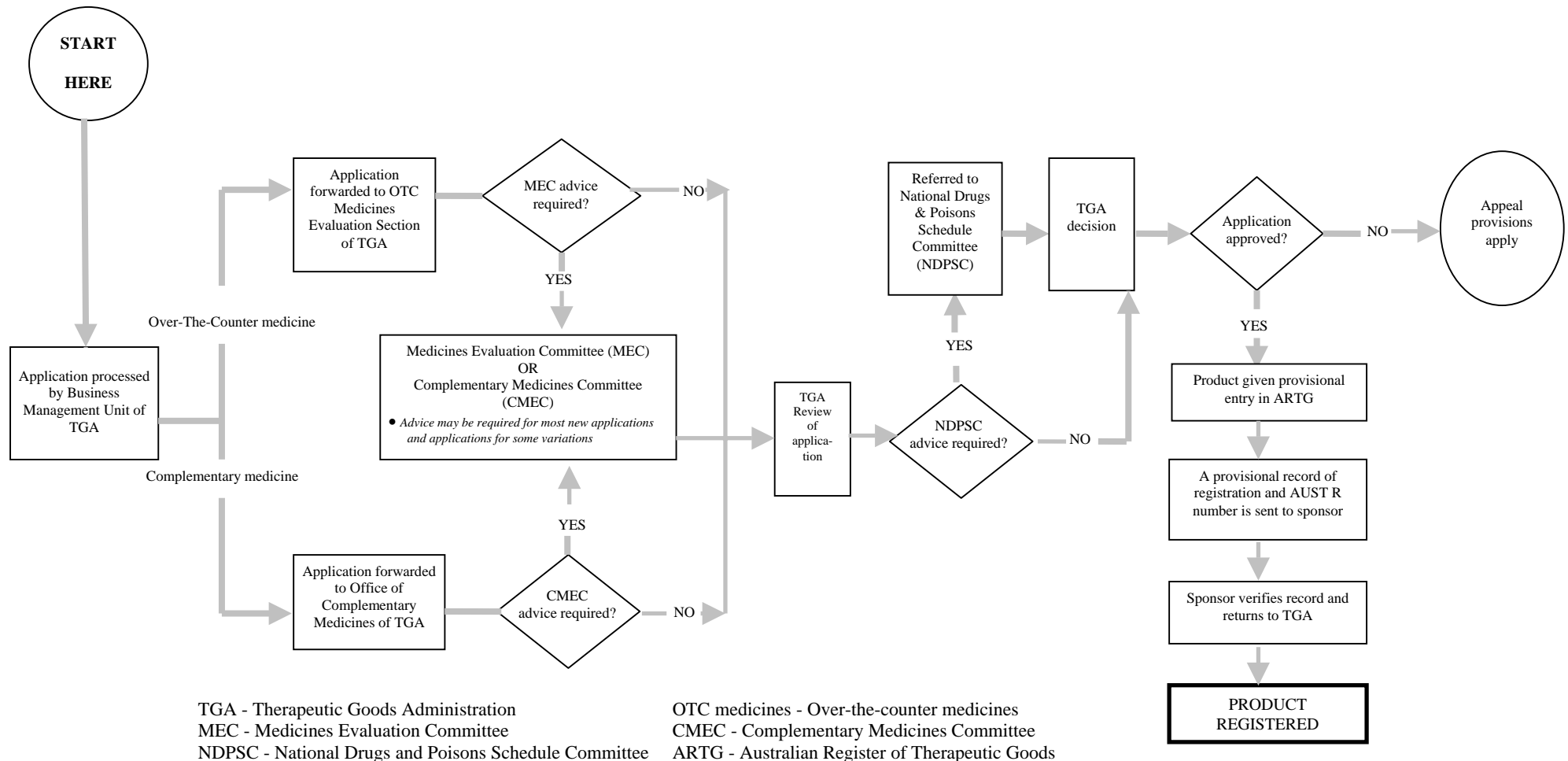
¹⁴ The Administrative Appeals Tribunal provides independent review of administrative decisions made by the Australian Commonwealth government and some non-government bodies. It consists of judges of the Federal Court of Australia, Family Court of Australia, lawyers and people who have special expertise in areas such as accountancy, medicine, insurance, social welfare, etc.

Diagram 3 - A Roadmap to Listing Medicines in the Australian Register of Therapeutic Goods



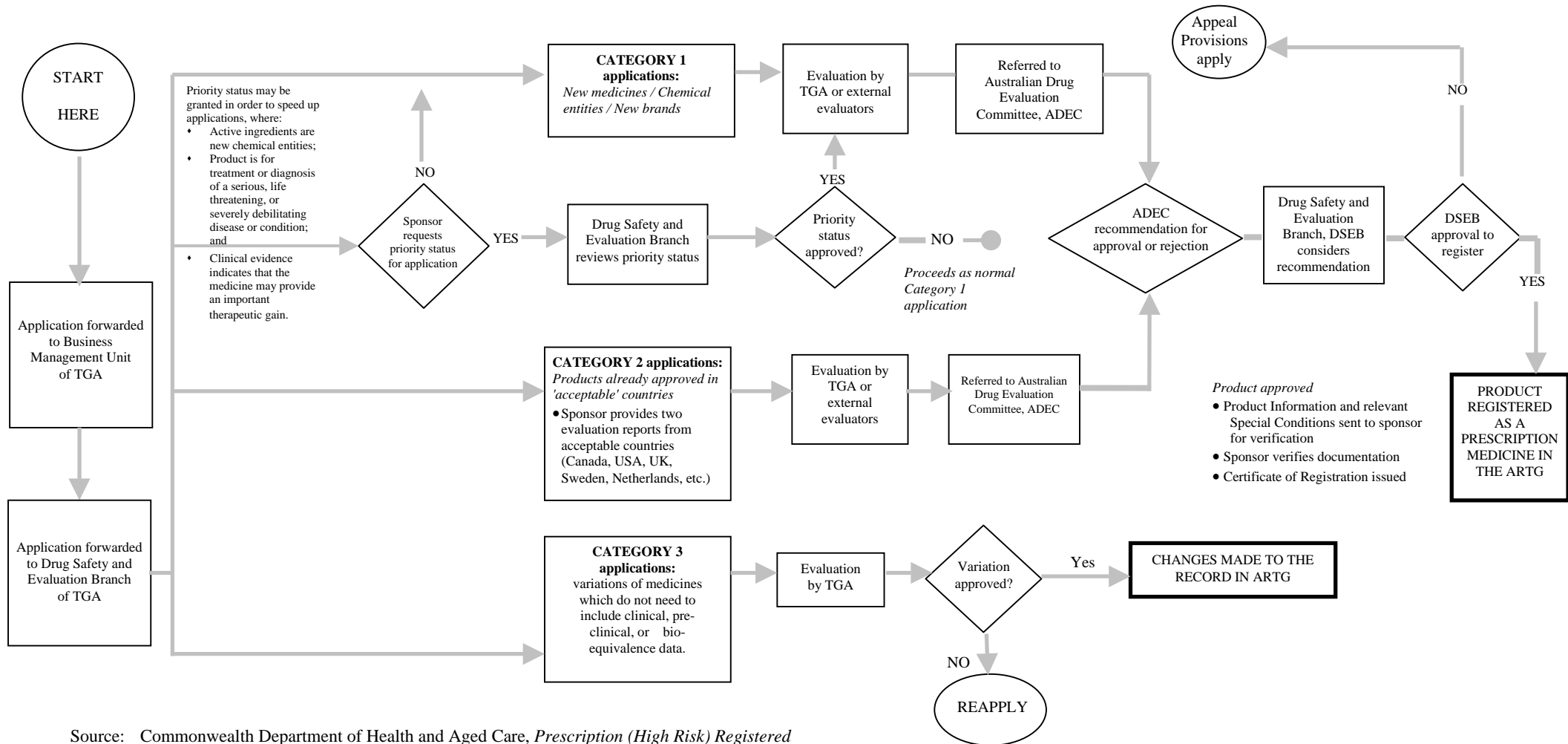
Source: Commonwealth Department of Health and Aged Care, *Listed Medicines*, at <http://www.health.gov.au/tga>.

Diagram 4 - A Roadmap to Registering Non-Prescription (Low Risk) Medicines in the Australian Register of Therapeutic Goods



Source: Commonwealth Department of Health and Aged Care, *Non-Prescription (Low Risk) Registered Medicines*, at <http://www.health.gov.au/tga/>

Diagram 5 - A Roadmap to Registering Prescription (High Risk) Medicines in the Australian Register of Therapeutic Goods



Source: Commonwealth Department of Health and Aged Care, *Prescription (High Risk) Registered Medicines*, at <http://www.health.gov.au/tga/>

8.3 Tables 1 and 2 show the target time and the actual time for processing applications for the entry of non-prescription and prescription medicines onto the Australian Register of Therapeutic Goods in 1999-2000.

Table 1 - Timeframes for Processing Applications for the Entry of Non-Prescription Medicines onto the Australian Register of Therapeutic Goods in 1999-2000

Type of application	Target time (working day)	Average time (working day)
Listed medicines Lodged via the electronic lodgment facility	10	5.6
Listed medicines Lodged via paper form	30	15.2
Variations of non-prescription (low risk) registered medicines	No information available	No information available
New non-prescription (low risk) registered medicines	71	59.5

Source: Commonwealth Department of Health and Aged Care, *Annual Report, 1999-2000*.

Table 2 - Timeframes for Processing Applications for the Entry of Prescription Medicines onto the Australian Register of Therapeutic Goods in 1999-2000

Category	Statutory time limit ¹ (working day)	No. of applications processed in the period	No. of applications resolved within time limit
1*	255	371	371
2**	175	0	Not applicable
3***	45	831	831

Remarks:

1. Statutory time limit exists only for processing applications for the entry of *prescription* medicines onto the Australian Register of Therapeutic Goods.
2. * Category 1 application is an application to register a prescription medicine via the normal process of evaluation.
3. ** Category 2 application is an application to register a prescription medicine with the same formulation, dosage and indications as in two acceptable countries and for which two independent evaluation reports are available.
4. *** Category 3 application is an application to register or to vary the registration of a prescription medicine where the application does not require the support of clinical, pre-clinical or bio-equivalence data.

Source: Commonwealth Department of Health and Aged Care, *Annual Report, 1999-2000*.

