The Auditor-General
Audit Report No.2 2000–2001
Performance Audit

Drug Evaluation by the Therapeutic Goods Administration —Follow-up Audit

Department of Health and Aged Care
Therapeutic Goods Administration

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
25 July 2000

Dear Madam President
Dear Mr Speaker

The Australian National Audit Office has undertaken a follow-up performance audit in the Department of Health and Aged Care and the Therapeutic Goods Administration in accordance with the authority contained in the *Auditor-General Act 1997.* I present this report of this audit, and the accompanying brochure, to the Parliament. The report is titled *Drug Evaluation by the Therapeutic Goods Administration—Follow-up Audit.*

Following its tabling in Parliament, the report will be placed on the Australian National Audit Office's Homepage—http://www.anao.gov.au.

Yours sincerely

P. J. Barrett
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

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Abbreviations/Glossary

ADEC	Australian Drug Evaluation Committee, which advises the Minister, Departmental Secretary or other persons or bodies as the Minister directs on matters related to the safety of therapeutic substances.
ADRAC	Australian Drug Reaction Advisory Committee, a subcommittee of the Australian Drug Evaluation Committee.
AGRD	Australian Guidelines for the Registration of Drugs, with which submissions for drug evaluation must conform.
APMA	Australian Pharmaceutical Manufacturers Association Inc.
ARTG	Australian Register of Therapeutic Goods. A product for which therapeutic claims are made must be included in the Australian Register of Therapeutic Goods before it can be supplied in Australia.
ADRU	Adverse Drug Reactions Unit.
CHF	Consumer Health Forum.
DHAC/Health	Department of Health and Aged Care.
DSEB	Drug Safety and Evaluation Branch of TGA.
NCE	New Chemical Entity
TGA	Therapeutic Goods Administration, a Division of the Department of Health and Aged Care (DHAC), whose responsibilities include evaluating therapeutic drugs in accordance with the *Therapeutic Goods Act 1989* and monitoring adverse reactions to drugs.
Therapeutic	A 'therapeutic' good is essentially a product for use in, or in connection with, the prevention, diagnosis, cure or treatment of human disease; or in testing susceptibility for a disease; or in the replacement or modification of parts of the human anatomy.
Therapeutic Goods Act 1989	provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are imported to, manufactured or supplied in, or exported from Australia.

Summary and Recommendations

Summary

1. If one of Australia's 120 pharmaceutical companies wishes to market a prescription drug in Australia, it must apply for inclusion of the product on the Australian Register of Therapeutic Goods (the Register, ARTG). The Therapeutic Goods Administration (TGA), a Division of the Department of Health and Aged Care (DHAC or Health), is responsible for the Register. TGA evaluates the claims made by the pharmaceutical company (called a 'sponsor') for the effects, on human health, of its product. This audit report is about that process, and about TGA's monitoring of any unexpected and adverse patient reactions to drugs after the latter are included on the Register. Although 'therapeutic goods' include both medicines (prescription, non-prescription and complementary) and devices (for example, prostheses), this report deals only with prescription medicines[1].

2. The *Therapeutic Goods Act 1989* (the Act) prescribes the requirements for inclusion on the Register. The Act and associated regulations set out prescribed steps, time frames and fees for drug evaluation processes. In 1998–99, TGA received 1113 submissions for inclusion of prescription medicines in the Register. A single submission may contain more than one application.

3. TGA has responsibilities to protect public health as well as to serve industry by timely approval of products for the Australian pharmaceutical market. Those with interests in TGA's efficiency and effectiveness include Parliament, the Government, consumers of pharmaceutical products, national and multinational pharmaceutical manufacturers, medical and pharmaceutical institutions and medical and pharmaceutical practitioners. TGA has processes for consultation and negotiation with those stakeholders. It works with overseas agencies towards international alignment or 'harmonisation' of regulatory requirements and towards developing international comparisons of regulatory agencies' performance.

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[1] The terms 'medicine', 'prescription medicine', 'drug' and 'prescription drug' are used interchangeably in this report.

4. TGA's operations are funded by cost recovery from industry, through charges and fees for services. In 1991–92, the cost recovery requirement was set initially at 50 per cent of operating costs. In the 1997–98 Budget, the rate accelerated to a target of 75 per cent in that year and to 100 per cent in 1998–99. The Government's cost recovery decision applies to all activities within the scope of the Act, including industry regulation and the TGA's responsibilities both in public health and as part of a Commonwealth agency— for example, providing ministerial advice.

5. When TGA receives an application from a pharmaceutical company for approval of a prescription drug, it first appraises the application for acceptability and calculates the fees payable by the drug sponsor for the evaluation. If an application is accepted for evaluation, TGA considers the sponsor's data in terms of the legislated quality, safety and efficacy requirements. After evaluating the proposed product, TGA may approve its inclusion in the Register.

6. TGA's evaluation of products is crucial to pharmaceutical companies because no therapeutic good may be imported, exported, manufactured or supplied in Australia unless included in the Register. The research and development of a new medicine costs, on average, $750 million and takes 15 years.[2] Effective and timely evaluations of registration applications, once they are received by TGA, are essential to a viable pharmaceutical sector in Australia.

7. Australia's market for prescription drugs had a turnover of $6 billion in 1998–99. Between 1990 and 1995, the Australian pharmaceutical industry grew by 7.5 per cent and its ratio of exports to imports increased from 33.3 per cent to 41.9 per cent. European manufacturers produced 77 per cent of the pharmaceutical drugs for human use that were imported to Australia in 1998–99.[3]

8. Australia's pharmaceutical manufacture represents about one per cent of a world market that is dominated by large multinational companies, which apply, typically, for drug evaluations in Australia after having made similar applications to regulatory authorities overseas.

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[2] TGA has no role in the research and development of pharmaceutical products by sponsor companies.

[3] Australian Pharmaceutical Manufacturers Association (APMA) 1999, *APMA Facts Book* 1999–2000, APMA, Sydney.

9. TGA requires pharmaceutical companies to supply it with data on any patients' adverse reactions to their medicines. In addition, it encourages reporting by medical personnel of all suspected adverse reactions to medicines. The receipt of reporting cards is acknowledged by TGA.

ANAO's 1996 Report

10. In October 1996, the Auditor-General presented *Audit Report No.8 of 1996–97* ('ANAO's 1996 Report' or 'ANAO's 1996 recommendations')[4]. The audit's objective was to assess the efficiency, effectiveness and accountability of TGA's evaluation and approval of prescription drugs for public use. ANAO reported that the TGA's drug evaluation process was efficient, but that there was scope (with the assistance of the pharmaceutical companies) for the evaluation time to be reduced, particularly the time to obtain and assess additional data. The report found that TGA could increase the effectiveness of its drug evaluation processes by:

- improving its information technology;
- developing an adequate system to assess the cost of TGA's services to the pharmaceutical industry; and
- giving more attention to monitoring adverse drug reactions.

11. The report also found that TGA could strengthen its external accountability by providing clearer information to parliamentarians and consumers of prescription drugs.

Follow-up audit

12. The purpose of this follow-up audit was to review the extent to which TGA had implemented the recommendations of ANAO's 1996 Report. This audit was conducted because of the importance of effective drug evaluation processes to public health.

13. The follow-up audit was conducted from late September 1999, with field work in Canberra and Sydney. ANAO invited the Department of Health and Aged Care, (DHAC or 'Health'), and TGA in particular, to provide evidence of the implementation of recommendations. ANAO met departmental managers; reviewed documents they and industry bodies provided; and discussed relevant issues with industry and community stakeholders.

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[4] Australian National Audit Office 1996, *Drug Evaluation by the Therapeutic Goods Administration*: *Department of Health and Family Services*, Audit Report No.8 1996–97, AGPS, Canberra.

Overall conclusion

14. TGA has implemented, or partly implemented, 12 of the 14 recommendations in the ANAO's 1996 Report and is addressing the remaining recommendations through alternative means. Generally, TGA's implementation has been consistent with the thrust of that Report to improve TGA's efficiency, effectiveness and reporting to its stakeholders.

15. In summary, TGA has:

- scheduled a review in 2000 of the Australian Guidelines for the Registration of Drugs as a joint project with the Australian Pharmaceutical Manufacturers Association (APMA);
- worked with industry to reduce the time industry needs to respond to TGA's requests for additional information to enable evaluation of applications to register drugs;
- reviewed its procedures for producing more timely minutes of the meetings of the Australian Drug Evaluation Committee, but has not made significant change;
- completed a major review of its information technology requirements and commenced implementation of a strategy to improve its information management;
- largely implemented ANAO's recommendation that the monitoring and reporting of adverse reactions to drugs be improved. TGA established an Adverse Drug Reaction Unit;
- identified a suitable pricing structure as a basis for its cost recovery;
- implemented activity-based costing of its activities; and
- implemented full cost recovery across *all* activities within the scope of its legislation, including those related to drug evaluation.

16. The implementation status of ANAO's 1996 recommendations is shown in Appendix 1. As to previous recommendations not implemented, TGA advised the ANAO that it was addressing the issue underlying Recommendation 2 (categorisation of applications). In relation to Recommendation 8 (the training of external evaluators), TGA considered that its current measures to assist and guide new evaluators were adequate for quality assurance, although TGA had agreed to ANAO's 1996 recommendation for the use of internal audit for quality assurance. TGA advised that the ANAO's 1996 recommendations relating to improvements in the drug evaluation process were given high-level policy consideration.

17. Of the other partially implemented recommendations, the most notable is that part of Recommendation 1 related to reporting time elapsed in the drug–evaluation process. TGA has confirmed that this is being addressed as part of its major information technology redevelopment project scheduled for completion in 2001.

18. TGA has advanced reasons for not implementing some other parts of ANAO's 1996 recommendations. TGA advised ANAO that these had been superseded by later reviews, and that TGA's allocation of resources to other priorities hampered its ability to fully implement some recommendations. These matters are discussed in this report.

19. This report has made one recommendation to TGA about an outstanding matter from ANAO's 1996 audit (timeliness of drug evaluation) and two additional recommendations, the first is to improve performance management of the monitoring of adverse reactions to registered drugs, and the second is to improve performance indicators.

20. ANAO noted a high level of industry confidence in TGA's evaluation processes.

Key Findings

21. The more significant issues, identified in the course of the follow-up audit, are summarised below.

Business processes and support

Minutes of Australian Drug Evaluation Committee take 10 weeks to be received

22. TGA has implemented ANAO's 1996 recommendation that it review its procedures for producing minutes of the meetings of the Australian Drug Evaluation Committee. This Committee advises TGA on whether prescription drugs should be included in the Register. However, pharmaceutical companies often receive the minutes up to 2.5 months after the meeting at which their products were considered.

23. The timing of the availability of minutes is important because there is a legislative deadline for appeals against TGA's decisions in relation to drugs proposed for registration. A person (or company) whose interests are affected by a decision may ask the Minister to review it within 90 days (about three months) of the decision coming to the applicant's notice. If a decision-maker decides not to approve a drug for registration, the minutes produced by the Australian Drug Evaluation Committee are an important source of information to sponsors, explaining the reasons for rejection and serving as a basis for any appeal.

24. Distribution of the records of the Australian Drug Evaluation Committee's deliberations in the timeframe recommended by the Baume Report[5] would assist those pharmaceutical companies seeking reconsideration, within legislated timeframes, of adverse decisions by TGA on applications. ANAO suggests that TGA consult with its industry stakeholders on an acceptable timeframe for the production and distribution of records of Committee deliberations. ANAO appreciates that there may be resource implications of quicker production and distribution of records of Committee deliberations, which would be a matter for TGA to manage, with the support of its industry stakeholders, through its cost recovery measures. The TGA has advised that it negotiates its fees and charges with the relevant industry association with the objective of achieving an appropriate balance between costs and

[5] Baume, Peter 1991, *A Question of Balance: Report on the Future of Drug Evaluation in Australia*, AGPS, Canberra.

service standards. In this context, TGA is of the view that, within the current level of fees and charges, and other priorities, the resources it allocates to the Australian Drug Evaluation Committee secretariat are adequate.

Information about TGA's management of patient reaction data is needed

25. During the audit fieldwork, TGA did not have performance targets for processing reports of patients' adverse reactions to drugs. TGA subsequently advised that, in response to the audit recommendation from the original audit, these targets have now been developed and are being implemented. TGA does not inform sponsor companies about its methodology for determining that a pharmaceutical product's registration should be cancelled. If it did, the information would serve as an assurance that TGA had followed rigorous processes in arriving at its decisions to alter the status of a registered medicine. TGA advised that it is monitoring international developments in this area.

26. Although few medicines are withdrawn from the Register on the basis of patients' adverse reactions, the cost of drug development and marketing make it important that a product's sponsor is satisfied that due process was followed in reviewing the safety and efficacy of the product.

