Therapeutic Goods

Report 295

Joint Committee of Public Accounts

Parliament of the Commonwealth of Australia 1988

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

JOINT COMMITTEE OF PUBLIC ACCOUNTS

REPORT 295

THERAPEUTIC GOODS

A Review of the

Therapeutic Goods Evaluation and Testing Program

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Inquiry staff: Ms K A Malmberg
Mrs Y M Huddleston

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> Subject to sub-section (2), the duties of the Committee are:
>
> (a) to examine the accounts of the receipts and expenditure of the Commonwealth including the financial statements transmitted to the Auditor-General under sub-section (4) of section 50 of the Audit Act 1901;
>
> (aa) to examine the financial affairs of authorities of the Commonwealth to which this Act applies and of intergovernmental bodies to which this Act applies;
>
> (ab) to examine all reports of the Auditor-General (including reports of the results of efficiency audits) copies of which have been laid before the Houses of the Parliament;
>
> (b) to report to both Houses of the Parliament, with such comment as it thinks fit, any items or matters in those accounts, statements and reports, or any circumstances connected with them, to which the Committee is of the opinion that the attention of the Parliament should be directed;
>
> (c) to report to both Houses of the Parliament any alteration which the Committee thinks desirable in the form of the public accounts or in the method of keeping them, or in the mode of receipt, control, issue or payment of public moneys; and
>
> (d) to inquire into any question in connexion with the public accounts which is referred to it by either House of the Parliament, and to report to that House upon that question,
>
> and include such other duties as are assigned to the Committee by Joint Standing Orders approved by both Houses of the Parliament.

Preface

This Report presents the Committee's findings in respect of its inquiry into the therapeutic goods evaluation and testing function of the Department of Community Services and Health.

The therapeutic goods program is of major significance to the health and safety of the Australian population. Therapeutic goods include drugs, vaccines, hormones and medical devices.

The Committee has been most disturbed at a number of matters during the inquiry.

One particular concern is that there is still no uniform national legislation in Australia to give an enforceable national standard to ensure that therapeutic products on the market are safe and effective.

The Committee was advised that such legislation was first suggested in 1966. The Committee views as most serious the fact that, up until late October 1988, no detailed consultation had been undertaken on a bill the Department acknowledges as essential . It is now anticipated by the Department that the bill will be introduced into the Parliament in the Budget Sittings 1989.

The lack of national legislation means that the Commonwealth has no legal rights in relation to a number of issues that directly concern public health. These include:

- an inability to ensure an enforceable national standard of good manufacturing practice, the overriding purpose of which is quality control;

- licensing of manufacturers which is currently a State responsibility with varying standards, precluding in some cases the power to close down sub-standard and unsafe premises;

- no requirement to evaluate any Australian made medical device prior to sale and use in Australia;

- no control over the importation into Australia of the vast majority of medical devices with the result that some devices banned overseas can be legally imported into Australia without any inquiry; and

- no evaluation of the majority of diagnostic products.

The Committee was seriously concerned to hear evidence from the Commonwealth that one-third of manufacturers in Australia had not complied with the internationally recognised Code of Good Manufacturing Practice and a significant number had deficiencies of a major or critical nature that had been identified over a number of years.

The Committee also supports the development of a national drug policy including educating professionals and the community about therapeutic products and their use. One benefit that may follow is a reduction in pharmaceutical costs to the government.

The Committee hopes that this report will stimulate discussion and change within all health authorities in Australia - Commonwealth, State and Territory - and the community. The Committee believes that the issues raised are fundamental to a well balanced and effective program for the benefit of all.

The Committee appreciates the interest shown in this inquiry by individuals and manufacturers, professional, industry and consumer groups and State, Territory and Commonwealth Government Departments. In particular, the assistance provided by the various State governments and health authorities which appeared as witnesses at public hearings was most helpful. The Committee found the ready co-operation of officers of the Therapeutics Division, Department of Community Services and Health to be most valuable. The Committee also extends its appreciation to its Secretariat for the support given.

For and on behalf of the Committee.

R E Tickner, MP
Chairman

M J Talberg
Secretary
Joint Committee of Public Accounts
Parliament House
CANBERRA
16 December 1988

CONTENTS

Preface (v)

1. Introduction

Background 1
Public Service Board Review 2
Overview of Committee's inquiry 3

2. Program Framework

Therapeutics Division 7
Advisory committees 9
Legislation 13
National drug policy 21

3. Drugs – Gaining Marketing Approval

Background 25
The evaluation process 26
Concerns and staffing 29

4. Devices and Diagnostic Products – Gaining Marketing Approval

Background 33
Legislative controls 34
National Register of Therapeutic Goods 36
Evaluation 38
Extension of designated categories 45
Delays in the process 48
Diagnostic products 49

5. Good Manufacturing Practice

Inspections	51
ACT Community and Health Service	58
NSW Department of Health	59
South Australian Health Commission	62
Western Australian Health Department	64
Overseas manufacturers	67
Use in evaluations and PBS listing	70
WHO Export Certification Scheme	71

6. Post-Marketing Surveillance

Background	77
Testing	77
Recalls	79
Adverse reactions	80
Advertising and promotion	82

7. A Statutory Authority and Charges

Background	85
Statutory authority	86
Location of the drug evaluation function	87
Fees	88

ATTACHMENTS

A	Terms of reference	93
B	Submissions received	95
C	Conduct of inquiry	97
D	Summary of recommendations	103

Chapter 1

INTRODUCTION

Background

1.1 The Therapeutics Division of the Department of Community Services and Health has responsibility for administering the therapeutic goods program. The program aims to ensure the quality, safety and effectiveness of drugs, vaccines and therapeutic devices on the Australian market.[1]

1.2 Therapeutic goods includes drugs, biological products such as vaccines, hormones and blood products and therapeutic devices. Therapeutic devices encompass any material, instrument, apparatus, machine, implement, contrivance, implant etc used in health care. They are distinguished from drugs by not achieving their principal intended purpose through chemical action within or on the human body.[2]

1.3 Officers of the Division evaluate and test drugs, biological products and a limited number of critical devices before and after their release on the Australian market.