8.4 It is noted that during the evaluation of an application, the Therapeutic Goods Administration may request the sponsor to provide further information. However, the time taken by sponsors to respond to requests for further information is excluded from the processing time. Therefore, the actual time taken to process and evaluate an application is longer than the target time stated above. There is no information about the average actual time taken to process and evaluate an application. According to the Therapeutic Goods Administration, they were able to meet all the target times in 1999-2000.

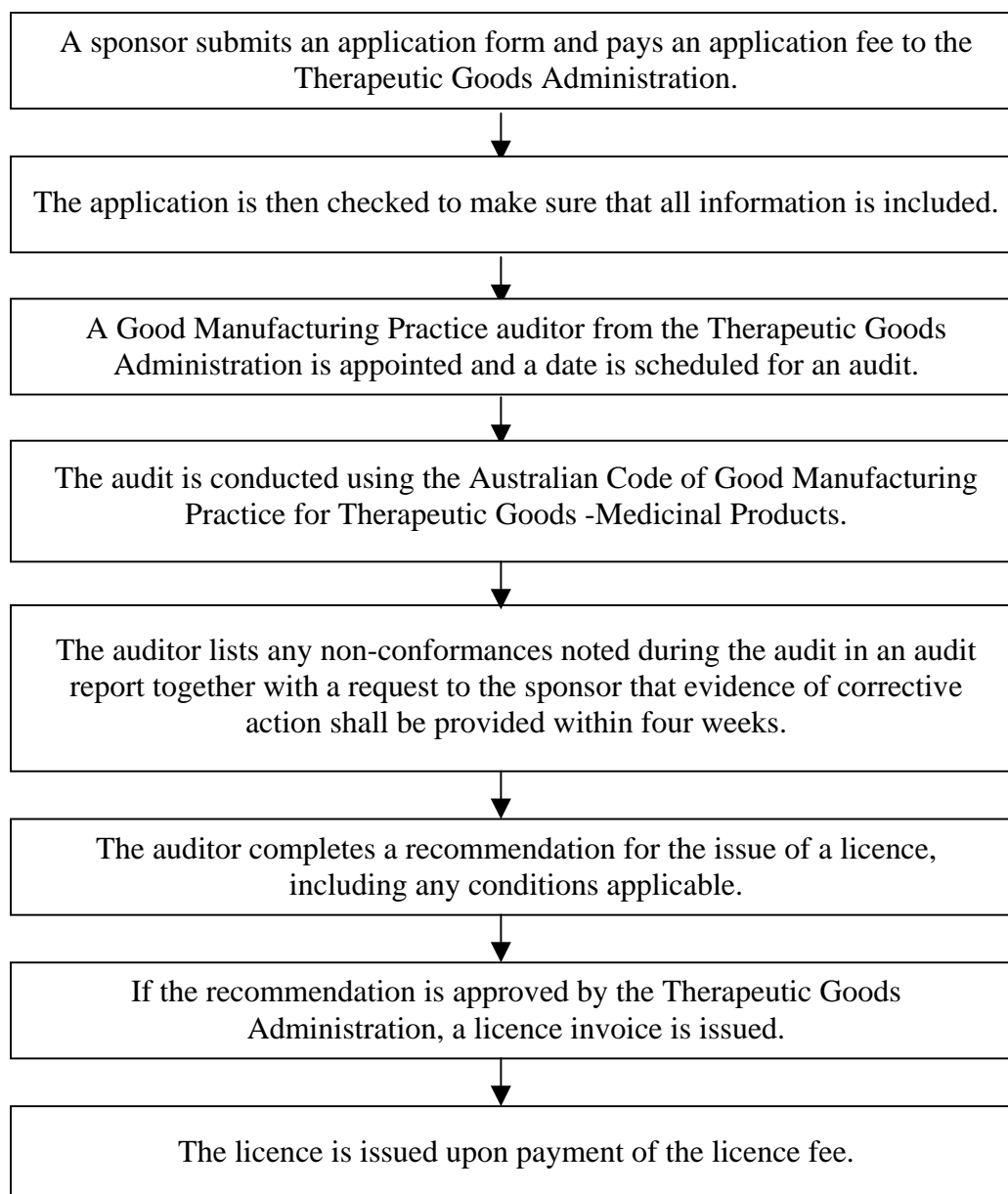
9. Manufacturing Requirements

9.1 Australian manufacturers of medicines must be licensed under the Therapeutic Goods Act 1989. Their manufacturing processes must comply with principles of Good Manufacturing Practice. The aim of licensing is to protect public health by ensuring that medicines meet definable standards of quality assurance and are manufactured in conditions which are clean and free of contaminants.

Licensing of Manufacturers

9.2 Applications for a manufacturing licence are assessed through an inspection of the manufacturing premises, i.e. an audit. Auditors from the Therapeutic Goods Administration conduct audits of the manufacturing premises and a licence is issued only after all the requirements have been met. Audits are conducted before a licence is issued, and at regular intervals after the licence has been granted -- generally every 15 to 24 months, depending on the complexity of the manufacturing process and whether previously identified deficiencies have been corrected.

9.3 The sequence of events in applying for a manufacturing licence is outlined below:



Once issued, a licence remains in force until it is suspended, cancelled, or revoked.

10. Post-Market Vigilance

10.1 In Australia, post-market vigilance activities include the following:

1. investigating problems which have been reported through the Adverse Drug Event Reporting System (to be detailed in paragraphs 10.4-10.5);
2. conducting inspections of the manufacturing premises to ensure their compliance with the relevant Code of Good Manufacturing Practice;
3. conducting laboratory testing of products on the market and if necessary, conducting recalls of deficient medicines (to be detailed in paragraphs 10.6-10.7); and
4. conducting surveillance activities.

10.2 According to the Therapeutic Goods Administration, these activities are conducted regularly and in response to problem reports received.

10.3 In 1999-2000, a total of 1 658 samples were tested whereas in the previous year, only 1 346 samples were tested. Over 10 000 tests were performed on the samples.¹⁵

Adverse Drug Event Reporting

10.4 In Australia, the Adverse Drug Reactions Advisory Committee (ADRAC) is responsible for monitoring drug safety in the post-marketing phase. Reports from the Adverse Drug Event Reporting System are received by the ADRAC Secretariat where they are assessed. This involves checking the report, assigning a causality rating between the adverse reaction and the suspected drug, and making the decision as to whether further information such as clinical or laboratory testing results are required. The reports are then entered into a database and reviewed by the ADRAC which would provide advice on the appropriate responses to adverse reactions such as a recall of deficient medicines to the relevant authorities (e.g. Australian Drug Evaluation Committee for pharmaceutical products, Medicines Evaluation Committee for over-the-counter medicines, Office of Complementary Medicines of the Therapeutic Goods Administration for complementary medicines, etc.).

¹⁵ Commonwealth Department of Health and Aged Care, *Annual Report, 1999-2000*.

10.5 In 1998, ADRAC received almost 11 000 adverse drug events reports with 46% from pharmaceutical companies, 26% from general practitioners, 21% from hospitals and 7% from other sources including community pharmacists and specialists.¹⁶

Recall of Medicines

10.6 A recall is a permanent removal of deficient medicines from the market. Most recalls are conducted on a voluntary basis. However, the recall procedures are underpinned by the Therapeutic Goods Act 1989 and the Trade Practices Act 1974. Where a request for a recall is refused, or is not carried out satisfactorily, the Minister for Health and Aged Care may order a mandatory recall. Failure to comply with such an order may result in substantial fines.

Recall Figures

10.7 Table 3 shows the number of recalls of therapeutic goods (including medicines and medical devices) made between 1997 and 1999. Approximately one-third of the products recalled were medicines and two-thirds were medical devices.¹⁷ Most medicine recalls required the affected products to be recovered from pharmacies and other retailers. In cases where it is necessary to stop all usage of a product, a consumer level recall¹⁸ is conducted. There were 42 consumer level recalls in 1997, 14 in 1998 and six in 1999.¹⁹

Table 3 - Number of Recall of Therapeutic Goods (including medicines and medical devices) Between 1997 and 1999

Year	Number of Recall
1997	216
1998	218
1999	229

Source: Therapeutic Goods Administration, *TGA News*, Issue 32, May 2000.

¹⁶ Commonwealth Department of Health and Aged Care, *Australian Statistics on Medicines 1998, 1999*.

¹⁷ Therapeutic Goods Administration, *TGA News*, Issue 32, May 2000.

¹⁸ There are four levels of recall: wholesale, hospital, retail and consumer. A wholesale level recall refers to a recall from state purchasing authorities. A hospital level recall includes a wholesale level recall and recalls from nursing homes, hospital pharmacies, etc. A retail level recall includes a wholesale level recall, a hospital level recall and recalls from retail pharmacists, medical practitioners, retail outlets, etc. A consumer level recall includes a wholesale level recall, a hospital level recall, a retail level recall and recalls from patients and other consumers.

¹⁹ Therapeutic Goods Administration, *TGA News*, Issue 32, May 2000.

11. Regulation of Therapeutic Claims of Medicines

11.1 Medicines may carry three levels of therapeutic claims - high, medium and general. While listed medicines are allowed to carry medium and general levels of therapeutic claims, registered medicines are allowed to carry all three levels of therapeutic claims. Appendix II summarizes the definitions of different levels and types of therapeutic claims.

11.2 There are two types of evidence which may be used to support therapeutic claims. They are scientific evidence, and evidence based on traditional use of a substance or a product.

11.3 Scientific evidence refers to quantifiable data which include clinical trials in humans, epidemiological evidence, animal studies and other evidence of biological activity. Scientific evidence can be used to support all three levels of therapeutic claims, i.e. high, medium and general.²⁰

11.4 Evidence of traditional use refers to documentary evidence that a substance has been used over three or more generations of recorded use for a specific health related or medicinal purpose. Where tradition of use has been recorded as an oral rather than written history, then evidence of such is required to be obtained from the appropriate practitioner or indigenous groups, who maintain such a history.²¹

11.5 Evidence of traditional use may only be used to support medium and general levels of therapeutic claims. There is also a restriction on the wordings of the claims if the claims are solely supported by evidence of traditional use; in the product label, there should be a statement stating clearly that this product has been *traditionally* used for a particular indication and the claim is based on traditional use. Appendix VI summarizes the types of evidence required to support the three levels of therapeutic claims and the conditions associated with the use of them.