Information management will improve in 2001

27. TGA recognised the importance of the ANAO's 1996 recommendations relating to its information technology capacity. It embarked on a total redevelopment of all its major applications as a result. The new system will be introduced in 2001. ANAO noted the significant progress by the TGA towards the redevelopment of its management information systems that, when fully implemented, should enable an all-around improvement in reporting to industry. Such reporting will include information about the total elapsed time involved in drug evaluations. Notwithstanding, ANAO noted continuing delays by TGA in reporting to industry information about the total elapsed time involved in drug evaluations. These delays were associated with the long-awaited remedy of its information technology deficiencies.

28. This long lead time has affected TGA's management information capability in the interim because it lacks a quick, reliable system to track the progress of applications until the redevelopment is completed.

Categorisation of applications for registration of drugs has not altered

29. TGA has not reviewed the appropriateness of including evaluations of new chemical entities with less-complex submissions (Recommendation 2 in ANAO's 1996 Report**).** However, the 1996 Government Review of TGA considered the categorisation of applications. Subsequently, TGA had examined the options for the conversion of the existing Australian categorisation of drug applications into categorisations used by the European Agency for the Evaluation of Medicinal Products (EMEA), concluding that the potential costs of the change outweighed the potential benefits. TGA advised ANAO that it is working towards harmonising its regulatory requirements with those of overseas regulators and towards benchmarking its performance against that of its counterparts overseas. TGA considers that these approaches will address the performance matters underlying ANAO's initial Recommendation 2. In this light, ANAO considers that TGA has responded adequately to the performance management issues underlying Recommendation 2 in ANAO's 1996 Report.

Timeliness, Fees and Quality Assurance

Statutory timeliness was achieved, although the timeliness for evaluation of new chemical entities declined as TGA's workload increased

30. The ANAO found that the TGA continues to process all applications within statutory timeframes. The ANAO notes that a comparison of data from the second half of 1996 with the second half of 1999 shows TGA's average time for evaluating one sub-group of applications, the new chemical entities (NCEs), has increased while remaining well within statutory timeframes. However, given the time it takes to evaluate an NCE (some 18 months after the application is made) and considering the workloads in 1994–95 and 1996–97, it is apparent that during the last half of 1999 the TGA was processing a much higher workload than in the last half of 1996.

31. ANAO also notes that the largest number of applications are not new chemical entities. These applications compete for the same evaluation resource pool within the TGA. Many of these, such as extensions of indications, are also of great importance to industry and others. During this time the workload associated with these applications also increased significantly.

Elapsed time is not reported

The Baume Report commented that the actual processing time for an application is much less than the total time taken from receipt of an application to written approval. Reporting of the total elapsed time

involved in evaluations, recommended by both the 1996 Government Review of TGA and by ANAO in its 1996 Report, will not be available until 2001. ANAO appreciates the reasons for the freeze on amendments to TGA's existing information technology existing system. ANAO has been advised that, in 2001, TGA's new information technology system will have the capability to report drug approval times to stakeholders in both 'calendar days' as well as 'working days'.

Cost recovery and fees have been implemented

32. The Department implemented full-cost recovery for all operations within the scope of the Therapeutic Goods Act, including its drug evaluation activities, from the beginning of 1998–99. In 1998–99, TGA's total revenue from independent sources was $38.7 million (compared to a total operating budget of $49.1 million). Within the revenue from independent sources, $37.4 million was raised through fees for evaluation services and annual charges met by the sponsors of the range of therapeutic goods on the Register (for example, fees and charges related to prostheses as well as to pharmaceutical items)[6].

33. In late 1999, TGA sought endorsement of increased fees and charges from TGA's Industry Consultative Committee to allow the fees and charges to align more closely with 100 per cent cost recovery targets. TGA undertook that, if it could increase its fees and charges, the increased resources would enable TGA to re-gain the performance levels it had achieved in 1997–98.

Quality assurance and related skills are in the process of being addressed.

34. ANAO's 1996 Report commented that training of external evaluators contracted by TGA was almost non-existent, but noted that one section of TGA provided regular advice to its external evaluators. In 1996, TGA agreed to ANAO's recommendation for the use of internal audit programs relating to external evaluators in all relevant evaluation sections within TGA.

35. As regards ANAO's 1996 recommendation that training programs be developed for evaluators of drug submissions, TGA advised ANAO in the course of the follow-up audit that it engages only subject-matter experts as external evaluators. Therefore, TGA now considers—contrary to its views in 1996—that training of external evaluators is not required.

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[6] Annual charges are payable for all items listed on the Australian Register of Therapeutic Goods, except where turnover of those goods is of low volume and low value or involves hospitals.

Information to stakeholders and the community

Public information about TGA's performance has partially improved

36. The Department's information about TGA in its annual report conforms to requirements for departmental annual reports. The annual report includes information that TGA is meeting the legislative requirements for timeliness in its drug evaluation. However, it includes no data on the efficiency of TGA's drug evaluation processes, although TGA provides the pharmaceutical industry with some such data.

37. TGA does not have adequate performance indicators of the efficiency of its drug evaluation. The absence of adequate performance indicators of the efficiency of processing limits the ability of industry, the Parliament and other stakeholders to understand variations in TGA's processing performance.

Implementation of ANAO's 1996 recommendations

ANAO's 1996 recommendation have been implemented adequately

38. ANAO considers that, with the exception of issues identified in the preceding paragraphs, TGA has adequately implemented the recommendations of ANAO's Audit Report No.8 1996–97, *Drug Evaluation by the Therapeutic Goods Administration*.

ANAO has made three new recommendations

39. Three recommendations follow. Recommendation No.1 addresses additional issues about management of adverse drug reactions, which were identified in this follow-up audit. Recommendation No.2 emphasises the importance of TGA continuing to address part of a 1996 recommendation, which was to report the total time necessary for drug evaluations. Recommendation No.3 addresses the issue of performance indicators.

TGA's Comment

40. TGA considered that it had taken the most comprehensive approach possible to consideration of the ANAO's 1996 recommendations on drug evaluation. It stated that it had committed substantial resources to ensuring they were considered in the light of current best practice and in the context of the Government's wishes for the direction of drug evaluation in Australia.

Recommendations

Set out below are the ANAO's recommendations formed as a result of this follow-up audit. Report paragraph references and abbreviated responses are also included. More detailed responses are shown in the body of the report.

Recommendation No.1 Para. 2.46

ANAO recommends that TGA:

- develop and publish performance targets for processing reports of adverse reactions to drugs; and
- in each instance where a decision is made to alter the status of a product on the Australian Register of Therapeutic Goods in response to reported adverse reactions, advise the sponsor of the reasons for the decision including the process by which the decision was made and the information upon which the TGA decision is based.

TGA's response: Agreed.

Recommendation No.2 Para. 2.65

ANAO recommends that TGA, as part of its development of a new information technology system by 2001:

- report the status of drug evaluation applications and TGA's drug evaluation performance in total elapsed time ('calendar days') as well as 'working days', as recommended by the ANAO's 1996 Report.

TGA's response: Agreed.

Recommendation No.3 Para. 3.17

ANAO recommends that, to permit Parliament, industry and other stakeholders to understand variations in TGA's evaluation performance:

- TGA publish performance indicators of the efficiency of its drug evaluation processing.

TGA's response: Agreed in principle.

Audit Findings and Conclusions

1. Introduction

This Chapter outlines the background to this follow-up audit of drug evaluation by the Therapeutic Goods Administration; the audit approach; overall audit conclusions; and report structure.

Background

1.1 If one of Australia's 120 pharmaceutical companies wishes to market a prescription drug in Australia, it must apply for inclusion of the product on the Australian Register of Therapeutic Goods (the Register or ARTG). The Therapeutic Goods Administration (TGA), a Division of the Department of Health and Aged Care (DHAC or Health), is responsible for the Register. TGA evaluates the claims made by the pharmaceutical company (the 'sponsor[7]') for the effects, on human health, of its product. This audit report relates to that process, and to TGA's monitoring of any patients' unexpected and adverse reactions to drugs after their inclusion on the Register. Although 'therapeutic goods' encompasses both medicines (prescription, non-prescription and complementary) and devices (for example, prostheses), this report deals only with prescription medicines[8], which were also covered by the ANAO's 1996 Report.

1.2 When therapeutic claims for a drug are accepted, TGA includes the product on the Register. The *Therapeutic Goods Act 1989*[9] (the Act) details the requirements for inclusion. The Act and associated regulations set out prescribed steps, time frames and fees for drug evaluation processes. In 1998–99, TGA received 1113 submissions for the inclusion of prescription medicines in the Register.[10] A single submission may comprise more than one application.

1.3 TGA has responsibilities in public-health protection as well as serving industry by timely approval of products for the pharmaceutical market. Those stakeholders with interests in TGA's efficiency and effectiveness ('stakeholders') include Parliament, the Government, consumers of pharmaceutical products, national and multinational pharmaceutical manufacturers, and medical and pharmaceutical

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7 Under the *Therapeutic Goods Act 1989*, a 'sponsor' is someone who manufactures, imports or exports a therapeutic good.

8 The terms 'medicine', 'prescription medicine', 'drug' and 'prescription drug' are equivalent terms in this report.

9 The *Therapeutic Goods Act 1989* (the Act) sets out the legal requirements for the manufacture and supply of medicines in Australia and for export.

10 In the first quarter of 1999–2000, 260 applications were received. This was 12 fewer than in the previous quarter and 51 fewer than in the first quarter of 1998–99.

institutions and practitioners. TGA has established processes for consulting and negotiating with its stakeholders. It is working with overseas agencies towards international alignment ('harmonisation') of regulatory requirements and towards international comparisons of regulatory agencies' performance.

1.4 TGA's operations are funded by cost recovery from industry, through charges and fees for services. In 1991–92 the cost recovery requirement was set, initially, at 50 per cent of operating costs. In the 1997–98 Budget, the cost-recovery rate accelerated to a target of 75 per cent in that year and to 100 per cent in 1998–99.[11]

1.5 This cost-recovery decision applies to all activities within the scope of the Act, including industry regulation and the TGA's responsibilities both in public health and as part of a Commonwealth agency— for example, providing ministerial support.

1.6 When TGA receives an application from a sponsor for approval of a drug, it first appraises the application for acceptability for evaluation[12] and calculates the fees payable for the evaluation. If an application is accepted, TGA considers the data provided by the sponsor in terms of the legislated quality, safety and efficacy requirements.

1.7 Figure 1 represents the stages of TGA processes for evaluating and approving a medicine.

1.8 After evaluating the product[13], TGA may decide to approve its inclusion on the Register. Alternatively, the decision-maker might submit the results of the evaluation to the Australian Drug Evaluation Committee (ADEC)[14], an advisory committee to the Minister. That Committee considers TGA's evaluation report on the drug application and advises TGA whether to approve or reject the registration. The decision-maker

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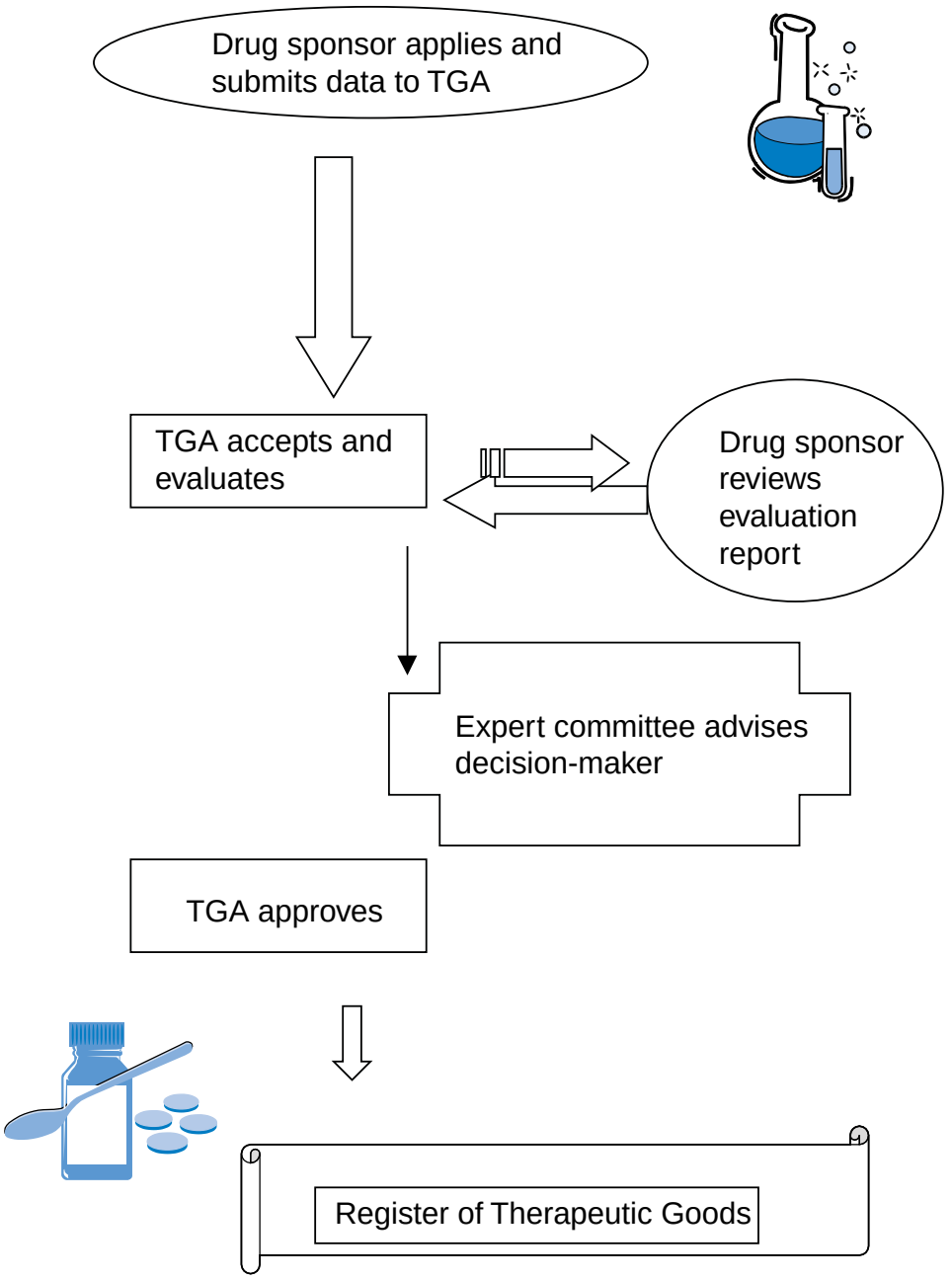
11 The 1996 Budget increased the level of cost recovery for TGA activities. Targets were set at 50 per cent in 1995–96, 58 per cent in 1996–97, 67 per cent in 1997–98 and 75 per cent in 1998–99. These targets were overtaken by a 1997 Budget initiative to increase the level of cost recovery.

12 Applications must conform to guidelines. In the case of 'restricted' substances that are abortion-inducing drugs, the Minister must approve the evaluation or inclusion of the drug on the Australian Register of Therapeutic Drugs. For these drugs, the Minister's written approval must be laid before each House of Parliament within five days of the Minister's decision.

13 Under TGA's operating procedures, the evaluator of an application may not be the decision-maker on that application. Applications to register NCEs will always have at least three evaluators working separately on chemistry and quality control, animal toxicology, and human clinical data tasks. Having a separate decision-maker, who is a more experienced officer, results in a better outcome by ensuring a balanced overall decision is made and introduces quality control into the process. Further, although not obliged by law to send any application to the ADEC for its advice, TGA routinely sends all applications for new chemical entities to ADEC.

14 The Australian Drug Evaluation Committee's functions include making medical and scientific evaluations of any drugs that the Minister of the Secretary may refer to it for evaluation; and to provide advice to the Minister, the Secretary or to other persons or bodies as the Minister may direct.

Figure 1
Evaluating and monitoring a new drug



(a delegate of the departmental Secretary) is not obliged to accept the Committee's advice. In the case of a rejected application, a sponsor may ask a delegate of the Minister to review the original decision.

1.9 TGA's evaluation of products is crucial to pharmaceutical companies because no therapeutic good may be imported, exported, manufactured or supplied in Australia unless included on the Register. The research and development of a new medicine costs $750 million and takes 15 years, on average.[15] Effective and timely drug evaluations of registration applications, once they are received by TGA, are essential to a viable pharmaceutical sector in Australia.

1.10 Australia's market for prescription drugs had a turnover of $6 billion in 1998–99. Between 1990 and 1995, the Australian pharmaceutical industry grew 7.5 per cent[16]; and its ratio of exports to imports increased from 33.3 to 41.9 per cent. European manufacturers produced 77 per cent of the pharmaceutical drugs for human use that were imported to Australia in 1998–99.

1.11 Australia's pharmaceutical manufacture represents around one per cent of a world market dominated by large multinational companies which, typically, apply for drug evaluations in Australia after making similar applications to overseas regulatory authorities.

1.12 After a drug is marketed, there may be an adverse reaction to it by a patient. Medical personnel and pharmaceutical companies in Australia are asked to report patients' unusual reactions to TGA. They use forms to do so and TGA enters summary reports in its computer system. Data are reviewed by TGA medical personnel and considered by the Adverse Drug Reaction Advisory Committee (ADRAC), a subcommittee of the Australian Drug Evaluation Committee. TGA may cancel items' inclusion on the Register, or otherwise alter their status, on the grounds of patients' serious adverse reactions. It would be exceptional for a product to be removed from the Register on the grounds of a single adverse event report. When such action is taken, a sponsor has a legal right of appeal. However, it is more likely that there will be a restriction of usage or additional warnings in the product labellings.

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15 APMA 1999, 'At a glance': APMA Fact sheet 1998–99, APMA, Sydney.

16 APMA 1999, *APMA Facts Book* 1999–2000, APMA, Sydney.

Previous reviews

1.13 Successive governments have initiated reviews into TGA's operations.

- In 1991, the Commonwealth Government commissioned Professor Baume to review Australia's drug evaluation system, and accepted all 164 of his resulting recommendations. The Baume Report[17] led to amendment of the Act to include, as a goal, timely availability of therapeutic goods; and the introduction of evaluation deadlines, providing for financial penalties for TGA if they were not met. That report also recommended a restructure of TGA, adoption of the European Community's format for drug applications and wider use of overseas data to speed evaluations;
- The Industry Commission's 1996 report, *The Pharmaceutical Industry*[18], considered TGA's drug evaluation processes, within terms of reference about the pharmaceutical industry in Australia, its relationship to the global industry and its potential for further development; and
- The incoming Government in 1996 commissioned a review of TGA by consultants (the 1996 Government Review of TGA). This was conducted largely after ANAO's 1996 audit was completed. Recommendations from both the Industry Commission Report and the 1996 ANAO Report were referred to and considered by this Government-initiated review of TGA.

1.14 In addition, TGA has commissioned studies of its own administrative processes.

Audit Report No.8 of 1996–97

1.15 In October 1996, the Auditor-General presented *Audit Report No.8 1996–97* ('ANAO's 1996 Report' or 'ANAO's 1996 recommendations')[19]. Its objective was to assess the efficiency, effectiveness and accountability of TGA's evaluation and approval for public use of prescription drugs.

1.16 ANAO reported that the TGA's drug evaluation process was efficient, but that there was scope (with the assistance of the pharmaceutical companies) for the evaluation time to be reduced, particularly the time to obtain and assess additional data. The report

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17 Baume, Peter 1991, *A Question of Balance: Report on the Future of Drug Evaluation in Australia,* AGPS, Canberra.

18 Industry Commission 1996, *The Pharmaceutical Industry*, Industry Commission Report No.51, AGPS, Canberra.

19 Australian National Audit Office 1996, *Drug Evaluation by the Therapeutic Goods Administration*: Department of Health and Family Services, Audit Report No.8 1996–97, AGPS, Canberra.

found that TGA could increase the effectiveness of its drug evaluation processes by:

- improving its information technology;
- developing an adequate system to assess the cost of TGA's services to the pharmaceutical industry; and
- giving more attention to monitoring adverse drug reactions.

1.17 The report also found that TGA could strengthen its external accountability by providing clearer information to parliamentarians and consumers of prescription drugs.

1.18 The report made 14 recommendations. TGA agreed with all of them, although it offered comments on four of them. The recommendations and TGA's comments are presented in Appendix 1.

Follow-up audit: objective, scope and cost

1.19 The purpose of this follow-up audit was to review the extent to which TGA had implemented ANAO's 1996 recommendations. It was initiated because of the importance to public health of effective drug evaluation.

1.20 It was conducted from late September 1999, with field work in Canberra and Sydney. ANAO invited the Department of Health and Aged Care (DHAC, or 'Health'), and TGA in particular, to provide evidence of implementation of its recommendations. ANAO met Health's managers; reviewed documents provided by them and industry bodies; and discussed issues with industry and community stakeholders.

1.21 ANAO records its appreciation of the assistance of TGA, the Australian Pharmaceutical Manufacturers Association (APMA), the Consumer Health Forum and other industry stakeholders. Stakeholders provided useful background information in relation to the issues covered in this report.

1.22 The audit was conducted in accordance with ANAO Auditing Standards. Its estimated cost was $160 000.

Audit findings

1.23 TGA has implemented or partially implemented 12 of the 14 recommendations in ANAO's 1996 Report, and is addressing the remaining recommendations through alternative means. Generally, TGA's implementation has been consistent with the theme of that Report to improve TGA's efficiency, effectiveness and reporting to its stakeholders.

1.24 In summary, TGA has:

- scheduled a review in 2000 of the Australian Guidelines for the Registration of Drugs as a joint project with the APMA;
- worked with industry to reduce the time industry needs to respond to TGA's requests for additional information to enable evaluation of applications to register drugs;
- reviewed its procedures for producing more timely minutes of the meetings of the Australian Drug Evaluation Committee, but has not made significant change;
- completed a major review of its information technology requirements and commenced an implementation strategy to completely replace its existing IT systems with a redeveloped, integrated approach to address its management information requirements;
- largely implemented ANAO's recommendation that the monitoring and reporting of adverse reactions to drugs be improved. TGA established an Adverse Drug Reaction Unit;
- identified a pricing structure as a basis for its cost recovery;
- implemented activity-based costing of its activities; and
- implemented full cost recovery as a whole, including those related to drug evaluation.

1.25 As to previous recommendations not implemented, TGA advised the ANAO that it was addressing the issue underlying Recommendation 2 (categorisation of applications). In relation to Recommendation 8 (the training of external evaluators), TGA considered that its current measures to assist and guide new evaluators were adequate for quality assurance, although TGA had agreed to the ANAO's 1996 recommendation for the use of internal audit for quality assurance. TGA advised that the ANAO's 1996 recommendations relating to improvements in the drug evaluation process were given high-level policy consideration. The implementation status of ANAO's 1996 recommendations is shown in Appendix 1.

1.26 TGA has advanced reasons for not implementing all parts of ANAO's 1996 recommendations. TGA advised ANAO that some parts of the recommendations had been superseded by later reviews, and that its allocation of resources to other priorities hampered its ability to fully implement some of them. These matters are discussed in this report.

1.27 ANAO noted a high level of industry confidence in TGA's evaluation processes.

Report structure

1.28 The next two chapters discuss TGA's approach to implementing ANAO's 1996 recommendations for strengthening the administration of drug evaluation, with coverage as follows:

- Chapter 2 covers TGA's improvements to its processes for including medicines on the Australian Register of Therapeutic Drugs and for monitoring adverse reactions to registered drugs.
- Chapter 3 reviews TGA's performance management and its communication with its stakeholders.

2. Business Processes and Support

This Chapter discusses, first, TGA's improvements of its processes for inclusion of products on the Australian Register of Therapeutic Drugs; then its management of voluntary reporting of adverse reactions to drugs; and, last, its redevelopment of its information technology.

ANAO found that TGA had made significant improvements, the two most important being its contracting for improved information technology support for drug evaluation and its monitoring of adverse reactions to drugs.

Business processes—Recommendations 1, 2, 3, 10 and 11

2.1 Figure 2 presents ANAO's 1996 recommendations 1, 2, 3, 10 and part of 11, relating to drug evaluation and monitoring processes.

2.2 TGA accepted all the above recommendations in 1996. However, in accepting Recommendation 11, it commented that it believed its Adverse Drug Reaction System compared favourably with those of other countries. It agreed, nonetheless, to undertake a review to ensure that its system conformed to international best practice.

2.3 TGA advised ANAO that it had improved its drug evaluation processes. ANAO considers that, with the exception of reporting drug evaluation elapsed time to its stakeholders, it has broadly improved those processes as recommended by ANAO in 1996. TGA's actions to streamline its handling of applications are discussed in the following paragraphs.

2.4 However, stakeholders raised with ANAO, via the APMA, some aspects of TGA's processes for accepting applications that they considered could be improved. These included delays[20] and costs involved in preparing submissions in a format acceptable to the TGA. These issues too are discussed in the following paragraphs. TGA advised that it had challenged on previous occasions industry claims that considerable resources and costs were involved in making sure a submission met TGA's requirements. TGA advised that there are no unique Australian requirements and that applications in the European Union format are acceptable to the TGA. The only exception to this is the Australian Product

[20] Some industry sponsors of drug applications informed ANAO, via the APMA, that the time elapsed for TGA's acceptance of an application as suitable for evaluation was more than five months. TGA advised ANAO that there are time limits for acceptance of an application. This time may be extended if a company's application has been found to be deficient and as an alternative to rejection of the application.