11.6 The Therapeutic Goods Administration is responsible for determining the standards which each therapeutic claim must meet. Sponsors of medicines have the primary responsibility to ensure that claims made about the medicines are true, valid and not misleading. If a question arises about the appropriateness of evidence supporting a therapeutic claim, the final evaluation of that evidence will be made by the Therapeutic Goods Administration.

²⁰ Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods - Draft - For Consultation*, 14 November 2000.

²¹ Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods - Draft - For Consultation*, 14 November 2000.

12. Regulation of Advertisements

12.1 In Australia, only non-prescription (low risk) registered medicines and listed medicines can be advertised publicly and the advertisements must comply with the Therapeutic Goods Advertising Code. Prescription (high risk) registered medicines are not subject to the Therapeutic Goods Advertising Code as it is illegal to advertise them publicly. However, prescription (high risk) registered medicines may be advertised to health professionals.

Advertising of Non-Prescription (Low Risk) Registered Medicines and Listed Medicines

12.2 The Therapeutic Goods Regulations require that all advertising for non-prescription (low risk) registered medicines and listed medicines in the mainstream media²² must comply with the Therapeutic Goods Advertising Code and go through a system of prior approval. Other non-mainstream media advertising must also comply with the Therapeutic Goods Advertising Code but a formal prior approval is not required.

12.3 The responsibility for the approval of mainstream advertising of non-prescription medicines (excluding complementary medicines²³) has been delegated to the Australian Self-Medication Industry (ASMI) (formerly known as the Proprietary Medicines Association of Australia). Industry Code of Practice is also developed by ASMI to guide companies engaged in marketing the medicines.

²² Mainstream media means any magazines or newspapers for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

²³ The responsibility for approving mainstream advertisements of complementary medicines is delegated to the Complementary Healthcare Council of Australia. For details, please refer to the research paper entitled "Regulation of Health Food in Australia" RP04/00-01.

The Approval Process

- 12.4 The approval process is outlined below:
1. Draft advertisements of non-prescription medicines are submitted to the Australian Self-Medication Industry for approval.
 2. The advertisements are reviewed and the applicant will be notified of any changes or will be requested to submit further evidence to substantiate the therapeutic claims made.
 3. If the advertisements are approved, an approval number will be allocated for each approved print advertisement and this approval number must appear on the advertisement. However, for broadcast advertisements, no approval numbers are issued.
 4. Approvals are valid for a period of two years. When the approval expires, the advertisements must be submitted again for re-approval.
 5. In the event of non-approval, the applicant may appeal to the Minister for Health and Aged Care and ultimately, to the Administrative Appeals Tribunal.

Complaints About Advertising

12.5 Any person may lodge a complaint about an advertisement (print or broadcast) of a non-prescription medicine. If the complaint is about an advertisement in the mainstream media, it will be considered by the Complaints Resolution Panel, an independent committee established under the Therapeutic Goods Regulations. If the complaint is about an advertisement in other forms of publication such as indoor posters, brochures, catalogues, fact sheets, etc., it will be considered by the industry complaints panel, the Australian Self-Medication Industry's Complaints Panel.

12.6 The Complaints Resolution Panel is chaired by a person elected by the Therapeutic Goods Advertising Code Council. The membership of the Panel consists of representatives from industry, consumer groups, healthcare professionals and government.

12.7 The complaints handling procedures are outlined below:

1. A complaint is submitted to the Complaints Resolution Panel. The complaint must be in writing and must include a copy of the advertisement in question.
2. The company whose advertisement is in question is invited to respond to the complaint and the complainant may also respond to the company's response.
3. The Complaints Resolution Panel considers the complaint and all the submissions and decides whether the complaint is justified.
4. Where the complaint is found justified, the company may be requested to withdraw the advertisement in question or to publish a retraction. In the case of a failure to comply with the request, the Complaints Resolution Panel may make a recommendation to the Secretary of the Department of Health and Aged Care for further action²⁴.

12.8 According to the Complaints Register²⁵, there were 55 complaints handled by the Complaints Resolution Panel in the year 2000. About 80% of these complaints were found justified and sponsors of advertisements were requested to withdraw the advertisements in question.

12.9 As mentioned in paragraph 12.5, the Australian Self-Medication Industry's Complaints Panel ("Industry Panel") hears complaints about advertisements in non-mainstream media. A representative from the Therapeutic Goods Administration is an observer to the Industry Panel and the Industry Panel can impose a range of sanctions, including corrective advertising and pecuniary fines against advertisements in violation of the Industry Code of Practice.

²⁴ The Complaints Resolution Panel may recommend to the Secretary of the Department of Health and Aged Care to do one or more of the following: (a) withdraw the approval of the advertisement; (b) cancel the registration or listing of the medicinal product; (c) order the publication of a retraction; (d) order the publication of a correction; (e) order the recovery of any advertisement which is still in circulation; (f) order the destruction of the advertisement. Regulation 42ZCAI of the Therapeutic Goods Regulations.

²⁵ Therapeutic Goods Advertising Code Council, *Complaints Register*, at <http://www.tgacc.com.au/complaintsList.cfm>.

Advertising of Prescription (High Risk) Registered Medicines

12.10 Advertisements of prescription (high risk) registered medicines may only be directed to health professionals and they are restricted to the indications²⁶ included in the Australian Register of Therapeutic Goods. There is also an industry Code of Practice setting standards of conduct for marketing prescription medicines. The Code entitled the "Code of Conduct of the Australian Pharmaceutical Manufacturers Association" is developed by the Australian Pharmaceutical Manufacturers Association (APMA)²⁷. The APMA has established a Monitoring Committee²⁸ to review promotional materials of medicines in the market to ensure compliance with the Code of Conduct.

Complaints About Advertising

12.11 Anyone may lodge a complaint about the promotional or marketing practice of a medicine to the Code of Conduct Secretary at the APMA. The complaint is then considered by an independent Code of Conduct Committee. This Committee is chaired by a lawyer with Trade Practice experiences and includes representatives of Australian Medical Association, Royal Australian College of General Practitioners, patient support groups, consumers, and APMA etc. There is also an observer from the Therapeutic Goods Administration on the Committee.

²⁶ Indications are conditions which a particular product claims to alleviate, aid or treat.

²⁷ The Australian Pharmaceutical Manufacturers Association is a non-profit professional and trade association of Australia's prescription pharmaceutical industry. Its member companies represent 95% of the prescription market in Australia and are engaged in the research, development, manufacture, marketing and export of prescription pharmaceuticals. Source: Australian Pharmaceutical Manufacturers Association, *1999-2000 APMA Facts Book: Pharmaceutical and Health Industry Information*, at <http://www.apma.com.au/>.

²⁸ The Monitoring Committee consists of representatives of Australian Medical Association, Royal Australian College of General Practitioners, and an expert in the therapeutic category under review. Source: Australian Pharmaceutical Manufacturers Association, *APMA Code of Conduct*, at <http://www.apma.com.au/>.

12.12 The complaints handling procedures are outlined below:

1. Any individual or company may lodge a complaint to the Code of Conduct Secretary at the APMA.
2. Once a complaint is received, it is sent to the company whose promotional activities are questioned and this company provides a response to the issues raised in the complaint.
3. The complaint and the response are considered by the independent Code of Conduct Committee, which determines whether the complaint is justified, i.e. whether a breach of the Code of Conduct has occurred, and if so, the appropriate sanction.
4. The company found in breach of the Code of Conduct may lodge an appeal against the decision of the Code of Conduct Committee and this appeal will be heard by an independent Code of Conduct Appeals Committee²⁹.

12.13 Sanctions which may be imposed by the Code of Conduct Committee include an immediate withdrawal or cessation of the promotional activity, the publication of corrective advertising, corrective letters to general practitioners and pharmacists, fines and suspension or expulsion from APMA membership.³⁰

13. Regulation of Labelling

13.1 Labelling of medicines is governed by the Order (No. 48) under the Therapeutic Goods Act 1989 and under other relevant state/territory legislation. It is the responsibility of the manufacturer, packer or distributor of a medicine to ensure that the product is correctly and adequately labelled.

²⁹ The Code of Conduct Appeals Committee is chaired by a lawyer with Trade Practice experiences and includes representatives of the College from the therapeutic class of the product, target audience to which the promotional activity was directed, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists and APMA. Source: Australian Pharmaceutical Manufacturers Association, *APMA Code of Conduct*, Edition 13, 16 February 2000. p.96.

³⁰ Australian Pharmaceutical Manufacturers Association, *APMA Code of Conduct*, at <http://www.apma.com.au/>.

13.2 Information on the labels of medicines includes: --

1. Names and quantities of all active ingredients;
2. Name of the product;
3. Quantity of the product (pack size);
4. Dosage form;
5. Batch number, expiry date and storage conditions;
6. An AUST R number if registered, or an AUST L number if listed;
7. Name and proportion of preservative used;
8. Name and address of the sponsor;
9. Relevant warning statements; and
10. Statement of purpose of use of the medicine.

14. Control of Imports

Good Manufacturing Practice for Medicines Manufactured Overseas

14.1 If a medicine is manufactured overseas, before it can be supplied to consumers in Australia, the sponsor is required to demonstrate to the Therapeutic Goods Administration that the manufacturer is operating under conditions which meet the Australian Code of Good Manufacturing Practice or other equivalent standards.

14.2 Two ways are open to the sponsor to establish Good Manufacturing Practice:-

1. To provide an acceptable form of evidence that the overseas manufacturer can produce the goods to the standard required by the Australian Code of Good Manufacturing Practice, or
2. To engage the Therapeutic Goods Administration to conduct an audit at the place of manufacture.

14.3 For the first method, the Therapeutic Goods Administration will accept Good Manufacturing Practice certification only from countries where the Therapeutic Goods Administration is satisfied that the standard of the overseas Good Manufacturing Practice inspections is equivalent to the Good Manufacturing Practice inspections in Australia. Examples of these countries are Austria, France, Germany, the United Kingdom, New Zealand, Singapore, and the United States.³¹

14.4 For the second method, the manufacturer must agree to the audit and the sponsor is required to pay the costs of the audit, including the relevant inspection fee, travel and accommodation costs, before the audit takes place.

Imported Medicines Manufactured Overseas

14.5 Sponsors who wish to import medicines for supply in Australia are required to obtain the appropriate licence³²/permit³³ prior to the goods arriving in Australia. The import licence or permit for a prescription medicine will only be issued to a registered medical practitioner or a pharmacist. This requirement is made in order to fulfil obligations under several international conventions³⁴, to which Australia is a signatory. These international conventions request the control of the availability of certain drugs/medicines, chemical substances, endangered species etc.

14.6 Table 4 summarizes the licences/permits required to be obtained. Failure to obtain the appropriate licence/permit may result in the destruction of the goods and criminal prosecution.

³¹ Therapeutic Goods Administration, *Guidelines on Standard of Overseas Manufacturers*, September 2000.

³² An import licence is issued to a sponsor who imports medicines.

³³ An import permit is issued for a single consignment of medicines and it cannot be reused.

³⁴ Examples of the international conventions include the Single Convention on Narcotic Drugs 1961, the Convention on Psychotropic Substances 1971, and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

Table 4 - Licences/Permits Required For Importing Medicines in Australia

Licence/Permit	Issuing Authority	Purpose
Both an import licence and an import permit	Therapeutic Goods Administration	To import medicines containing substances listed in Schedule 4 of the Customs (Prohibited Imports) Regulations. Examples are methadone, morphine, etc.
An import permit	Therapeutic Goods Administration	To import medicines containing substances listed in Schedule 8 of the Customs (Prohibited Imports) Regulations. Examples are thalidomide, or preparations that purport to be a remedy for drunkenness, alcoholic habit or drug habit.
A quarantine permit	Australian Quarantine and Inspection Service	To import medicines containing biological ingredients.
An Australian CITES ¹ permit	Department of Environment and Heritage	To import medicines containing ingredients which are subject to the treaties governing the trade in protected species of plants and animals.

Remark:

1. CITES stands for Convention on International Trade in Endangered Species of Wild Fauna and Flora.

Sources:

1. Therapeutic Goods Administration at <http://www.health.gov.au/tga/>.
2. Department of Environment and Heritage at <http://www.environment.gov.au/>.
3. Australian Quarantine and Inspection Service of the Department of Agriculture, Fisheries and Forestry at <http://www.aqis.gov.au/>.

14.7 In 1999-2000, 170 import licences and 2 668 import permits were issued for the importation of controlled drugs and other substances.³⁵

³⁵ Commonwealth Department of Health and Aged Care, *Annual Report, 1999-2000*.

15. Patent Medicines

15.1 In Australia, the standard patent³⁶ protection (i.e. competition free period) offered to a new medicine is 20 years.³⁷ Taken into account "the relatively long approval process of medicines"³⁸, the term of patent protection can be extended by a maximum of five years³⁹. IPAustralia⁴⁰ is a federal government agency which grants patents but it does not have a role in the enforcement of patent rights. Enforcement is the responsibility of the patent right holder who has recourse to the courts for infringement proceedings. Therefore, during the patent protection period, it is the responsibility of the patent right holder to monitor the market to identify potential infringement of his patent rights, enforce his patent rights and prosecute unauthorized users of his patent rights.

15.2 When the patent expires, other companies can apply to manufacture and sell a similar medicine, i.e. a medicine containing an identical amount of the same active ingredients, in the same strength and in the same dosage form as the patented medicine. The Therapeutic Goods Administration is required to assess this similar medicine before marketing approval is given to sell and distribute that product.

16. Infringement of Regulations

16.1 It is an offence to make false or misleading statements in an application for listing or registering in the Australian Register of Therapeutic Goods, or in an application for an import licence/permit, or in an application for a Good Manufacturing Practice licence. It is also an offence to manufacture, import and supply medicines in Australia without the appropriate licences/permits. Any person who is convicted of the above offences is subject to a fine and/or imprisonment.

³⁶ A patent is a monopoly right to the exclusive use of an invention for a certain period of time. It is granted in consideration of a complete disclosure of the invention.

³⁷ Section 67 of the Patent Act 1990 stipulates that the term of a standard patent is 20 years from the date of patent. Section 65 of the same Act defines that the date of patent is (a) the date of filing of relevant complete specification, or (b) where the regulations [regulations made by the Governor-General of Australia] provide for the determination of a different date as the date of a patent - the date determined under the regulations.

³⁸ Reply from IPAustralia (IP stands for intellectual property).

³⁹ Section 77 of the Patents Act 1990.

⁴⁰ IP stands for intellectual property.

Infringement

16.2 Between 1 July 1999 and 30 June 2000, there were 668 cases of alleged infringement reported to the Surveillance Unit of the Therapeutic Goods Administration. Over half of them were related to illegal importation, and one-third related to illegal supply of medicines in Australia. Please see Table 5 for details.

Table 5 - Number of Alleged Offences Between 1999 - 2000

Alleged Offences Relating to Medicines	Number of Alleged Offences
Illegal importation	373
Illegal supply	243
Illegal advertising / therapeutic claims	51
Illegal manufacture	21
Illegal export	9
Other	29

Remarks:

1. Other includes non-compliance with standards and offences under other legislation, such as the Trade Practices Act 1974.
2. Multiple offences may be included in one case.

Source: Commonwealth Department of Health and Aged Care, *Annual Report, 1999-2000*.

Counterfeit Medicines

16.3 It is also an offence to manufacture, supply, import or export counterfeit medicines. Counterfeit medicines are those which are falsely labelled or advertised as to their composition, manufacture or source. Any person who is convicted of the offence is subject to a fine and/or imprisonment.

16.4 The Parliamentary Secretary for Health and Aged Care, stated that 87 of the 577 offences prosecuted between 1992 and 1995 under the Therapeutic Goods Act 1989 involved counterfeiting activities.⁴¹

16.5 Counterfeit medicines also undermine patent protection for medicines and place the health of the public at risk. An action for patent infringement may be brought by the patent right holder or an exclusive licensee before the Federal Court of Australia or before a state court having appropriate jurisdiction.

⁴¹ Parliament of Australia, *Therapeutic Goods Amendment Bill (No.2) 2000 (Bills Digest No. 139 1999-2000)*, at <http://www.aph.gov.au/>.

16.6 The Australian patent law provides for three forms of remedy for patent infringement:

1. injunction - the infringer is refrained from further infringement;
2. damages - damages are awarded on the basis of compensation for loss suffered by the patentee as a result of the infringement; and
3. accounts of profits - the infringer must account to the patentee for any profit he has made as a result of the infringement.

16.7 Since enforcement of patent rights is the responsibility of individual patent right holders, there is no readily available statistics or data showing the seriousness of the infringement of patent rights in Australia.

17. Dispensing of Medicines

Dispensing Outlets

17.1 Prescribed medications are available from pharmacists upon the presentation of a doctor's prescription. They can also be provided by a doctor or hospital.

17.2 Non-prescribed medications do not require a doctor's prescription and can be obtained from a variety of places such as chemists and some supermarkets, doctor's surgery or hospital.

Pharmaceutical Benefits Scheme

17.3 In Australia, apart from controlling the dispensing outlets of medicines, the government also makes certain arrangements which aim to increase the public's access to important medicines by subsidizing their cost. For example, around 75% of non-public hospital prescriptions are dispensed under two subsidization schemes -- the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS).⁴² These schemes are established to provide the general community (PBS) and entitled veterans, war widows and widowers (RPBS) with access to necessary medicine products.

⁴² Department of Health and Aged Care, *Australian Statistics on Medicines 1998, 1999*.

17.4 The Pharmaceutical Benefits Advisory Committee (PBAC) recommends what medicines are to be listed on the Pharmaceutical Benefits Scheme. Whereas the pre-market evaluation of medicines addresses the issues of quality, safety and efficacy, the PBAC considers effectiveness and cost-effectiveness of the product relative to other alternatives. Once listing has been agreed by the government, the price of drug is negotiated with the company by the Pharmaceutical Benefits Pricing Authority (PBPA). The PBPA consists of government, industry and consumer representatives. Appendix VII summarizes the operation of the Pharmaceutical Benefits Scheme.

18. Regulation of Pharmacies

18.1 Pharmacies are subject to the control of state/territory legislation. Different states and territories may impose different controls on pharmacies.

Ownership of Pharmacies

18.2 The ownership of pharmacies is restricted in all of the six states in Australia but not in the two territories. Among the states in Australia, the ownership of pharmacies is restricted to registered pharmacists. However, in the Northern Territory, the Northern Territory Pharmacy Act requires a pharmacy business to be managed (not necessarily owned) by a pharmacist. The Australian Capital Territory legislation does not specifically restrict ownership of pharmacies.⁴³

18.3 Each state has restrictions on the number of pharmacies which a pharmacist can own or can have an interest although the restrictions vary: in Western Australia and Tasmania, the maximum number is two; in New South Wales and Victoria, it is three; in Queensland and South Australia, it is four. The two Territories do not have any restrictions on the number.⁴⁴

Registration of Pharmacists

18.4 Each state and territory varies in its requirements for the registration of pharmacists. In general, the registration requirements include a completion of a recognized university course in pharmacy, and a completion of a prescribed period of practice of clinical pharmacy in a community or hospital pharmacy under the supervision of a registered pharmacist. Some states may further require that a pharmacist possess good character, a knowledge of the English language, etc.

⁴³ Commonwealth Department of Health and Aged Care, *Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation*, 1999.

⁴⁴ Commonwealth Department of Health and Aged Care, *Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation*, 1999.

18.5 Pharmacists are required to renew their registrations annually on the payment of a prescribed registration fee, even if the pharmacists are not active in the profession. Pharmacists may have their registrations cancelled, suspended or restricted on health grounds or improper professional conduct. The Pharmacy Board⁴⁵ in each state/territory has authority to investigate complaints and discipline those who fail to comply with the regulations.

19. Fees and Charges

19.1 From 1 July 1998, the Therapeutic Goods Administration has been required by the Government to fully recover its operating costs for all activities that fall within the scope of the Therapeutic Goods Act 1989, including regulation of the industry and the Therapeutic Goods Administration's public health responsibilities.

19.2 The Therapeutic Goods Administration collects its revenue mainly through annual charges, evaluation fees and licence fees.