Information and proposed Australian labelling, and there has never been any suggestion that this be harmonised with European requirements. TGA advised that a recent example of difficulty with the data package submitted by a company related specifically to their submission of supporting material in the French rather than the English language.

Figure 2

ANAO's 1996 recommended improvements to drug evaluation and monitoring

Processes	Suggested improvements
Drug company applies for evaluation of a drug, complying with the Australian Guidelines for the Registration of Drugs (AGRD). AGRD provides for categories of applications for drug evaluation	• Review requests from pharmaceutical companies for additional information (Recommendation 1) • Amend, if necessary, the AGRD (Recommendation 1) • Work with industry to reduce response times for information requests (Recommendation 1) • Review appropriateness of including evaluations of complex new chemical entities in the same category as less complex submissions (Recommendation 2) • Reassess requirements to determine if more evaluations, or parts of them, can be accepted from other international regulatory authorities (Recommendation 10)
▼	
TGA accepts or rejects application for evaluation	
▼	
TGA evaluates drug within prescribed time frames	• Report drug approval times to stakeholders in both 'working-day' and 'calendar-day' formats (Recommendation 1)
▼	
Australian Drug Evaluation Committee (ADEC) considers evaluator's report	• Reassess current procedures for producing minutes of meetings, so as to meet the 20–day time frame recommended in the Baume report and accepted by the Government (Recommendation 3)
▼	• Furthermore, TGA should assess when it can actually meet this time frame. (Recommendation 3)
Secretary's Delegate decides to accept or reject application	
▼	
Appeal against unsuccessful application	
▼	
TGA includes product on ARTG	
▼	
Post-market surveillance of product for adverse reactions	• Review promotion and encouragement of adverse drug reactions (Recommendation 11) • Disseminate information to all health professionals concerned (Recommendation 11) • Review the adequacy of resources for adverse reactions monitoring (Recommendation 11)

2.5 ANAO observed in the course of the follow-up audit that TGA is readily accessible to its clients and willing to collaborate with industry to improve drug evaluation processes. For example, TGA is alert to the potential of electronic applications for drug registration, which could reduce the need for freight and handling of large volumes of paper. Electronic data submission for prescription medicines is still at the research stage. Notwithstanding, TGA's information systems development project will allow for electronic data submission for the evaluation of prescription drugs, when internationally agreed standards emerge. At this stage, this is expected to be within the next five years. However, TGA cautioned that there is not evidence from the European experience, to date, that electronic data submission speeds the review process.[21] TGA advised ANAO that there are some constraints on the possible use of electronic transmission. Some relevant data are not available in electronic form. Also, screen–based assessment of material would be necessarily limited because of the occupational health and safety concerns associated with screen–reading large volumes of data. Figure 3 illustrates TGA's receipt of one application, in written form, for registration of a drug.

Figure 3

Receipt at TGA of data supporting one application for drug evaluation

[21] TGA cautioned that the potential for electronic data submission should not be overstated. It advised ANAO of constraints in the implementation of systems for electronic data submission in several overseas countries related to such issues as the need for training of the evaluators and difficulties caused by diversity of data presentation.

Information requests—Recommendation 1

2.6 In response to ANAO's 1996 recommendation that TGA work with industry to improve the industry's speed of response to information requests, TGA surveyed some of its clients informally in 1998. Its aim was to discover why nearly half the applications for drug evaluation required additional information from the sponsors before evaluation could proceed.

2.7 The survey identified two problem areas: perceived difficulties on the part of sponsor companies with the nature of some of TGA's requests; and drug applications being presented in ways that did not comply with the Australian Guidelines for the Registration of Drugs. TGA advised ANAO in the current audit that it had raised with its drug evaluation managers the importance of appropriateness in their information requests to industry. The need for applications to comply with the Guidelines has long been of concern to TGA and is discussed in the next section of this Chapter.

2.8 ANAO received a suggestion from an industry stakeholder in the course of this audit that TGA could improve its client service by coordinating its requests to applicants for additional information. This could reduce the paperwork involved in processing requests and, through concurrent handling of requests by the sponsor, could reduce the total time taken to process the application. TGA advised ANAO that it is willing to consider this option, although it had some doubt as to whether the objective would be achieved. Because individual components of data packages are evaluated in different areas and at different times, the coordination of a consolidated request for additional information could, in fact, unnecessarily delay the final evaluation.

2.9 ANAO notes that TGA has reviewed its information requests to industry, as ANAO proposed in its Recommendation 1 of 1996.

Australian Guidelines for the Registration of Drugs—Recommendation 1

2.10 Drug evaluation applications must conform to the Guidelines. (ANAO identified in 1996 that these Guidelines, last revised in 1994, needed review.) In the course of the current audit, TGA advised ANAO that it intended to work with APMA in 2000 to review the Guidelines in the light of changes in legislation and also to improve the efficiency of evaluation processes.

2.11 TGA also advised ANAO during the course of the follow-up audit that it had listed, on its Internet website, all European Union Rules

Governing Medicinal Products in the European Community accepted in Australia; and that it will continue to list all additional guidelines and their status. ANAO found that, in the interim, it has not been unusual for pharmaceutical companies to institute their own procedures for identifying the current requirements of the Guidelines. One APMA member commented to ANAO that applicants found the Guidelines hard to follow because of the difficulty in discerning which Guidelines were current and which were not.

2.12 To summarise, TGA has:

- scheduled a review of the Australian Guidelines for the Registration of Drugs as a joint project with APMA, to be undertaken in 2000; and
- worked with industry to reduce the time taken to respond to TGA's requests for information.

2.13 These initiatives respond adequately to those parts of Recommendation 1 of ANAO's 1996 Report concerning acceptance of registrations for evaluation, although ANAO notes the delay of some four years in TGA scheduling a review of AGRD. Another part of Recommendation 1, related to reporting to stakeholders of the total elapsed time involved in drug evaluations, is discussed later in this report.

Categorisation of drug applications—Recommendation 2

2.14 ANAO recommended in 1996 that TGA review its categorisation of drug applications. There are three categories:

Category 1: a new chemical entity, a new indication of a drug's use or a new route for administration of the drug;

Category 2: a drug that has been approved for general marketing in two 'acceptable' countries; and

Category 3: a variation of the information on a prescription drug already on the Register.

2.15 Because the legislation defines different time requirements for each category of drug evaluation, it is important that an application be categorised appropriately. As a hypothetical example, if an application is treated as requiring evaluation of a complex 'new chemical entity' when it involves only a revised trade name for an approved product, the time limit for processing it may be longer than it should be.

2.16 TGA agreed in 1996 to review its drug categorisation. In May 1997, TGA stated that its categorisation of applications would be changed

to align with regimes of regulators in the European Union.[22] However, it has not done so. TGA has advised ANAO that the proposed alignment proved more complex than was envisaged at the time of the last ANAO review.

2.17 TGA advised ANAO that benchmarking its handling of subcategories of Category 1 would achieve a better result for its clients than altering its categorisation of applications. TGA has established performance targets for processing various types of applications within categories. These targets were agreed with the APMA. ANAO considers that TGA's specification of performance targets and informing industry of those targets are positive steps.

2.18 ANAO noted that, overall, there was a high level of industry confidence in TGA's evaluation processes. Continued effort by TGA to align its regulatory regime with those of the principal international regulators will ensure that TGA retains the confidence of its industry stakeholders.

2.19 To summarise, TGA has not reviewed the appropriateness of including evaluations of new chemical entities with less-complex submissions (Recommendation 2 in ANAO's 1996 Report). However, the 1996 Government Review of TGA considered the categorisation of applications. TGA stated that it had subsequently examined the options for the conversion of the existing Australian categorisation of drug applications into categorisations used by the European Agency for the Evaluation of Medicinal Products (EMEA), concluding that the potential costs of the change outweighed the potential benefits. TGA advised ANAO that it is working towards harmonising its regulatory requirements with those of overseas regulators and towards benchmarking its performance against that of its counterparts overseas. TGA considers that these approaches will address the performance matters underlying ANAO's initial Recommendation 2. In this light, ANAO considers that TGA has responded adequately to the issues underlying that recommendation.

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[22] In 1997, the Government asked TGA to develop an administrative system that would allow the existing Australian categorisation of drug evaluations to be converted for benchmarking purposes into the categorisation used by regulators in the European Union. TGA advised ANAO that it completed a detailed assessment of the European Union's categorisation system and established that there was no benefit and there would be considerable cost in implementing the system in Australia. The preferred approach was to continue to work towards harmonisation of TGA's regulatory requirements with those of overseas regulators and towards benchmarking its performance against that of its counterparts overseas.

Use of overseas evaluations—Recommendation 10

2.20 ANAO's recommendation that TGA review its requirements to determine if more evaluations or parts of them could be accepted from international regulatory authorities was, to some extent, overtaken by the 1996 Government Review of TGA. The Review investigated the increased use of medicinal evaluation reports and decisions from overseas regulatory agencies in countries that have comparable regulatory standards, with a view to enhancing product approvals. The Review concluded[23] that progress towards using overseas evaluation material could be made only on a case-by-case basis, and noted that data exchange would involve developing confidence in the regulatory standards of potential partner agencies. It noted also that the format and content of reports from some overseas countries might not permit ready use of the evaluation in an Australian report.

2.21 TGA advised ANAO that the legislative deadlines for drug evaluation affect its ability to use medicinal evaluation reports and decisions by overseas agencies. To summarise, TGA has addressed ANAO's recommendation that it consider reassessing its requirements in relation to its use of overseas evaluations.

Australian Drug Evaluation Committee—Recommendation 3

2.22 TGA may refer its evaluation of a drug to the Australian Drug Evaluation Committee for medical or scientific evaluation or for advice. The Committee, which meets at approximately two-monthly intervals, produces detailed minutes of its technical discussions and recommendations. Its discussions span topics related to the chemistry, toxicity, manufacture and clinical trials of the medicine under consideration and an assessment of the risk-benefit considerations in its use. Because of the volume of highly technical data considered over two days of deliberations, its minutes may run to 60–100 pages; and their production, approval and distribution may take months.

2.23 If a decision-maker decides not to approve an application, the Committee's minutes are an important source of information to sponsors, explaining the reasons for rejection and serving as a basis of any appeal.

2.24 The timing of the availability of minutes is important because there is a legislative deadline for appeals against TGA's decisions in relation to drugs proposed for registration. A person (or company) whose interests are affected by a decision may ask the Minister to review it within 90 days (about three months) of its coming to the applicant's notice.

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[23] In response to its findings, the Government reaffirmed its commitment to maintaining a *'sovereign, high quality and efficient'* drug-regulation capacity in Australia.

2.25 ANAO recommended in 1996 that TGA reassess its procedures for producing minutes of the Committee's meetings and make a new estimate of when it could be in a position to produce the minutes within 20 working days of each meeting. ANAO's recommendation supported a similar recommendation by the Baume Report of 1991.

2.26 The TGA agreed to reassess the time needed to produce the minutes and commissioned a consultant's review of the Committee's administrative support. The consultant's report described the recommendation for a 20–working-day production schedule as *'impractical and unnecessary'* and recommended that draft minutes be finalised in 30 working days for circulation to members before the next meeting, with a view to ratifying all the minutes at that meeting.

2.27 ADEC meetings are held every two months. TGA stated that, at the end of the first week following a meeting, it provides companies with ratified resolutions arising from that meeting. In the second week, ratified minutes of the previous meeting are dispatched. In the course of the follow-up audit, TGA advised ANAO that minutes of meetings were prepared within 30 working days (1.5 months) of the Committee's meeting[24], which permitted their clearance at the subsequent meeting. Industry stakeholders advised ANAO that they received minutes up to 2.5 months[25] after the meetings were held[26].

2.28 In deciding not to pursue the time frame for the production of minutes recommended in the Baume Report, TGA had access to advice from its consultant that:

> *From a practical point of view it is stretching things to argue that the minutes are important to lodging an appeal. There should be no obligation on the Australian Drug Evaluation Committee or its Secretariat to produce minutes for that reason. The purpose of the minutes is to provide the Australian Drug Evaluation Committee with a competent record of its business.*

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[24] Resolutions of the Australian Drug Evaluation Committee meetings were available within six working days of an Australian Drug Evaluation Committee meeting. Stakeholders advised ANAO that resolutions did not provide an adequate basis on which to respond to a rejection of an application. Therefore they required timely access to minutes of Committee meetings.

[25] Secretariat processes and postal distribution could be expected to account for the additional period of four weeks from the date on which minutes were ratified by the Committee to the date of receipt of relevant extracts by interested parties, although ANAO did not test this.

[26] On this basis, a decision made, on the Australian Drug Evaluation Committee's advice, shortly after a meeting would not afford a sponsor adequate time to formally consider its position and its grounds for appeal against that decision.