Annual Charge

19.3 Each product included in the Australian Register of Therapeutic Goods attracts an annual charge. The charge varies according to the product group. For example, prescription medicines attract an annual charge of AUS\$950 (or HK\$4,303.5), non-prescription medicines attract an annual charge of AUS\$465 (or HK\$2,106.5) and listed medicines, AUS\$350 (or HK\$1,585.5).⁴⁶

Evaluation Fee

19.4 Evaluation fees are calculated according to the number of pages included in a submission for evaluation. They may vary widely depending on the product group. For example, the evaluation fee for a new prescription medicine may be in excess of AUS\$150,000 (or HK\$679,500) whereas the fee for a complementary medicine is AUS\$270 (or HK\$1,223.1).⁴⁷

⁴⁵ The composition of different Pharmacy Boards may vary in different states/territories. In some cases such as the Pharmacy Board in Victoria and Tasmania, all members are registered pharmacists. In other cases such as in New South Wales and South Australia, members of Pharmacy Boards include lawyers, registered pharmacists, and lay persons. The selection method of Board members is also different from different states/territories. In Victoria and Queensland, all members are appointed by state governors while in Tasmania, all members are elected by registered pharmaceutical chemists. In New South Wales and South Australia, some members are appointed by state governors and some are elected by their own functional constituencies.

⁴⁶ Therapeutic Goods Administration, *Summary of Fees and Charges at 28 September 2000*.

⁴⁷ Therapeutic Goods Administration, *TGA Fees and Charges Explanatory Note*, 8 March 2000.

Licence Fee

19.5 The application fee for a Good Manufacturing Practice licence is AUS\$540 (or HK\$2,446.2) and the examination fee of a plant master file⁴⁸ is AUS\$5,625 (or HK\$25,481.3). There is also an annual licence charge which is charged according to the type of the products. For example, for herbal products, the annual licence charge is AUS\$3,500 (or HK\$15,855). The Good Manufacturing Practice certification fee (formerly known as the site inspection fee) is charged according to the time taken by an auditor. The hourly rate of an auditor is AUS\$355 (or HK\$1,608.2) for local inspection and AUS\$745 (or HK\$3,374.9) for overseas inspection.⁴⁹

19.6 The Therapeutic Goods Administration meets industry representatives each year and discusses with them changes to the level of fees and charges.

20. Effectiveness of the Medicines Evaluation Process

20.1 In an audit conducted by the Australian National Audit Office in October 1996, it confirmed that *"the medicines evaluation process [of the Therapeutic Goods Administration] was efficient"* but there was still room for improvement. The audit report made 14 recommendations to the Therapeutic Goods Administration to improve its efficiency, effectiveness and accountability of the evaluation and approval of prescription medicines.

20.2 A follow-up audit was conducted in September 1999 to review the extent to which the Therapeutic Goods Administration had implemented the recommendations contained in the 1996 audit report. It was noted in the 1999 audit report that *"...Generally, TGA's [Therapeutic Goods Administration's] implementation has been consistent with the thrust of that Report [1996 audit report] to improve TGA's efficiency, effectiveness and reporting to its stakeholders. ...[there was] a high level of industry confidence in TGA's evaluation process"*.⁵⁰ The Therapeutic Goods Administration had implemented or partly implemented 12 of the 14 recommendations listed in the 1996 audit report. For the remaining recommendations, the Therapeutic Goods Administration had addressed them through alternative means. Please see Appendix VIII for details.

⁴⁸ A plant master file contains information relevant to understand the manufacturing operations of a firm.

⁴⁹ Therapeutic Goods Administration, *Summary of Fees and Charges at 28 September 2000*.

⁵⁰ Australian National Audit Office, *Audit Report. Drug Evaluation by the Therapeutic Goods Administration - Follow-up Audit*, Audit Report No.2, 1999.

PART 6 - ANALYSIS

21. Introduction

21.1 This research report describes the means through which the Australian government regulates medicines.

22. Regulation of Medicines

22.1 It may be fair to say that rigid control has been placed on the manufacturing, evaluation, labelling, import, and sale of medicines in Australia.

Mandatory Licensing of Manufacturers of Medicines

22.2 All Australian manufacturers of medicines are required to hold a licence which certifies compliance with the Code of Good Manufacturing Practice. Overseas manufacturers are required to provide evidence to prove that they have met standards equivalent to that expected of Australian manufacturers. This provides quality assurance about conditions of the manufacturing site of products.

Mandatory Pre-Market Assessment and Regular, Responsive Post-Market Vigilance of Medicines

22.3 All medicines must be submitted to pre-market assessments for safety, quality and/or efficacy before they can be put for sale. There are also post-market activities carried out by the Therapeutic Goods Administration and relevant committees to ensure that these products are of an acceptable standard after they are entered into the market. Control is exercised pre- and post-market.

Timely Evaluation of Medicines

22.4 The evaluation of medicines conducted by the Therapeutic Goods Administration and other relevant committees is crucial to pharmaceutical companies because no medicines can be imported, exported, manufactured or supplied in Australia unless they are included in the Australian Register of Therapeutic Goods. That is, they have met all the requirements of safety, quality and/or efficacy. Since it takes on average 15 years to research and develop new medicines, an effective and timely evaluation of an application for listing or registration in the Australia Register of Therapeutic Goods is essential to a viable pharmaceutical sector in Australia.

"Stopping The Clock", If And When Necessary

22.5 As noted in paragraph 8.4, the Therapeutic Goods Administration is able to process all applications for listing or registering in the Australian Register of Therapeutic Goods within statutory timeframes. However, the Therapeutic Goods Administration may 'stop the clock' on its evaluation when there arises a need to request further information from the applicant. This 'stopping the clock' may result in a difference between the number of 'working days' clocked by the Therapeutic Goods Administration for an evaluation and the total number of 'calendar days' counted from the time an application is received to the time the processing of the application is finished. At the moment, there is no information as to the actual time taken in processing and evaluating an application. The Therapeutic Goods Administration plans to install a new information technology system in 2001 so that it would have the capability to report the time taken to approve medicines in both 'calendar days' and 'working days'.⁵¹

Mandatory Labelling

22.6 All medicines are required to carry either the "Aust R" or "Aust L" labels which indicate whether or not the efficacy of products has been evaluated. Such labelling provides useful information and more protection for consumers.

Mandatory Licensing of Importers of Medicines

22.7 Sponsors who wish to import medicines for supply in Australia are required to obtain the appropriate licences/permits prior to importing the goods. Moreover, import licences or permits for prescription medicines will only be issued to registered medical practitioners or pharmacists. This ensures that only qualified persons may import medicines and the Australian government has taken the necessary actions to ensure the legitimate use of medicines containing controlled substances.

Compulsory Registration of Pharmacists

22.8 Pharmacies may only be owned or managed by pharmacists and all states and territories require the registration of pharmacists. One reason for this measure of control is that an increasing number of people are dependent on pharmacists to provide them with information on medicines or their drug therapy. Therefore, the compulsory registration may serve as a means to ensure public trust and confidence in the professional services pharmacists provide. The restriction of the ownership of pharmacies to registered pharmacists is also another means to safeguard the quality use of medicines.

⁵¹ Australian National Audit Office, *Audit Report. Drug Evaluation by the Therapeutic Goods Administration - Follow-up Audit*, Audit Report No.2, 1999.

23. Acceptance of Evidence of Traditional Use for Substantiating Therapeutic Claims

23.1 In Australia, both scientific evidence and evidence of traditional use are allowed to be used to substantiate therapeutic claims. Traditional medicines have been used by Australians extensively and over a long period of time. Many Australians depend on traditional medicines to satisfy their primary health care needs. However, not all traditional medicines have undergone scientific assessment or scrutiny and they have been criticized⁵² as "insufficiently tested", "rely ... on anecdotes and theories", and they were "possibly dangerous". Nevertheless, traditional medicines are viewed by many people as useful and effective in promoting the general well-being of the whole body, with the emphasis of prevention of disease and not just treatment of the affected areas of the body. A growing number of health care professionals show increasing open-mindedness about the therapeutic possibilities of traditional medicines. If only scientific evidence is allowed for the substantiation of therapeutic claims, then consumers may be denied many useful traditional medicines.

23.2 Care has been taken by the Australian government to handle therapeutic claims based solely on evidence of traditional use as such claims have not gone through scientific assessment. First, the Therapeutic Goods Administration has defined what is admissible evidence of traditional use. Secondly, therapeutic claims supported solely by evidence of traditional use have been restricted to general and medium levels of therapeutic claims. Thirdly, the wordings of the claims are restricted so as to avoid the implication that the medicine has been evaluated scientifically. (Please see Appendix VI for details.) In this way, sponsors are able to market more medicines and consumers are given a greater degree of choice and accessibility to a variety of medicines while at the same time people are alerted that these medicines are supported by evidence of traditional use only and have not undergone any scientific assessment.

24. Differentiated Control Over Advertising of Medicines Between Different Target Audience

24.1 Advertising is one of the means through which the general public and health professionals become aware of the existence of a medicine and the usefulness of it. Therefore, it is essential that the promotional information about medicines is accurate, evidence-based and not misleading. The Therapeutic Goods Regulations require that only non-prescription (low risk) registered medicines and listed medicines can be advertised publicly and the advertisements must comply with the Therapeutic Goods Advertising Code and go through a prior approval system. Prescription (high risk) registered medicines may only be advertised to health professionals.

⁵² Josefek, Kristen J., "Alternative Medicine's Roadmap to the Mainstream" in *American Journal of Law & Medicine*, Summer-Fall, 2000.

24.2 Unlike the non-prescription (low risk) registered medicines and listed medicines, there is no requirement that advertisements of prescription (high risk) registered medicines should be approved prior to publishing. Therefore, although there is a complaint handling mechanism in place, it starts to operate only when any breaches of the Code of Conduct are detected by the Monitoring Committee or complaints are made by individuals or companies *after* the advertisements have been published. Therefore, unless and until a detection of breaches is made or a complaint is lodged, there exists a possibility that misleading or inaccurate advertisements might be able to reach health professionals and influence their prescriptions.

25. Possible Extension of Patent Protection

25.1 Adequate patent protection is of fundamental importance for the pharmaceutical industry. As aforementioned, it takes on average 15 years to research and develop new medicines and only three out of 10 approved medicines can make sales which cover the research and development costs. The high risks and costs involved in developing new medicines mean manufacturers rely on intellectual property protection (i.e. patent protection) to protect their investment in research and development.

25.2 Since the term of patent starts from the date of filing of relevant complete specification, in view of the lengthy approval process of medicines, the patent protection for pharmaceutical products was allowed to be extended from 20 years from the filing date for another five years under the Patents Act 1990. This extension compensates for the erosion of the patent term by the time taken for regulatory approval procedures, and hence, encouraging further research and development activities.

26. Drawing Expertise to the Regulatory System

26.1 Whether a regulatory system is effective depends to a large extent on its access to professional expertise. In Australia, committees which include members who are non-government officials play an equally important role as a government agency in the regulation of medicines. They are involved in the pre-market assessment of medicines, registration or listing of medicines, post-market vigilance, regulation of advertisements of medicines, etc. These committees consist of members of a wide range of expertise: healthcare practitioners, professionals, industry representatives and consumers. With this wide range of expertise available in the regulatory system, the Australian government is able to respond quickly to the concerns of both industry and consumers and the rapidly growing industry of medicines.

27. Adoption of a Risk Management Approach in the Pre-Market Assessment of Medicines for Flexibility

27.1 The Therapeutic Goods Administration adopts a risk management approach in the pre-market assessment of medicines, i.e. the degree of control imposed over a medicine is directly related to the risk level of that medicine. Therefore, between registered and listed medicines, registered medicines are required to meet higher standards of safety, quality and efficacy, more tests results and evidence are required to be provided to substantiate their therapeutic claims, and they have to undergo more stages of assessments before they can be entered onto the Australian Register of Therapeutic Goods. Listed medicines are not generally subject to the same level of scrutiny and evaluation, and they are assessed only for safety and quality.

27.2 This risk management approach allows the Therapeutic Goods Administration to maintain a certain degree of regulatory control over medicines while at the same time freeing industry from any unnecessary regulatory burden.

Appendix I**Definition of a Therapeutic Good**

Given below is the definition of a therapeutic good contained in the Therapeutic Goods Act 1989.

"therapeutic goods" means goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) for therapeutic use; or
 - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes goods declared to be therapeutic goods under an order in force under section 7, but does not include:
 - (c) goods declared not to be therapeutic goods under an order in force under section 7; or
 - (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
 - (e) goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or
 - (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Section 7 - Declaration that goods are/are not therapeutic goods:

- (1) Where the Secretary [Secretary of the Department of Health and Aged Care] is satisfied that particular goods or classes of goods:
 - (a) are or are not therapeutic goods; or
 - (b) when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods;

the Secretary may, by order published in the Gazette, declare that the goods, or the goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of this Act, therapeutic goods.

- (2) The Secretary may exercise his or her powers under this section of his or her own motion or following an application made in writing to the Secretary.
- (3) A declaration under this section takes effect on the day on which the declaration is published in the Gazette or on such later day as is specified in the order.

Appendix II

Levels and Types of Therapeutic Claims

Level of Claim	Type of Claim	Definition of Claim
High	Disease management claim	A claim that a product or substance can treat, cure or manage a particular disease, disorder, condition or ailment.
	Preventive claim	A claim which relates to preventing a particular disease, disorder, condition, symptom or ailment.
	Claims relating to vitamin or mineral deficiency diseases	Claims which refer to the name of a vitamin or mineral and a recognized deficiency disease.
Medium	Health enhancement claim	A claim which relate to health enhancement for normal healthy people, such as improving, promoting, enhancing or optimizing (or words to that effect) body organs or systems.
	Risk reduction claim	A claim which relates to reducing the risk of a particular disease, disorder, condition, symptom or ailment.
	Discrete event claim	A claim which refers to the ability of a product or substance to reduce the frequency of a discrete event such as migraine.
	Aids/assist claim	A claim which describes how a product or substance may aid/assist in the management of a named symptom/disease or disorder.
	Symptom claim	A claim which relates specifically to the temporary relief of a particular symptom. All symptom claims must be accompanied by the statement "If symptom persist, consult your healthcare practitioner".

Level of Claim	Type of Claim	Definition of Claim
General	Health maintenance claim	A claim which refers to an effect a product or substance may have in maintaining health (or words to that effect), but not including health enhancing or prevention claims. Health maintenance claims may also relate to the normal physiological consequences for good health associated with a product or substance, or to the provision of nutritional support and to the use of the terms, cleansing, detoxification and tonic.
	Claims relating to vitamin or mineral supplementation	Claims that refer to supplemental intakes of the vitamin or mineral. Vitamin or mineral supplementation claims are only permitted where the recommended daily dose of the product provides at least 25% of the Recommended Dietary Intake (RDI) for that vitamin or mineral. Vitamin and mineral claims of any kind should not refer to the presence of vitamins or minerals unless they are present in the recommended daily dose of the product to at least the level of 10% of the RDI, unless there is evidence to support a therapeutic effect below this level.
	Symptom claim	A claim which relates specifically to the temporary relief of a particular symptom. All symptom claims must be accompanied by the statement "If symptom persist, consult your healthcare practitioner".

Source: Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods*, April 2000.

Appendix III**Legislative Framework of the Regulation of Medicines in Australia**

Listed below is a summary of important elements of the legislative framework of the regulation of medicines in Australia.

Key Legislation

1. Acts

- ♦ Therapeutic Goods Act 1989 and amendments; and
- ♦ Therapeutic Goods (Charges) Act 1989 and amendments.

2. Regulations

- ♦ Therapeutic Goods Regulations and amendments; and
- ♦ Therapeutic Goods (Charges) Regulations and amendments.

3. Orders

- ♦ Therapeutic Goods (Groups) Order No. 1 of 1992;
- ♦ Therapeutic Goods (Excluded Goods) Order No. 1 of 1998;
- ♦ Therapeutic Goods Order No. 20, 29, 48, 56 and 63.

4. Determination

- ♦ Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 1999.

Other Legislation

5. General

- ♦ National Health Act 1954 and amendments; and
- ♦ Veteran's Entitlement Act 1986 and amendments.

6. Scheduled Substances

- ♦ Standard for the Uniform Scheduling of Drugs and Poisons; and
- ♦ Relevant State / Territory legislation governing access to scheduled substances, e.g. New South Wales Poisons and Therapeutic Goods Act.

7. Advertising

- ♦ Therapeutic Goods Advertising Code;
- ♦ Broadcasting Services Act 1992;
- ♦ Trade Practices Act 1974 and amendments;
- ♦ Trade Practices Regulations and amendments;
- ♦ Relevant State / Territory Acts which govern advertising, e.g. New South Wales Fair Trading Act;
- ♦ Relevant Codes of Conduct produced by Australian Pharmaceutical Manufacturers Association (for prescription medicines), Proprietary Medicines Association of Australia (for all non-prescription medicines) and Complementary Healthcare Council (for complementary medicines).

8. Manufacturing

- ♦ Australian Code of Good Manufacturing Practice for Therapeutic Goods - medicinal products.

9. Importing / Exporting

- ♦ Customs Act 1901 and amendments;
- ♦ Quarantine Act 1908 and amendments;
- ♦ Wildlife Protection (Regulation of Imports and Exports) Act 1982;
- ♦ Customs (Prohibited Imports) Regulations; and
- ♦ Customs (Prohibited Exports) Regulations.

Source: Department of Health and Aged Care, *Where Do You Get It? A List of Important TGA and Industry Contacts, Publications and Legislation*, 1999

Appendix IV

Committees Involved in the Regulation of Medicines

Name	Membership	Function
Adverse Drug Reactions Advisory Committee, ADRAC	<ul style="list-style-type: none"> ♦ Members are appointed on the basis of their expertise in the assessment of pharmaceutical products and their integrity to provide advice in the public interest. 	A subcommittee of ADEC (see below). ADRAC collects data on adverse drug reactions and provides advice on any appropriate responses to adverse reactions.
Australian Drug Evaluation Committee, ADEC	<ul style="list-style-type: none"> ♦ Six or seven core members appointed by the Minister for Health and Aged Care and 10-20 associate members. Associate members are invited by the ADEC Chairman to attend meetings according to the agenda of each meeting. ♦ Core members include medical practitioners, specialists in clinical medicines, pharmacologist or someone who specializes in pharmaceutical science. ♦ Associate members include pharmaceutical chemists with recent manufacturing experience in therapeutic good, toxicologists and medical practitioners in general practice. 	An expert committee which provides advice to the Therapeutic Goods Administration's (TGA) Drug Safety & Evaluation Branch in relation to applications for prescription medicines. Primarily involved with new medicines / chemical entities.

Name	Membership	Function
Australian Pharmaceutical Advisory Council, APAC	♦ The Council consists of peak health professional representatives, industry groups, media groups, government and consumer groups.	A consultative forum which advises the Commonwealth Government on a range of medicines policy issues and needs in health care.
Complaint Resolution Panel, CRP	♦ Eight members with the Chairman nominated by the Therapeutic Goods Advertising Code Council. Members are drawn from industry, consumers groups, advertising agencies, and healthcare professionals.	An independent committee which handles complaints against advertisements for non-prescription medicines (including complementary medicines).
Complementary Medicines Evaluation Committee, CMEC	♦ 11 members appointed by the Minister for Health and Aged Care.	A statutory expert committee which provides advice to the TGA's Office of Complementary Medicines in the Chemical & Non-prescription Medicines Branch on whether a new complementary substance or medicine should be permitted in the Australian Register of Therapeutic Goods (ARTG) as a listed or registered product.
External Reference Panel on Interface Matters, ERPIM	♦ The Panel consists of representatives from TGA, Australia New Zealand Food Authority, State/Territory and New Zealand health authorities, the Australian Quarantine Inspection Service, industry and consumers.	An advisory panel which manages matters at the interface between therapeutic goods and foods.