2.29 However, ANAO notes that access to the minutes enables unsuccessful sponsors of applications for drug registration to make informed decisions about possible grounds for reconsideration or review of the applications. In the absence of a detailed statement of reasons for rejection of an application by the decision-maker in the letter of rejection,[27] sponsors rely on records of the Committee's deliberations to determine whether they should seek review of decisions. Applicants need time to seek and consider expert advice, including advice from overseas sources, on the records of the Committee's consideration of their applications, before they can reasonably decide whether to appeal.

2.30 ANAO considers that TGA should make the record of the Australian Drug Evaluation Committee's deliberations available to stakeholders well in advance of the legislated deadline for appeal. TGA advised ANAO that the Minister's delegate would always allow additional time should it be requested, although it held no summary data on extensions requested or granted.[28] ANAO notes that reliance on the waiving of a deadline, as a standard operating procedure, may be inequitable. Applicants who are unaware of TGA's willingness to waive a deadline could be disadvantaged relative to those who are prepared to request such a waiver to afford them the time they need to seek advice in relation to a possible appeal.

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[27] Before ADEC finalises its minutes, TGA can and does advise sponsor companies whether ADEC has recommended inclusion of a drug on the Australian Register of Therapeutic Goods. However, it does not provide detailed information or reasons. The decision-maker, who writes to a sponsor advising rejection of an application for inclusion in the Australian Register of Therapeutic Drugs, does not always provide detailed information on which the sponsor company could determine whether an appeal should be lodged. Decisions by delegates of the Secretary are subject to usual administrative law requirements. TGA stated that a detailed statement of reasons can and is provided on request.

[28] One pharmaceutical company advised ANAO, via the APMA, in November 1999 that it had twice requested extension of the deadline for submission of appeals against a departmental decision. In each case the extension had been granted. The extensions had been necessary because, in each case, the reasons for the ADEC's opinion had not been given in the Delegate's letter advising his rejection of the application. Consequently, the company could not begin working on its appeal until ADEC minutes had been received. These had been received respectively 55 and 63 days after advice of the Delegate's decisions. The sponsor company commented: *'We believe it is totally unacceptable to pay $200 000 to the TGA for evaluation of an application and not to receive a list of specific reasons to support the Delegate's 'initial decision' for rejecting our application. If specific reasons were offered these could be clearly and accurately addressed in subsequent S60 appeals. The present system places the sponsor in the situation where they have to identify (correctly or incorrectly) the main issues that led to a negative 'initial decision'. We also find it totally unacceptable to have to wait 55–65 days to receive the ratified ADEC minutes. This leaves us with only 25–35 days from the legislated 90 days in which to prepare and submit an appeal. This is insufficient time especially when international expert input is usually required for such appeals. We suggest the Delegate provide specific reasons for rejecting an application in his 'initial decision' letter*.'

2.31 TGA advised ANAO that, given existing resources, it was not possible for the secretariat to improve the speed of production of the Committee's minutes and that difficulties in recruiting staff impeded increase of the secretariat's resources. TGA negotiates its fees and charges with the relevant industry association with the objective of achieving an appropriate balance between costs and service standards. In this context, TGA is of the view that, within the current level of fees and charges and given other priorities, the resources allocated to the ADEC secretariat are adequate.

2.32 In summary, TGA has implemented ANAO's 1996 recommendation that it review its procedures for producing minutes of the Committee's meetings, but pharmaceutical companies often receive the minutes as many as 10 weeks after the meetings. ANAO suggests that TGA consult with its industry stakeholders on an acceptable timeframe for the production and distribution of records of Committee deliberations. ANAO appreciates that there may be resource implications of quicker production and distribution of records of Committee deliberations, which would be a matter for TGA to manage, with the support of its industry stakeholders, through its cost recovery measures. The Australian Drug Evaluation Committee's secretariat might also benefit from improved technological support.

Adverse Drug Reaction System—Recommendation 11

2.33 TGA requires pharmaceutical companies to supply it with data on any patients' adverse reactions to their medicines. In addition, it encourages reporting by medical personnel of all suspected adverse reactions to medicines. The receipt of reporting cards is acknowledged by TGA.

2.34 In 1996, ANAO recommended that TGA improve its management of monitoring and reporting of adverse reactions to drugs. In agreeing to undertake such a review, TGA commented that its Adverse Drug Reaction System compared favourably with those of other developed countries.

2.35 TGA has largely implemented ANAO's recommendation. In response to ANAO's 1996 Report, TGA reviewed the post-marketing surveillance of registered drugs in 1996–97. The review's recommendations included increased staff allocations to the post-market surveillance function; and the separation of post-market surveillance from pre-market evaluation.

2.36 As a result of the review, TGA established the Adverse Drug Reaction Unit as a separate entity from its drug evaluation function. A temporary appointment to the position of head of the unit was made in May 1999.

2.37 The reporting of adverse patient reactions to medicines by medical personnel is voluntary in Australia. Therefore, the monitoring of public health issues related to reactions to medicines depends on the cooperation and motivation of relevant professionals. In 1998–99, TGA recorded more than 12,000 reports of suspected adverse drug reactions. In the same year, one product was recalled on the basis of adverse drug reaction.

2.38 Table 1 presents TGA's data for incoming adverse medicines reaction notification, as published in the TGA Quarterly Performance Reports for 1999–2000 Second Quarter[29]:

Table 1

TGA records of adverse medicine reaction notification, 1996–97 to 1999–2000 1st half year

Source	*1996–97 full year total*	*1997–98 full year total*	*1998–99 full year total*	*1999–2000 1st half year total*
Hospitals	2377	2241	2682	1371
Companies	2981	4071	5669	2910
General Practitioners	2871	2769	3076	1472
Specialists	417	358	264	147
Pharmacists	302	292	327	198
Others [dentists etc]	74	81	80	32
General list [cause of reaction unclear]	102	282	223	205
Total	9124	10 094	12 323	6466

Note: The disaggregated figures do not sum to the 'total' figures. TGA advised ANAO that disaggregated figures comprise reports entered on TGA's computer system while the 'total' figures have been calculated manually by TGA.

2.39 Extrapolation of the half year figures for 1999–2000 in Table 1 to a full year estimate of about 13 000 suggests that reporting of adverse reactions to medicines increased by around 40 per cent between 1996–97 and 1999–2000. However, this increase needs to be viewed in the context of a backlog of adverse patient reaction data for entry to TGA's computer, which was largely cleared during the first half of 1999–2000.

2.40 The Adverse Drug Reaction Unit managed a significant backlog in unprocessed reports in 1999. A backlog of 3325 unprocessed reports in mid-July 1999 was reduced to 1827 by mid–September 1999. Temporary staff and the temporary modification of quality assurance processes were used to tackle the backlog.[30]

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[29] TGA Quarterly Performance Reports, 1999–2000, 2nd Quarter October–December 1999.

[30] Approval arrangements by the coding staff were changed in an effort to reduce the backlog of reports. More experienced coding staff were allowed to approve their own reports as entered into the system.

2.41 Public-health assurance requires timely processing of reports of adverse reactions to drugs. ANAO observed that the costs associated with a backlog of unprocessed reports included:

- risks to the health of patients who are using products;
- an increased likelihood that an important signal of adverse events could be missed; and
- a reduction in the accuracy of summary data on adverse drug reactions.

2.42 TGA seeks advice from its expert committees in determining the appropriate regulatory response to reports of adverse reactions to drugs. Until recently, it has not been customary for drug regulatory agencies to have a clear, pre-determined methodology for guiding appropriate regulatory action based on reports of adverse reactions. TGA advised ANAO that it is aware of international developments in this area. It intends to consider their applicability to Australia, with the aim of developing a more standardised methodology for guiding regulatory actions flowing from concerns about the safety of products; and it expects to consult with representatives of industry on these matters.

2.43 Generally, ANAO received favourable comments on TGA's promotion of the reporting of adverse drug reactions. Nonetheless, ANAO considers that TGA's management of the reporting of adverse reactions to drugs would be improved by TGA:

- articulating its rationale for an 'acceptable' level of unprocessed reports of adverse reactions to registered drugs;
- setting and publishing performance targets for processing reports of adverse reactions to drugs; and
- advising industry sponsors of registered medicines about the methodology it used in determining that a product should be withdrawn from the market, after reports of adverse reactions to registered drugs. This information would serve as an assurance to stakeholders that TGA had followed rigorous processes in arriving at its decision to alter the status of a registered medicine.

2.44 ANAO noted that there was potential for some degree of 'double counting' of adverse reactions as reports may be received from a pharmaceutical company and from a family physician about the same patient. This anomaly could be remedied by improved data matching, which could be facilitated by the introduction of TGA's new information technology system by 2001.

2.45 ANAO sighted World Health Organisation summary data relating to adverse reactions to prescription drugs for the years 1995–99. However, a high degree of variation in the figures reported by several nations precluded reliable interpretation of Australia's reporting levels compared to those of other countries that have comparable systems for monitoring adverse reactions to prescription drugs[31].

2.46 Recommendation No.1:

ANAO recommends that TGA:

- develop and publish performance targets for processing reports of adverse reactions to drugs; and.
- in each instance where a decision is made to alter the status of a product on the Australian Register of Therapeutic Goods in response to reported adverse reactions, advise the sponsor of the reasons for the decision including the process by which the decision was made and the information upon which the TGA decision is based.

2.47 TGA's response:

- Agreed. The TGA has advised ANAO that, in response to the audit recommendation, these targets have now been developed and are being implemented.

Business support—Recommendations 6, 7 and 9

2.48 The main computerised information management systems used by TGA are the Drug Applications for Registration and Tracking System (DART), the Adverse Drug Reaction System (ADRS) and the Australian Register of Therapeutic Drugs. These systems are not integrated.

2.49 ANAO's 1996 Report recommended that TGA improve the information management systems that support its drug evaluation and monitoring activities. ANAO's recommendations for improvements in TGA's information technology systems (Nos 6, 7, and 9) are shown in Figure 4.

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[31] Australian monitoring of adverse drug reactions relies on voluntary reporting of adverse patient reactions by medical personnel and mandatory reporting by sponsors of pharmaceutical products. TGA advised ANAO that the United Kingdom and Canada have systems that are broadly comparable with that of Australia. World Health Organisation summary data of adverse reactions to prescription drugs could suggest that reporting in Australia compares favourably with that in Canada and the United Kingdom. For example, World Health Organisation data for 1995 record 6,687 Australian reports, compared with 4,584 for Canada (which had a population 30 per cent larger than Australia's population) and 16,060 for the United Kingdom whose population was approximately three times that of Australia. In respect of 1998, the data for these three nations were recorded as 6,570, 1,500 and 13,157. The declines in the figures recorded suggest possible anomalies in the World Health Organisation data, which were not investigated by ANAO.

Figure 4

ANAO's 1996 recommended improvements to information technology

- Undertake a review of the Drug Applications for Registration and Tracking (DART) computer system to make it more effective and user- friendly (Recommendation 6).
- Complete an information technology interfacing in order to achieve integration of the various computer systems operating within the TGA as soon as possible (Recommendation 6).
- Bring all computer system user documentation up to date and promulgate this to users so as to improve overall effectiveness (Recommendation 7).
- Assess the costs/benefits of a centralised computerised database which reflects current international regulatory information, such as drug evaluation activities, best practice and useful contacts (Recommendation 9).

2.50 ANAO reported in 1996 that TGA's information management systems were not considered efficient, effective or user-friendly. TGA has acted to improve those systems.

2.51 TGA advised ANAO that it had considered it premature to begin a major information technology redevelopment project until after the Government had responded to the 1996 Government Review of TGA, in April 1997.

2.52 TGA considered whether an appropriate information management system might be available overseas which could be adapted readily to meet its business needs. After an initial assessment, TGA concluded that no such system was available and the decision was taken to call tenders for the redevelopment project in November 1998. The preferred tenderer was selected and work commenced in March 1999 on the redevelopment of all TGA's systems to produce an integrated information management system. The new system is expected to be fully functional by 2001. A single system will replace a number of existing tracking systems, including the drug evaluation tracking system, to improve the sharing of corporate information and to enable consistent tracking procedures throughout TGA.

2.53 The development of TGA's new system was predicated on an analysis of its business processes and it seems to have been well-planned[32]. TGA has established a strategy to identify the potential benefits of the new system and to realise those benefits over time.

2.54 Implementation of the new information technology responds to several of the recommendations of ANAO's 1996 Report. However, there has been a considerable time lag between ANAO's notification of the need for remedial action and the expected implementation of improved capability in 2001. This long lead time has affected TGA's management information capability in the interim.

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[32] In undertaking the Strategic Information Plan, TGA undertook consultation with 41 internal users, which included broad representation of all parts of TGA and different levels within TGA.

2.55 Among the recommended improvements in TGA's processes was the reporting of drug-approval times to stakeholders in both 'working-day' and 'calendar-day' (the total elapsed time from the time an application is received until it is finalised) formats (Recommendation 1). Pharmaceutical companies use performance information related to TGA's timeliness in managing its workload in their planning of the development and marketing of new products.

2.56 Because drug development and marketing by pharmaceutical companies are competitive and time-critical, industry needs information about the total time elapsed since the submission of a drug evaluation application. That service is not available, other than by a laborious extrapolation by TGA from working-days data and aggregated 'clock stops' used by TGA while requesting, receiving and assessing additional data.

2.57 DART has the capacity to report working days spent by TGA on assessing an application and the number of working days a sponsor has been dealing with an information request. TGA advised ANAO in 1999:

> *There have been technical difficulties in downloading of 'calendar-days' performance information directly into quarterly reports, although it has been possible to obtain the same information from DART in a different format. Changes could have been made to DART; however, it has been decided, following the decision to proceed with the development of the new information technology system, not to make any changes to DART which are not critically necessary to the operation of the system.*

2.58 TGA believed that the capacity of DART to report working days spent by TGA on assessing an application and the number of working days a sponsor has been dealing with an information request is severely limited and data extraction processes require manual intervention. The reports that are available are not presented in a format that will allow accurate analysis of the data. There are practical difficulties in making extensive changes to the DART system in light of the imminence of TGA's major information technology system redevelopment.

2.59 This means that the issue of 'calendar-day' reporting on TGA's drug evaluations, identified in the Baume Report a decade ago and reported by the 1996 Government Review of TGA, has not been met. ANAO appreciates the reasons for the freeze on amendments to the DART system; and it has been advised that, in 2001, TGA's new information technology system will have the capability to report drug approval times to stakeholders in both 'calendar days' as well as 'working days'.

2.60 ANAO recommended in its 1996 Report that TGA assess the costs/benefits of a centralised computerised database that reflects current international regulatory information, such as drug evaluation activities, best practice and useful contacts (Recommendation 9). TGA has enabled access to this information by its staff through the Internet.

Conclusions concerning business processes and support

2.61 ANAO considers that TGA has taken a range of actions in response to ANAO's recommendations for improvements to its drug evaluation and monitoring processes. It is in the process of implementing significant improvements in its monitoring of adverse reactions to drugs and to its information technology support of its operations. Overall, TGA has either implemented or partially implemented Recommendations 1, 3, 10, and 11.

2.62 TGA has not implemented Recommendation 2, relating to the categorisation of applications, which issue was referred to the 1996 Government Review of TGA. However, ANAO considers that TGA has responded adequately to the issues underlying Recommendation 2 in ANAO's 1996 Report.

2.63 ANAO noted continuing delays by TGA in reporting to industry information about the total elapsed time involved in drug evaluations. TGA's implementation of its recommendations on the redevelopment of its information technology will result in, among other things, reports to industry about total elapsed time involved in drug evaluation.

2.64 TGA has made some improvements in its processes for evaluating drugs for inclusion on the Register. However, there is scope for TGA to do more to implement the spirit of improvements recommended in ANAO's 1996 Report.

2.65 Recommendation No.2:

ANAO recommends that TGA, as part of its development of a new information technology system by 2001:

- report the status of drug evaluation applications and TGA's drug evaluation performance in total elapsed time ('calendar days') as well as 'working days', as recommended by the ANAO's 1996 Report.

2.66 TGA's response:

Agreed. This requirement is an integral part of the information technology (IT) redevelopment project scheduled for completion in 2001. The capacity for the IT system to report in calendar days has been specified in the relevant Functional Requirement Specification.

3. Performance and Communication

This Chapter addresses TGA's actions to improve its performance management, including cost recovery and fee setting, quality assurance and recruitment, and its communication processes, including information to stakeholders, as recommended in the 1996 ANAO report.

3.1 ANAO's 1996 Report recorded a dramatic reduction in the time needed by TGA to evaluate medicines for inclusion on the Australian Register of Therapeutic Drugs over the previous 5 years. The time required by TGA for the evaluations of new chemical entities improved from 702 working days for evaluations completed in 1990 to 106 working days for the evaluations completed in 1995. ANAO's 1996 Report found that, notwithstanding this improvement, there was still scope for TGA to reduce the time. The Report identified a specific need for decreasing, with the assistance of pharmaceutical companies, the total elapsed time.

3.2 ANAO's 1996 Report also found that, although TGA produced much information for the pharmaceutical industry, it could strengthen its external accountability by providing clearer information on its activities to parliamentarians and consumers of therapeutic drugs. ANAO concluded that TGA should develop an adequate system to assess the cost of its services to the pharmaceutical industry, and improve the reporting of adverse reactions to drugs.

Performance management —Recommendations 1, 4, 13 and 14

3.3 ANAO made five recommendations for improvements in TGA's performance, listed below in Figure 5.

Figure 5

ANAO's 1996 recommended improvements to TGA's performance

- Report drug approval times to stakeholders, particularly for new chemical entities in both 'working-day' and 'calendar-day' formats (part of Recommendation 1).
- In order to 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 data (Recommendation 4).
- Identify international pricing structure options with a view to adopting the most cost-effective method for use in Australia (Recommendation 13).
- Seek the cooperation of the pharmaceutical companies in assisting TGA to forecast future workloads with a reasonable degree of confidence (Recommendation 13).
- Consistent with Government policy, introduce a method of calculating the industry-related costs of its operations to enable it to recover those cost (Recommendation 14).

3.4 TGA accepted all the above recommendations, although it commented on two of them. In relation to ANAO's recommendation that TGA review each phase of its evaluation process (Recommendation 4), TGA noted that improvements in efficiency since the Baume Report had been acknowledged by ANAO. As regards the recommendation that TGA introduce a method of calculating industry-related costs as a basis of cost recovery (Recommendation 14), TGA commented that it had already completed some activity-based costing of some TGA activities and other studies were either under way or planned for 1996.

Timeliness

3.5 The Act and associated regulations prescribe administrative deadlines for drug evaluations conducted by TGA. The timeliness of TGA's performance in evaluating drugs is within statutory limits[33], as it was in 1996. Nonetheless, the timeliness of TGA's administration of drug evaluation warrants discussion in the context of ANAO's focus in 1996 on how TGA could continue to improve its operations.

3.6 TGA's approach to ANAO's 1996 recommendation that the timeliness of drug evaluations be reported in 'calendar days' (Recommendation 1) was discussed in Chapter 2 in the context of information management. It is considered here also in the context of the timeliness of TGA's drug evaluation processes. Recommendation 4 relates also to timeliness; it concerns the time allocated to processes (such as acceptance of applications, scheduling of consideration by the Australian Drug Evaluation Committee and entry in the Register). TGA's actions in relation to timely processing of applications are discussed in the following paragraphs.

3.7 Drug evaluation applications are categorised according to the nature of the drug. Categories 1 and 2 relate to applications for new medicines for the Australian market, and also for applications to extend the indications or uses of products already on the market. Category 3 applications relate to variations in the information on a drug already on the Register where neither clinical nor toxicology data are required.

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[33] Department of Health and Aged Care's Annual Report 1998–99 stated that:

- 100 per cent of prescription medicines approved for listing on the Australian Register of Therapeutic Drugs had been approved within the statutory time frames;
- revenue raised had been within three per cent of the targeted revenue;
- there was a high level over all of satisfaction with services provided by TGA; and
- the Minister and Parliamentary Secretary indicated that the TGA had an excellent record of management and had met the Government's objectives.

Department of Health and Aged Care 1999,*Annual Report 1998–99*,AGPS, Canberra, pages 79–85.

3.8 Timeframes to evaluate various categories of submissions are specified in the Therapeutic Goods Regulations. These are presented in Table 2.

Table 2

Statutory time frames for drug evaluation, by category of application

Time Limits	*Category 1*	*Category 2*	*Category 3*
	A new chemical entity/new indication of a drug's use/new route of administration of the drug	A drug that has been approved for general marketing in two 'acceptable' countries	Variation of the information on a drug already listed on the ARTG
Acceptance time limits	40 working days	20 working days	not specified separately
Evaluation time limits	255 working days	175 working days	45 working days

3.9 The statutory time frames relate to the amount of time allowed for TGA to evaluate an application. After a sponsor lodges an application for drug evaluation with TGA, there may be a need for TGA to either request or receive additional data from the applicant. To enable this the TGA may 'stop the clock' on its evaluation until it receives additional data it has requested. There is also provision in certain circumstances for a company to submit further information or supplementary data with clock adjustment. 'Stopping the clock' may result in a significant difference between the number of TGA's 'working days' for an evaluation and the total 'calendar days' from the time an application is received until it is finalised.

3.10 The ANAO found that the TGA continues to process all applications within statutory timeframes. The ANAO notes that a comparison of the second half of 1996 with the second half of 1999 shows TGA's average time for evaluating one sub-group of Category 1 applications, the new chemical entities (NCEs), has increased while remaining well within statutory timeframes. However, given the time it takes to evaluate an NCE (some 18 months after the application is made) and considering the workloads in 1994–95 and 1996–97, it is apparent that during the last half of 1999 the TGA was processing a much higher workload than in the last half of 1996.

3.11 ANAO also notes that the largest number of Category 1 applications are not new chemical entities. These applications compete for the same evaluation resource pool within the TGA. Many of these, such as extensions of indications, are also of great importance to industry and others. During this time the workload associated with these applications also increased significantly.

3.12 The relationship between workload and evaluation process time is complex, but the complexities must be taken into account before

accurate conclusions can be drawn. The increase across a number of related work areas, such as new indications; the temporal relationship between application/submission and the completion of the evaluation; the difficulty in assessing workload by numbers of applications/ submissions alone must all be taken into account when assessing evaluation process time. Examination of these data shows a considerable increase in the workload reflected in the process time figures of the second half of 1999 and the number of applications in the preceding months. The data would support TGA's view that output has increased substantially to cope with the significant increase in evaluation workload.

3.13 In the course of the follow up audit, ANAO sought advice from the TGA if it had compared the amount of time it required for drug evaluations with the amount of time required by comparable regulators overseas. TGA advised ANAO that it had participated in a comparative study sponsored by the pharmaceutical industry of regulatory review times in nine countries, including Australia.[41] That study had reported in 1996[42] that factors affecting review times included the quality of the dossier, companies' ability to respond quickly to regulatory authorities' questions and the authorities' ability to manage the review effectively and efficiently.

3.14 TGA advised ANAO in the course of the current audit:

> *'These (comparative) exercises indicate that the TGA's performance is comparable to that of the other major overseas agencies when compared on a similar basis ('working day'). However, direct comparisons with the performance of other agencies is difficult and may be misleading because of differences between the legislated procedures under which the various agencies operate.'*

3.15 ANAO notes that the TGA has, as part of its fee and charges negotiations with the industry, agreed on a number of target evaluation times for various subcategories of Category 1 applications.

3.16 ANAO found that understanding TGA's performance in terms of timeliness was made more complex because TGA did not appear to have adequate performance indicators of the efficiency of its drug evaluation processing. TGA considers that there were no well accepted measures of efficiency in drug evaluation. However, it did report on markers of a number of these factors, such as timeliness of evaluation, product withdrawals, and budgeting to industry and consumer stakeholders. ANAO considers adequate performance indicators of TGA's efficiency would permit industry, the Parliament and other stakeholders to understand variations in TGA's evaluation performance.

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[41] The research was undertaken by The Centre for Medicines Research. It is a not-for-profit organisation, based in the United Kingdom, which is funded by the pharmaceutical sector.

[42] Centre for Medicines Research International 1997, Annual Report 1996, CMRI, Carshalton, UK.

3.17 Recommendation No. 3:

ANAO recommends that, to permit Parliament, industry and other stakeholders to understand variations in TGA's evaluation performance:

- TGA publish performance indicators of the efficiency of its drug evaluation processing.

3.18 TGA's response:

Agreed in principle. TGA already reports on a number of markers of efficiency to Parliament, industry and other stakeholders. Detailed reports are prepared and presented to industry and consumer stakeholders on a regular basis throughout the year. Specific performance targets are also agreed with industry representatives as part of its fee negotiations. As part of its IT redevelopment project, TGA is looking at its ability to extend its reporting.

Timeliness targets—Recommendation 4

3.19 The declining timeliness of TGA's evaluation of new chemical entities suggests a need for TGA to adjust its internal targets for timely processing of drug evaluations. Such a review had been recommended by ANAO in 1996 (Recommendation 4).