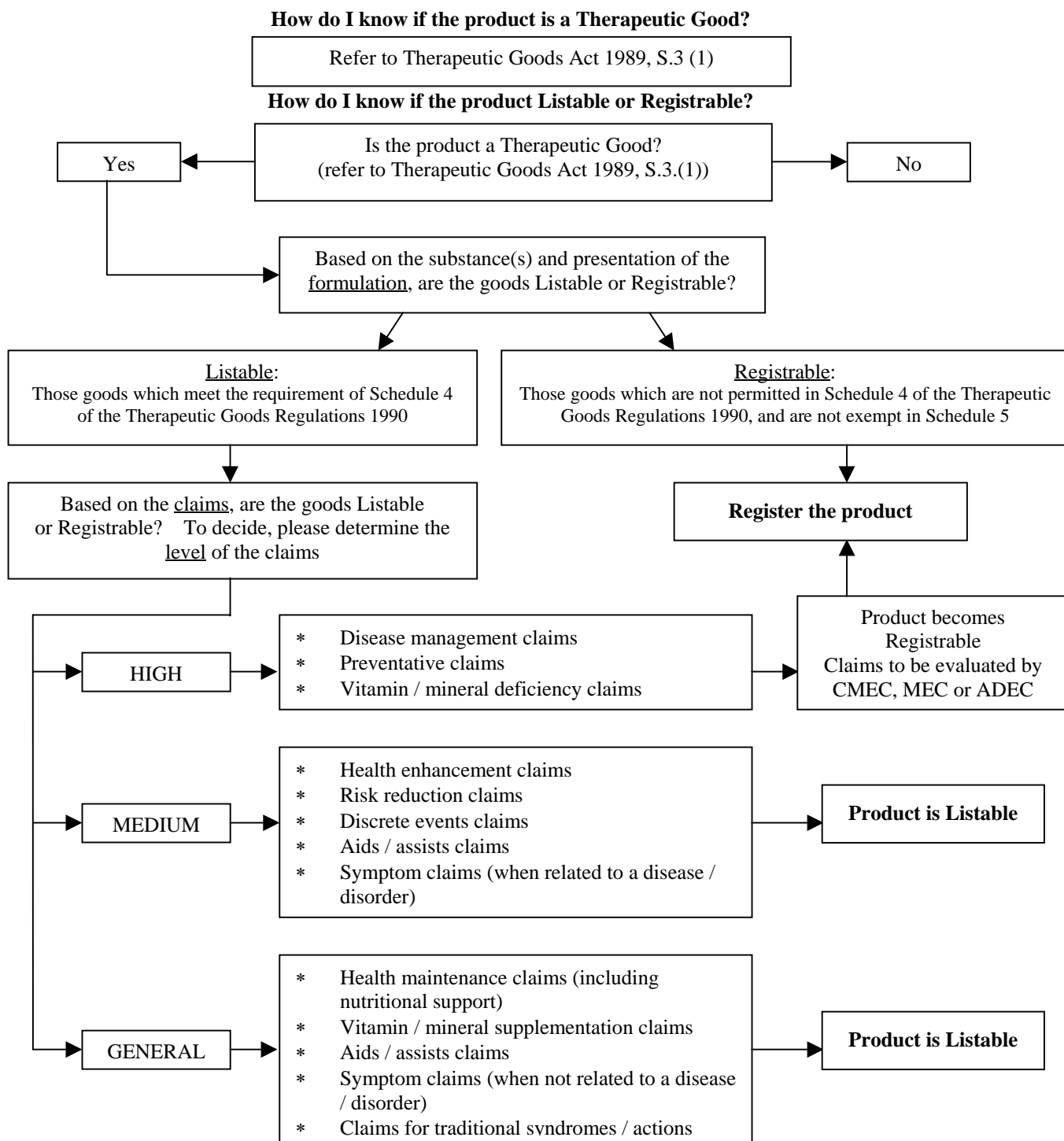
Name	Membership	Function
Medicines Evaluation Committee, MEC	<ul style="list-style-type: none"> ♦ Members are appointed by the Minister for Health and Aged Care. ♦ 11 members who have expertise in general medicine practice, specialist medicine practice including geriatric and paediatric medicine, clinical pharmacology and clinical toxicology, pharmaceutical chemistry, pharmacology, microbiology, community pharmacy, medicine manufacture and government regulation. 	A statutory committee which provides advice to the TGA's Chemicals & Non-prescription Medicines Branch on whether a new substance or medicine should be permitted on the ARTG as a listed or registered product. It is primarily involved in applications for non-prescription registered medicines (non complementary medicines).
National Co-ordinating Committee on Therapeutic Goods, NCCTG	<ul style="list-style-type: none"> ♦ Members include representatives from the Commonwealth, State and Territory health authorities. 	A Commonwealth, State and Territory committee which provides recommendations on administrative and regulatory controls for therapeutic goods.
National Drugs & Poisons Schedule Committee, NDPSC	<ul style="list-style-type: none"> ♦ The committee consists of state and territory government members and other persons appointed by the Minister for Health and Aged Care such as technical experts and representatives of various sectional interests. 	A committee which maintains the <i>Standard for the Uniform Scheduling of Drugs and Poisons</i> , which lists the various schedules for different substances.
Pharmaceutical Benefits Advisory Committee, PBAC	<ul style="list-style-type: none"> ♦ Members are appointed by the Minister for Health and Aged Care and they are medical practitioners and pharmacists. 	A committee which advises the Minister for Health and Aged Care about additions and deletions on the list of products on the Pharmaceutical Benefits Scheme (PBS). It also makes recommendations on prescribing restrictions, quantities and number of repeats for the PBS.

Name	Membership	Function
Pharmaceutical Health & Rational Use of Medicines Committee, PHARM	♦ Members are stakeholders in the industry.	A committee which co-ordinates the development and implementation of Australian policy on the quality use of medicines.
Pharmaceutical Subcommittee, PSC	♦ Members are appointed on the basis of their expertise in the assessment of pharmaceutical products and their integrity to provide advice in the public interest.	A subcommittee which advises ADEC about chemistry, quality control, bio-availability and bio-equivalence issues.
Therapeutic Goods Advertising Code Council, TGACC	♦ The Council consists of members of industry groups, government and consumer groups.	TGACC is responsible for the review and maintenance of the <i>Therapeutic Goods Advertising Code</i> .
Therapeutic Goods Committee, TGC	♦ Members are appointed on the basis of their expertise and knowledge in the field.	An expert committee which advises the Minister for Health and Aged Care on adoption of therapeutic standards, requirements for labelling/packaging and the manufacturing principles.

Source: Commonwealth Department of Health and Aged Care, *Where Do We Get It?* Nov 1999.

Appendix V

Determination of a Listable / Registrable Product



Note: This is a general guide only. Products should be considered on a case by case basis.

CMEC - Complementary Medicines Evaluation Committee; MEC - Medicines Evaluation Committee
ADEC - Australian Drug Evaluation Committee

Source: TGACC, *FAQ*, at <http://www.tgacc.com.au/flow1.cfm>

Appendix VI

Level and Types of Claims and the Evidence Required to Support Them

Level of Claim	Type of Claim	Type of Evidence	Wording of Claim ⁴	Evidence Required
High	<ul style="list-style-type: none"> ♦ Treats / cure / manages any disease / disorder / condition ♦ Prevention of any disease, disorder or condition ♦ Treatment of specific named vitamin or mineral deficiency diseases 	Scientific evidence only	Not applicable	High level. The products must be registered (not listed) in the Australian Register of Therapeutic Goods. The evidence must be evaluated by the Complementary Medicines Evaluation Committee, the Medicines Evaluation Committee or the Australian Drug Evaluation Committee.
Medium	<ul style="list-style-type: none"> ♦ Health enhancement¹ ♦ Reduction of risk of a disease / disorder ♦ Reduction in frequency of a discrete event ♦ Aids / assists in the management of a named symptom / disease / disorder ♦ Relief of symptoms of a named disease or disorder² 	Scientific evidence	Not applicable	Medium level. Sponsor must hold the evidence for listable goods
		Evidence of traditional use	This (tradition) medicine has been used for (indication) ⁵ . This claim is based on traditional use. ⁶	Primary evidence: two of the following four sources that demonstrate adequate support for the indications claimed: <ul style="list-style-type: none"> ♦ TGA-approved Pharmacopoeia ♦ TGA approved Monograph ♦ Three independent written histories of use in the classical or traditional medical literature⁷ ♦ Availability through any country's government public dispensaries for the indication claimed

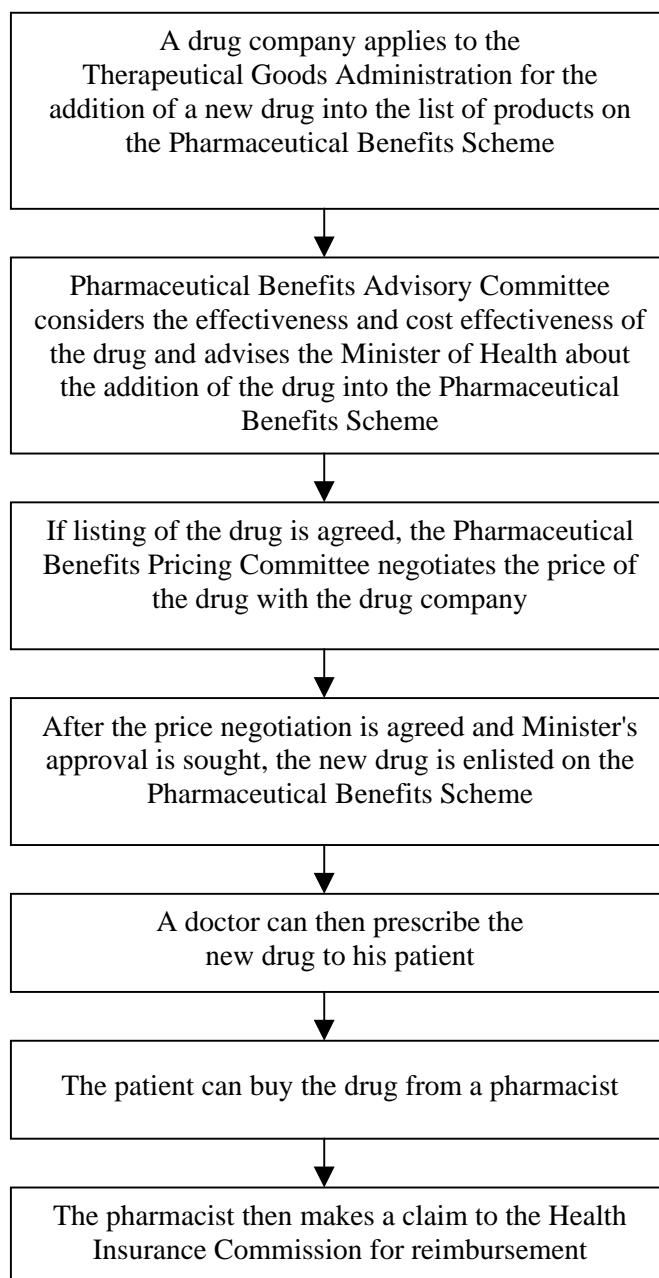
Level of Claim	Type of Claim	Type of Evidence	Wording of Claim ⁴	Evidence Required
General	<ul style="list-style-type: none"> ♦ Health maintenance, including nutritional support ♦ Vitamin or mineral supplementation³ ♦ Relief of symptoms (not related to a disease or disorder)² 	Scientific evidence	Not applicable	General level. Sponsor must hold the evidence for listable goods
	<ul style="list-style-type: none"> ♦ Health maintenance, including nutritional support ♦ Relief of symptoms (not referring to a disease or disorder)² ♦ Claims for traditional syndromes and actions⁵ 	Evidence of traditional use	This (tradition) medicine has been traditionally used for (indication). ⁵	Primary evidence: two of the following four sources that demonstrate adequate support for the indications claimed: <ul style="list-style-type: none"> ♦ TGA-approved Pharmacopoeia ♦ TGA approved Monograph ♦ Three independent written histories of use in the classical or traditional medical literature⁷ ♦ Availability through any country's government public dispensaries for the indication claimed