3.20 TGA evaluates a drug application in stages, against time targets, as shown in Table 3 below:

Table 3

TGA's Time targets for evaluating Category 1 applications 1996 –1999

Stage of process	*Target Working Days for a Category 1 product*
Acceptance process	40 working days, additional to the time allowed for decision and notification processes
Decision and notification processes, comprising:	255 days comprising:
• Evaluation	• 135 working-days
• Consideration by ADEC	• 80 working days
• Delegate's decision	• 40 days

3.21 ANAO noted that timeliness targets in 1999 were the same as those used at the time of ANAO's 1996 Report. On this basis, it would seem that TGA had not been able to move towards maximising the time allocated to actual evaluation activities (135 days) relative to other phases in handling an application, as had been envisaged by ANAO in 1996 and agreed by TGA. However, TGA advised ANAO in the course of the current audit that target dates were revised regularly in favour of the evaluation process at planning sessions that preceded each meeting of the Australian Drug Evaluation Committee. If necessary, timely

consideration by the Committee was achieved by TGA's negotiating with sponsor companies for shortened times for both the sponsors and TGA to comment on the evaluators' reports.

3.22 In the course of the follow-up audit, ANAO raised with TGA the possibility that scheduling an additional meeting of the Australian Drug Evaluation Committee each year could improve timeliness by reducing the interval between meetings. TGA did not agree that an additional meeting was a practicable option. It advised ANAO that Committee members could not be expected to allocate time to an additional meeting each year, because of their other professional commitments.

Tracking applications—Recommendation 4

3.23 TGA's capacity to review and revise target dates for processing applications for drug evaluations (Recommendation 4) depends on the quality of its management information.

3.24 In effect, TGA lacks a quick, reliable system to track the timely progress of drug evaluation applications. ANAO noted TGA's advice that its new information technology system is expected to have such a capability.

Data quality—Recommendations 1, 4, and 12

3.25 TGA provides Quarterly Performance Reports to its Industry Consultative Committee, presenting some statistical information about the volume of work handled by TGA and timeliness measures (relevant to Recommendations 1, 4 and 12).

3.26 In the course of the follow-up audit, ANAO sought TGA's advice on a number of discrepancies in the data reported in TGA's Quarterly Reports. In response, TGA advised ANAO that such discrepancies may be attributable to:

- backlogs of data entry;
- decisions in the course of an evaluation to treat an application as more than one application;
- altered reporting procedures resulting from staff turnover; and
- anomalies and errors in TGA's application-tracking system.

3.27 TGA expects the development of an integrated information management system to improve the accuracy of the reported data. In the meantime, TGA's performance measurement is problematic.

Cost recovery, fees and charges —Recommendations 13 and 14

3.28 ANAO's 1996 Report concluded that TGA should develop an adequate system to assess the cost of the services it renders to the pharmaceutical industry. ANAO made several recommendations aimed at ensuring that TGA had the systems necessary to plan and manage its resources. These recommendations are shown in Figure 7.

Figure 7

ANAO's 1996 recommended improvements to TGA's workload and resourcing

- Identify international pricing structure options with a view to adopting the most cost-effective method for use in Australia (Recommendation 13).
- Seek the cooperation of the pharmaceutical companies in assisting TGA to forecast future workloads with a reasonable degree of confidence (Recommendation 13).
- Consistent with Government policy, introduce a method of calculating the industry-related costs of its operations to enable it to recover those costs (Recommendation 14).
- Include in its annual report to Parliament the extent to which its costs are recovered. (Recommendation 14).

3.29 TGA agreed with ANAO's 1996 recommendation on pricing and workload forecasts (Recommendation 13). TGA agreed in principle with the recommended development of a method to calculate industry-related costs (Recommendation 14). However, it stated that it had completed already an activity-based costing of its manufacturer auditing and licensing functions; and that studies in other areas (including in the drug evaluation area) were either under way or planned for completion before the end of 1996.

3.30 TGA has substantially exceeded ANAO's 1996 recommendations in implementing systems to plan and manage its resources (Recommendations 13 and 14), as set out in the following paragraphs.

3.31 TGA's fee structure has been negotiated with industry, after a study commissioned by TGA that took account of international fee structures.

3.32 TGA advised ANAO that it had discussed the issue of workload prediction with its Industry Consultative Committee as recommended by ANAO. However, workload prediction had not been implemented because of commercial sensitivities related to research and development. Effectively, TGA has implemented ANAO's recommendation that it discuss workload prediction with industry (Recommendation 13), although it has not been able to secure industry support for this initiative.

3.33 ANAO's 1996 Report recommended that TGA introduce a method of calculating the industry-related costs to enable it to recover them.

TGA advised ANAO that it had begun its second round of activity-based costing and that it would estimate the costs incurred in all activities falling within the scope of its legislation, including pre-market evaluation and post-market monitoring and enforcement activities for the medicines program.

3.34 The Department of Health and Aged Care implemented full-cost recovery for all operations within the scope of the Therapeutic Goods Act, including its drug evaluation activities, from the beginning of 1998–99. In that year, TGA's total revenue from independent sources was $38.7 million (compared to a total operating budget of $49.1 million[34]). Within the revenue from independent sources, $37.4 million was raised through fees for evaluation services and annual charges met by the sponsors of the range of therapeutic goods on the Register (for example, related to prostheses as well as to pharmaceutical items).[35] The Department's Annual Report for 1998–99 did not report disaggregated figures related to TGA's drug evaluation activities, as distinct from other therapeutic goods.[36]

3.35 In late 1999, TGA sought the endorsement of its Industry Consultative Committee of increased fees and charges. TGA undertook that, if it could increase its fees and charges, the increased resources would enable TGA to regain the performance levels it had achieved in 1997–98.

3.36 Although acknowledging TGA's independence from the pharmaceutical industry, a few industry representatives expressed to ANAO some unease about paying increased fees and charges for drug evaluation activities while TGA's performance was not improving. They expressed some reservations that they fund the operations of TGA without the authority to influence its operational efficiency.[37]

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[34] In 1999–2000, TGA is managing a memorandum of understanding with the corporate area of the Department for the provision of some corporate services, at a cost of $2.9 million.

[35] Annual charges are payable for all items listed on the Australian Register of Therapeutic Goods, except where turnover of those goods is of low volume and low value or involves hospitals. The fees and charges reported in the annual financial statements may not relate only to the financial year under review. Payments of arrears and forward payments may be included in those accounts.

[36] ANAO was advised that with the move to 100 per cent cost recovery in 1998–99, the TGA took the view that an increase in fees and charges of 33.3 per cent to bring it to the 100 per cent cost recovery target would not be supportable. The ANAO was also advised that, in reaching this view, the TGA took into account budgetary assessments of application growth and performance expectations and the size of TGA's Reserve which stood at $21 million. As a consequence, the TGA drew down on its Reserve to enable trends on workload growth to be established before any further increased fees and charges were negotiated. This is reflected in the difference between TGA's total revenue for 1998–99 and its total operating expenses for the same period.

[37] Examples offered to ANAO related to TGA's recovery from industry of TGA's costs of serving the Government and the Parliament; and the cost of international travel by TGA personnel.

3.37 Because TGA is the sole regulator of the introduction of pharmaceutical products to Australia, some pharmaceutical companies may assume that the incentives for TGA to reduce costs are not strong. ANAO considers that TGA's relationship with its stakeholders would be enhanced by TGA's publishing information about the basis of its fees and charges in its TGA Quarterly Performance Reports and in the departmental annual report to Parliament.

3.38 TGA has implemented Recommendations 13 and 14 of ANAO's 1996 Report. However, ANAO notes that TGA has not published disaggregated financial information on its drug evaluation activities as distinct from its other activities.

Information to stakeholders—Recommendations 5, 12 and 14

3.39 In 1996, ANAO found that, although TGA produced much information for the pharmaceutical industry, it could strengthen its external accountability by providing parliamentarians and consumers of medicines with clearer information on its activity. ANAO's recommendations to improve TGA's focus on its stakeholders' needs for information and consultation are shown in Figure 8.

Figure 8

ANAO's 1996 recommended improvements to TGA's consultation and information

- Review consultative arrangements with consumer organisations, to ensure that consumer expectations of drug evaluations are given due consideration (Recommendation 5).
- Strengthen public reporting to better meet the information needs of Parliament and consumers in the interests of enhanced accountability (Recommendation 12).
- Include in the annual report to Parliament the extent to which TGA's costs are recovered (Recommendation 14).

3.40 TGA has implemented ANAO's recommendation that it strengthen its consultative arrangements with appropriate consumer organisations, as set out below.

3.41 TGA operates forums for consultation and cooperative strategic initiatives with industry and consumers. Since 1997, consumer representatives have been represented on the TGA Industry Consultative Committee and on specialist advisory committees. Industry and consumer groups both indicated that TGA had increased its consultation with consumer interests, albeit from a low base. APMA advised ANAO that it is, overall, satisfied with the level of communication and consultation between industry and TGA. It commented that, whilst there was always room for more frequent and effective communication, APMA would not

wish to imply that there is a large gap between the current situation and where APMA would like it to be.

3.42 In late 1999, TGA advised ANAO that it had reached agreement with the Consumer Health Forum on an initial framework for piloting input on consumers' perspectives on applications involving new chemical entities. The Consumer Health Forum advised the ANAO that TGA and the pharmaceutical industry do not appear to have considered consumer consultation in the cost recovery equation for drug evaluation.

3.43 The Consumer Health Forum advised ANAO that it 'urges TGA to work with consumers and other stakeholders to find a suitable vehicle for reporting on its consultations with consumers and other stakeholders and on how to maintain its accountability to consumers for the drug evaluation process. This transparency of process can only serve to improve community support and understanding of the drug evaluation process and help to justify the cost effectiveness of TGA'.

Reports to Parliament—Recommendations 12 and 14

3.44 The Minister for Health tables in Parliament the departmental annual report, which includes information on the administration and operations of TGA, as required in the Therapeutic Goods Act. TGA advised ANAO that it reviewed its reporting requirements in 1997 and considers that it provides comprehensive reporting on its performance, through operational and financial performance reports to its TGA Industry Consultative Committee; reports against performance indicators in the Portfolio Budget Statements and annual report; and publication of a three year corporate plan. As part of the Public Health program, TGA's performance was incorporated in the Department's reporting of 10 outcomes for 1998–99.

3.45 The introduction of an accrual-budgeting framework for Commonwealth agencies in 1999–2000 represents a major change in associated performance-reporting requirements. The Estimates Report of the Senate Community Affairs Legislation Committee observed in June 1999[38] that accrual budgeting required a great deal more work for agencies generally. When the Committee reviewed agencies' Portfolio Budget Statements for 1999–2000, two major areas of concern were attribution of costs and the need for disaggregation of figures. These views confirm the importance of ANAO's 1996 recommendation that information provided to Parliament about drug evaluation activities must be relevant to stakeholders' needs.

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[38] Senate Community Affairs Legislation Committee 1999, *Estimates Report, June 1999* page 3 [Online], Available: <www. aph.gov.au/senate/ committee/estimates/ doc/caljun99.doc> [14 February 2000].

3.46 The Department of Finance and Administration has provided guidance to agencies that their output specification and associated information should help the Government understand what it is paying for and what will be provided in terms of:

- the unit price of the output;
- the quantity of output units to be delivered;
- levels of quality to be assured in delivery, including, where appropriate, the timing, frequency or location of the delivery of the products or services; and
- the contribution of the output to achieving the planned outcome.[39]

3.47 ANAO considers that TGA could better serve its stakeholders, including Parliament, by providing information in the departmental annual report about:

- TGA's efficiency in relation to various categories of drug evaluations. In 1998–99, the Department informed Parliament that TGA had satisfied the legislated timeliness requirements for its drug evaluations. It did not inform Parliament that, even so, TGA's evaluation procedures seemed to be less efficient than in the previous year. On the other hand, TGA provided industry with information in the its Quarterly Performance Reports which would enable industry to chart its reduced efficiency;
- if data are available, the timeliness of TGA's performance in evaluating drugs proposed for inclusion on the Australian Register of Therapeutic Drugs, in comparison with the amount of time regulators in other countries require for similar work; and
- the basis of calculation of TGA's service fees and annual charges to the pharmaceutical sector for products included on the Australian Register of Therapeutic Drugs.

3.48 In 1997, the Consumer Health Forum suggested to TGA that it provide information through the Department's annual report on the extent to which TGA has given consumers and other stakeholders opportunities to be involved in policy development, standard setting and product evaluation and review. TGA advised ANAO in the course of the follow-up audit that it did not consider the annual report to Parliament an appropriate vehicle for detailed reporting. It did not identify a more suitable vehicle.

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[39] Department of Finance and Administration 1999, *Outcomes and Outputs: Guidance for Review*, [Online], Available:www.dofa.gov.au/budgetgroup/policies/guidance_and_manuals/outcomes_and_outputs/outcomes_and_outputs_guidance_for_review_26_Nov.doc [14 February 2000].

3.49 If TGA wished to disclose information about the extent of its cost recovery in relation to drug evaluation and registered medicines, and about the basis of its attribution of cost, suitable vehicles for conveying this information could be the departmental annual report to Parliament and the TGA's Quarterly Performance Reports.