Remarks:

1. Health enhancement claims apply to enhancement of normal health. They do not relate to enhancement of health from a compromised state.
2. All claims relating to symptoms must be accompanied by the advice "If symptoms persist consult your healthcare practitioner".
3. Vitamin or mineral supplementation claims are only permitted where the recommended daily dose of the product provides at least 25% of the Recommended Dietary Intake (RDI) for that vitamin or mineral. Where vitamins or minerals are the subject of other kinds of claims, the dose must be consistent with the evidence to support the claim being made. Claims should not refer to the presence of vitamins or minerals unless they are present in the recommended daily dose of the product to at least the level of 10% of the RDI, unless there is evidence to support a therapeutic effect below this level.
4. Or words to that effect.
5. Terms must be in the original language of the traditional medical culture, e.g. "shen" not "kidney" in traditional Chinese medicines.
6. Where scientific evidence is available to support the entire claim, the words, "This claim is based on traditional use" is optional.
7. In cultures where an oral tradition is clearly documented, evidence of use from an oral tradition would be considered acceptable provided the history of use was authenticated. Modern texts which accurately report the classical or traditional literature may be used to support claims.

Source: Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods. Draft-For Consultation*, 14 November 2000.

Appendix VII

Operation of the Pharmaceutical Benefits Scheme

Appendix VIII

Recommendations of the 1996 Audit Report and their Implementation Status

	Recommendations - That the Therapeutic Goods Administration	Implementation
1.	<ul style="list-style-type: none"> ♦ Undertake a review of its request for additional information from pharmaceutical companies to identify common omissions from drug evaluation applications, and determine whether or not the Australian Guidelines for Registration Drugs (AGRD) should be amended; 	Partly implemented
	<ul style="list-style-type: none"> ♦ Amend the AGRD if necessary; 	
	<ul style="list-style-type: none"> ♦ Work with industry to identify ways of reducing the time its members take to respond to TGA's request for information; and 	
	<ul style="list-style-type: none"> ♦ Report drug-approval times to stakeholders, particularly for new chemical entities, in both 'working-day' and 'calendar day' formats. 	
2.	<ul style="list-style-type: none"> ♦ Review the definition of Category 1 submissions for evaluation to determine the appropriateness of including evaluations of complex new chemical entities in a category with less-complex submissions. 	Use alternative means to address this issue
3.	<ul style="list-style-type: none"> ♦ Reassess current procedures for producing the Australian Drug Evaluation Committee's minutes so as to meet the 20-day time frame recommended in the Baume report and accepted by the Government. Furthermore, TGA should assess when it can actually comply with this time frame. 	Implemented
4.	<ul style="list-style-type: none"> ♦ Improve the effectiveness of drug evaluation, review the number of working days allocated to each phase of the evaluation process, with a view to giving more emphasis to the evaluation of submissions by the pharmaceutical industry. 	Implemented
5.	<ul style="list-style-type: none"> ♦ Review consultative arrangements with consumer organizations to ensure that consumers' expectations of drug evaluation are given due consideration. 	Implemented
6.	<ul style="list-style-type: none"> ♦ Review the Drug Applications For Registration and Tracking (DART) computer system to make it more effective and user-friendly; and 	Partly implemented
	<ul style="list-style-type: none"> ♦ The information technology interfacing project be completed to achieve integration as soon as possible of the various computer systems operating within TGA. 	
7.	<ul style="list-style-type: none"> ♦ Bring all computer-system user documentation up to date and promulgate this to users to improve overall effectiveness. 	Partly implemented

	Recommendations - That the Therapeutic Goods Administration	Implementation
8.	<ul style="list-style-type: none"> ♦ Expand the use of internal-audit programmes relating to external evaluators to encompass all affected evaluation sections in TGA, with the objective of using resources more efficiently; and ♦ Develop appropriate training programmes for external evaluators and incorporate them into operating procedures 	Use alternative means to address this issue
9.	<ul style="list-style-type: none"> ♦ Assess the cost/benefits of a central computerized database that reflects current international regulatory information, such as drug evaluation activities, best practice and useful contacts. 	
10.	<ul style="list-style-type: none"> ♦ Take full advantage of the efforts of other regulatory bodies and to reduce the costs to Australian of similar evaluations performed overseas, consider reassessing its requirements to determine if more evaluations, or parts of them, could be accepted from other international regulatory authorities. 	Implemented
11.	<ul style="list-style-type: none"> ♦ Improve the effectiveness of its drug evaluation, review: <ul style="list-style-type: none"> ~ its promotion and encouragement of the reporting of adverse drug reactions; ~ dissemination to all health professionals of information on adverse drug reactions; and ~ the adequacy of resource allocation, in TGA's budget, for adverse drug reactions. 	Implemented
12.	<ul style="list-style-type: none"> ♦ Strengthen its public reporting to better meet the information needs of Parliament and consumers in the interests of enhanced accountability. 	Partly implemented
13.	<ul style="list-style-type: none"> ♦ Identify international pricing-structure options with a view to adopting the most cost-effective method for use in Australia; and ♦ Seek the co-operation of the pharmaceutical companies in forecasting workloads with a reasonable degree of confidence. 	Implemented
14.	<ul style="list-style-type: none"> ♦ Introduce a method of calculating the industry-related costs of its operations to enable it to recover them, consistent with government policy; and ♦ Include in its annual report to Parliament the extent to which its costs are recovered. 	

Remarks:

1. The terms 'drugs' and 'medicines' are used interchangeably.
2. TGA - Therapeutic Goods Administration.

Source: Australian National Audit Office, *Audit Report. Drug Evaluation by the Therapeutic Goods Administration - Follow-up Audit*, Audit Report No.2, 1999.

References

1. Australian Bureau of Statistics, *2001 Year Book Australia*, 2001.
2. Australian Bureau of Statistics, *Australian Social Trends 1998: Health - Health Related Actions: The Use of Medication*, at <http://www.abs.gov.au/>.
3. Australian Bureau of Statistics, *Household Expenditure Survey, Australia: Detailed Expenditure Items*, at <http://www.abs.gov.au/>.
4. Australian Economic Analysis Pty Limited, *A Report on Australia's Pharmaceutical Industry*, December 1998.
5. Australian National Audit Office, *Audit Report. Drug Evaluation by the Therapeutic Goods Administration - Follow-up Audit*, Audit Report No.2, 1999.
6. Australian Pharmaceutical Manufacturers Association, *1999-2000 APMA Facts Book: Pharmaceutical and Health Industry Information*, at <http://www.apma.com.au/>.
7. Australian Pharmaceutical Manufacturers Association, *APMA Code of Conduct*, Edition 13, 16 February 2000. p.96.
8. Australian Pharmaceutical Manufacturers Association, *At A Glance: Pharmaceutical Fact Sheet*, at <http://www.apma.com.au/>.
9. Census and Statistics Department, *Hong Kong Monthly Digest of Statistics*, January 2001.
10. Commonwealth Department of Health and Aged Care, *Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation*, 1999.
11. Commonwealth Department of Health and Aged Care, *Annual Report, 1999-2000*.
12. Commonwealth Department of Health and Aged Care, *Australian Statistics on Medicines 1998*, 1999.
13. Commonwealth Department of Health and Aged Care, *National Medicines Policy*, 2000.
14. Commonwealth Department of Health and Aged Care, *Pharmaceutical Benefits Safety Net Arrangements* at <http://www.health.gov.au/>.
15. Environment Australia, *Wildlife Information Sheet No 9 - Medicines*, at <http://www.environment.gov.au/>
16. Health Insurance Commission, *Helpful Information for Pharmacists Approved to Supply PBS and RPBS Medicines*.
17. Parliament of Australia, *House Hansard*, 1999 -2000.
18. Parliament of Australia, *Senate Hansard*, 1999- 2000.

19. Smith, *Patent Protection for Pharmaceutical Products*, Library of Parliament of Canada, November 1993.
20. Therapeutic Goods Administration, *Advertising and Labelling Medicines in Australia*, 1999.
21. Therapeutic Goods Administration, *Conditions Standard and Specific. Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989, Standard Conditions Effective 1995, Specific Conditions Effective 1998*.
22. Therapeutic Goods Administration, *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods - Draft - For Consultation*, 14 November 2000.
23. Therapeutic Goods Administration, *Guidelines on Standard of Overseas Manufacturers*, September 2000.
24. Therapeutic Goods Administration, *Manufacturing Medicines for Supply in Australia*, 1999.
25. Therapeutic Goods Administration, *Medicines Regulation and the TGA*, December 1999.
26. Therapeutic Goods Administration, *Overview of the Regulatory Requirements for the Manufacture and Supply of Medicines in Australia and for Export*, 1999.
27. Therapeutic Goods Administration, *Summary Chart of the Classification of Medicines for Registering or Listing in the ARTG*, 1999.
28. Therapeutic Goods Administration, *Summary of Fees and Charges at 28 September 2000*.
29. Therapeutic Goods Administration, *TGA Fees and Charges Explanatory Note*, 8 March 2000.
30. Therapeutic Goods Administration, *TGA News*, 1999-2000.
31. Therapeutic Goods Administration, *Uniform Recall Procedure for Therapeutic Goods*, January 2000.
32. Therapeutic Goods Administration, *Where Do You Get It? A List of Important TGA and Industry Contacts, Publications and Legislation*, 1999.
33. Therapeutic Goods Advertising Code Council, *Complaints Register*, at <http://www.tgacc.com.au/complaintsList.cfm>.

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