Information in the community—Recommendation 12

3.50 In the course of the follow-up audit, ANAO received from stakeholders examples of ways in which they would wish to see TGA's information dissemination improved, including the following:

- The Pharmacy Guild of Australia informed ANAO that reporting of patients' adverse reactions to drugs could be enhanced by an increased awareness among retail pharmacists of the reporting system. An education program for pharmacists was proposed.
- The Consumer Health Forum emphasised the importance of better informing consumers of adverse drug reactions through the mainstream media in a way that informed and educated consumers without provoking sensational consumer responses.

3.51 In summary, TGA has partly implemented ANAO's 1996 recommendation that it strengthen its public reporting (Recommendation 12). TGA advised ANAO in the course of the follow-up audit that the extent to which information was disclosed depended on the identification of the intended audience and the availability of the appropriate format in which contextual information and analysis were also presented. TGA advised that this was potentially a resource-intensive process and not currently considered to have sufficiently high priority to require the diversion of resources from other tasks. ANAO considers that TGA would better meet the needs of its stakeholders if it were to enhance it public reporting.

Quality assurance—Recommendation 8

3.52 ANAO made a recommendation in 1996 for improved quality assurance and skills development for TGA's evaluators, as shown in Figure 9.

Figure 9

ANAO's 1996 recommended improvements to quality assurance and skills

- Expand the use of internal audit programs relating to external evaluators to encompass all relevant evaluation sections within the TGA, with the objective of using resources more efficiently; (Recommendation 8).
- Develop appropriate training programs for external evaluators and incorporate them into operating procedures (Recommendation 8).

3.53 ANAO's 1996 Report commented that training for external evaluators used by TGA was almost non-existent, but noted that one section of TGA provided the external evaluators it used with regular advice. TGA agreed to ANAO's recommendation on the use of internal audit programs relating to external evaluators in all relevant evaluation sections within TGA. However, it has not implemented it.

3.54 TGA advised ANAO during the follow- up audit that there are two aspects to training of its external evaluators: the first concerning professional skill and expertise; and the second related to requisite knowledge of TGA's processes. TGA considered that because external evaluators are engaged due to their expertise in a subject area, no specific professional training is required. Some guideline documents are provided to external evaluators to meet their needs for understanding of TGA processes. New evaluators receive model reports to assist in the preparation of their reports and may avail themselves of advice and guidance from senior medical staff of TGA.

3.55 TGA also advised ANAO that:[40]

- the work of all new evaluators is monitored to ensure that quality standards are maintained;
- the Australian Drug Evaluation Committee advises all evaluators on the quality of evaluation reports it receives; and
- information provided by Australian Drug Evaluation Committee members is taken into account by TGA in the appointment of external evaluators.

3.56 TGA also noted that its contracts with major institutions[41] included a requirement that they provide only appropriately qualified and experienced evaluators. At present, only one institution is contracted to provide evaluations—the University of Melbourne.

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[40] TGA stated that work is allocated externally on a one to one basis with advice and discussion. Extensive guidelines documentation is distributed to all external evaluators, though new evaluators receive extra material in the form of sample evaluations. All evaluation reports, whether internal or external, are assessed for their applicability by senior TGA delegates before the evaluation is regarded as complete. In the case of external evaluations, payment cannot be made without full clearance of each and every report. It is not unknown for reports to be sent back to even experienced evaluators for correction. Further review of the process occurs when an independent delegate reviews all evaluation reports related to a product and prepares a summary document. This and the evaluation reports routinely go to ADEC for review and further comment. Feedback is provided to external evaluators based on ADEC's review. Evaluations from major contracted institutions go through the same process.

[41] TGA may also engage individual experts to undertake drug evaluation. Their skills would be known to TGA before their engagement.

3.57 The University is contracted to ensure that the evaluations are *'performed with the high degree of professional skill, competence, care and diligence expected of a person experienced in work of the same type as the evaluations'*. ANAO notes that these standards were not defined in the contract or elsewhere.

3.58 TGA considers that adequate quality-assurance measures are in place, including the expression of opinions by members of the Australian Drug Evaluation Committee to TGA personnel, and peer review processes.

3.59 As regards ANAO's 1996 recommendation that training programs be developed for evaluators of drug submissions, TGA advised ANAO in the course of the follow-up audit that it now considers training of external evaluators is not required. Therefore TGA now considers—contrary to its views in 1996—that training of external evaluators is not required. TGA advised ANAO that it engaged only subject-matter experts as external evaluators; that extensive evaluation guidelines were provided; and, where necessary, there was liaison between the external evaluator and the internal specialist concerned.

Recruitment—Recommendations 1, 3, 4 and 11

3.60 TGA's corporate plan for 1997–98 to 1999–2000 includes goals that it create an environment that attracts and retains skilled and motivated staff; provide staff with information necessary to perform the work assigned; and enhance TGA's reputation as an evaluator and regulator of medicines.

3.61 In the course of the follow-up audit, TGA cited staff vacancies and recruitment difficulties as impediments to the:

- fully effective operation of its Adverse Drug Reactions Unit (Recommendation 11); and
- timely management of drug evaluation submissions (Recommendations 1 and 4).

3.62 ANAO considers that the recruitment and training of essential personnel should continue to be addressed by TGA as a matter of priority.

Conclusions concerning performance and communication

3.63 ANAO considers that, with the exception of 'calendar-day' reporting, TGA has implemented ANAO's 1996 recommendations for improved performance management, cost recovery, fees and charges. TGA has made some improvements to its communication with consumer representatives and industry stakeholders and has scope to do more.

3.64 TGA would better meet the information needs of stakeholders if it were to report on:

- TGA's efficiency in relation to various categories of drug evaluations;
- the timeliness of TGA's performance in evaluating drugs proposed for registration, in comparison with the amount of time regulators in other countries require for similar work, when such information is available; and
- the basis of calculation of TGA's service fees and annual charges to the pharmaceutical sector for products included on the Australian Register of Therapeutic Goods.

3.65 ANAO considers that the recruitment and training of essential personnel should continue to be addressed by TGA as a matter of priority.

Canberra A.C.T.
25 July 2000

P. J. Barrett
Auditor-General

Appendix

Appendix 1

Recommendations of Audit Report No.8 of 1996–97 —Implementation Status

RECOMMENDATION 1—that TGA:

- 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 of Drugs (AGRD) should be amended;
- amend the AGRD if necessary;
- work with industry to identify ways of reducing the time its members take to respond to TGA's request for information; and
- report drug-approval times to stakeholders, particularly for new chemical entities, in both 'working-day' and 'calendar-day' formats.

TGA agreed with this recommendation.

Implementation Status:

TGA has:

- reviewed requests for information from pharmaceutical companies in relation to AGRD;
- scheduled a review of AGRD as a joint project with APMA in 2000;
- worked with industry to reduce the time taken to respond to TGA's requests for information; and
- not reported drug approval time for new chemical entities in both 'working-day' and 'calendar-day' formats.

Overall, TGA has partially implemented this recommendation.

RECOMMENDATION 2—that TGA:

- 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.

TGA agreed with this recommendation.

Implementation Status:

TGA:

- has not reviewed the definition of Category 1 submissions for evaluation because it considers that timeliness is not a categorisation issue;
- is developing systems to compare the timeliness of its drug evaluations with the amount of time regulators in other countries require for similar work; and
- is working towards harmonising its regulatory requirements with those of overseas regulators and towards benchmarking its performance against that of its counterparts overseas. TGA considers that these approaches will address the performance matters underlying ANAO's initial Recommendation 2, as alternative measures to review of categorisations.

TGA has not implemented this recommendation although it is responding adequately to the underlying performance management issues.

RECOMMENDATION 3—that TGA:

- 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.

TGA agreed to undertake reassessment and review.

Implementation Status:

TGA has:

- reviewed procedures for the production of ADEC minutes; TGA commissioned a consultant to review the findings of the Baume and ANAO 1996 reports. That consultant recommended that the Baume and ANAO recommendations relevant to ADEC not be implemented as he considered them impractical.

TGA has implemented this ANAO recommendation.

RECOMMENDATION 4—that TGA:

- to 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.

TGA agreed with this recommendation.

Implementation Status:

TGA has:

- reviewed its internal time frames for the stages of drug evaluation.

TGA has implemented this recommendation.

RECOMMENDATION 5—that TGA:

- review consultative arrangements with consumer organisations to ensure that consumers' expectations of drug evaluations are given due consideration.

TGA agreed with this recommendation.

Implementation Status:

TGA has:

- strengthened its consultative arrangements with consumer organisations, by including a consumer representative on its Industry Consultative Committee.

TGA has implemented this recommendation.

RECOMMENDATION 6—that TGA:

- review the Drug Applications for Registration and Tracking (DART) computer system to make it more effective and user-friendly; and
- the information technology interfacing project be completed to achieve integration as soon as possible of the various computer systems operating within TGA.

The TGA agreed with this recommendation.

Implementation Status:

TGA has:

- not reviewed DART to make it more effective and user-friendly; instead, replacement of the information technology system has been initiated.

TGA has partially implemented this recommendation.

RECOMMENDATION 7—that TGA:

- bring all computer-system user documentation up to date and promulgate this to users to improve overall effectiveness.

The TGA agreed with this recommendation.

Implementation Status:

TGA has:

- complied with the spirit of these recommendations by contracting for provision of a new, integrated information technology system. However, computer-system user documentation has not been updated. TGA considered enhancement of existing systems not to be cost effective.

TGA has partially implemented this recommendation.

RECOMMENDATION 8—that TGA:

- expand the use of internal-audit programs relating to external evaluators to encompass all affected evaluation sections in TGA, with the objective of using resources more efficiently; and
- develop appropriate training programs for external evaluators and incorporate them into operating procedures.

TGA agreed with this recommendation.

Implementation Status:

TGA has:

- not expanded the use of internal-audit programs relating to external evaluators to encompass all affected evaluation sections in the TGA; and
- not developed appropriate training programs for external evaluators. TGA advised ANAO that it considered its existing procedures adequate.

TGA has not implemented this recommendation, although it is addressing the underlying issues of quality assurance through measures to assist and guide new evaluators.

RECOMMENDATION 9—that TGA:

- assess the costs/benefits of a central computerised database that reflects current international regulatory information, such as drug evaluation activities, best practice and useful contacts.

The TGA agreed with this recommendation.

Implementation Status:

TGA has:

- assessed the costs and benefits in the light of the availability of the Internet, which it uses to access regulatory information in comparable countries.

TGA has implemented this recommendation.

RECOMMENDATION 10—that TGA:

- to take full advantage of the efforts of other regulatory bodies and to reduce the costs to Australia 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.

TGA agreed with this recommendation.

Implementation Status:

TGA has:

- addressed this recommendation partly in the context of international 'harmonisation' of regulatory requirements. TGA considers that there is little scope for it to draw on the work of other regulatory authorities because of the time lag in receiving information from those authorities.

TGA has implemented this recommendation.

RECOMMENDATION 11—that TGA:

to improve the effectiveness of its drug evaluation processes, review:

- 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.

TGA responded that it believed its Adverse Drug Reaction system compared favourably with those of other developed countries but agreed to undertake a review to ensure that it conformed with international best practice.

Implementation Status:

TGA has:

- reviewed and improved its promotion and encouragement of reporting adverse drug reactions;
- initiated some information dissemination to health professionals, although more remains to be done; and
- reviewed its resource allocation to adverse drug reactions.

TGA has implemented this recommendation.

RECOMMENDATION 12—that TGA:

- strengthen its public reporting to better meet the information needs of Parliament and consumers in the interests of enhanced accountability.

TGA agreed in principle with this recommendation, but noted that TGA was not a separate authority and its formal reporting occurred through the Department's reports to Parliament.

Implementation Status:

TGA has:

- partly implemented this recommendation by implementing accrual budgeting and by consultation with consumers.

TGA has partly implemented this recommendation.

RECOMMENDATION 13—that TGA:

- identify international pricing-structure options with a view to adopting the most cost-effective method for use in Australia; and
- seek the cooperation of the pharmaceutical companies in forecasting workloads with a reasonable degree of confidence.

TGA agreed with this recommendation.

Implementation Status:

TGA has:

- identified international pricing structure options with a view to adopting the most cost-effective method for use in Australia; and
- sought the cooperation of the pharmaceutical companies in forecasting workloads with a reasonable degree of confidence. However, commercial considerations have proved an inhibitor of information exchange about future product development.

TGA has implemented this recommendation.

RECOMMENDATION 14—that TGA:

- 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.

TGA agreed in principle with the recommendation. It commented in 1996 that it had completed already an activity-based costing of its manufacturer auditing and licensing functions, and studies in other areas were either under way or planned for completion before the end of that year.

Implementation Status:

TGA has:

- introduced a method of calculating the industry-related costs of its operations;
- implemented full recovery of its costs; and
- identified in its annual financial statements (tabled in Parliament) the total amount of money raised by TGA from all activities within the scope of its legislation. The statements do not identify separately the funds raised from drug evaluation and registration.

TGA has implemented this recommendation.

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