1.4 Other elements of the program are inspection of manufacturing premises in conjunction with officials from State and Territory health departments, recalls of unsafe products and the collection and assessment of reports of adverse reactions to drugs and devices. The Division also provides information on therapeutic goods to professionals in the medical, pharmaceutical, scientific and dental communities.

1.5 The Therapeutics Division comprises five branches, three of which are collectively known as the National Biological

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1. Joint Committee of Public Accounts, Therapeutic Goods Evaluation and Testing, Minutes of Evidence, p 18
2. Therapeutic Device Bulletin, No 1, May 1987, Commonwealth Department of Community Services and Health, p 1

Standards Laboratory (NBSL). The NBSL carries out functions associated with the therapeutic goods program both independently and in conjunction with the other two branches of the Division, the Drug Evaluation Branch and the Evaluation Support Branch.

1.6 Total funding for the program is estimated as $13 160 000 for 1988-89 ($13 088 000 in 1987-88) with staffing of 317 (end-year target figure).[3]

Public Service Board Review

1.7 Over the last decade a number of reviews of the pharmaceutical industry and therapeutics goods program have been carried out. The most recent of the reviews was the Public Service Board's Review of Drug Evaluation Procedures.[4]

1.8 In February 1987 the Minister for Health announced a review of the drug evaluation functions of the Department of Health led by an Assistant Commissioner from the Consultancy and Management Review Group, Public Service Board (PSB). The review was established following concerns raised about the reliability of certain data used to help gain marketing approval for a number of different brands of prescription drugs.

1.9 The Review Team reported to the Minister in June 1987. It found that Australia's drug evaluators have succeeded in ensuring no calamities caused by the widespread use of unsafe therapeutic drugs have occurred since thalidomide in the early 1960's. It did find, however, that the Drug Evaluation Branch had not been very successful in reconciling the demands of thorough scientific and medical scrutiny with the requirements for expeditious processing and equitable regulation. It also found that the various components of drug regulation, ie evaluation, inspection and laboratory testing, had not achieved the integration required if the regulatory function is to be discharged in a fully effective way.[5]

1.10 It is in the area of laboratory testing that NBSL carries out its work. The PSB Review concentrated on the drug evaluation and related aspects, with reference to NBSL only where necessary. This Committee's inquiry had a wider purview and

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3. Explanatory Notes 1988-89, Community Services and Health Portfolio, Budget Related Paper No 8.4A, p 113; Minutes of Evidence, p 2029
4. Public Service Board, Review of Drug Evaluation Procedures, June 1987.
5. Ibid, pp i-ii

included all aspects of the therapeutic goods function, including evaluation, inspections, laboratory testing, liaison and interaction of these functions.

1.11 The Committee, in undertaking its inquiry, took into account the PSB's Review and recommendations in order to avoid unnecessary duplication of effort by the Committee, the Department and interested contributors when examining the drug evaluation process. To assist the Committee, the Department provided two detailed responses to the PSB Report showing the Department's acceptance, or otherwise, of the recommendations together with progress made to date in implementing the recommendation.

1.12 The Committee agrees with the general thrust of the PSB Report and the vast majority of the recommendations in relation to the drug evaluation function. Specific comment will be made in appropriate sections of this Report.

Overview of Committee's inquiry

1.13 The Committee previously inquired into the National Biological Standards Laboratory in May 1985 when examining the Report of the Auditor-General, March 1984 (Report 240). The Committee was 'very concerned that the NBSL's facilities are so inadequate, below standard and scattered that it cannot carry out its function effectively'.[6]

1.14 In May 1987, whilst considering Report 273, Response to Report 240 Report of the Auditor-General - March 1984, the Committee recognised that efforts had been made to improve the NBSL's resources. However, the Committee stated:

> The Committee considered that inadequate and insufficient resources prevented the NBSL from carrying out its functions effectively, and saw the need for appropriate legislative or policy changes to be implemented. The Committee notes that in response the Department of Health has taken steps to secure improved accommodation for the NBSL, establish national registers for pharmaceutical and therapeutic devices, establish an Advisory Committee on testing

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6. Joint Committee of Public Accounts, Report 240, Report of the Auditor-General - March 1984, Canberra, AGPS, 1985, p 27

> programs, and appoint additional staff for inspections of companies manufacturing pharmaceuticals in Australia. However, the Committee is so concerned that insufficient and inadequate resources continue to prevent the NBSL from carrying out its functions effectively that it has decided to embark upon a public inquiry into the National Biological Standards Laboratory, particularly in relation to its ability to carry out its responsibilities.[7]

1.15 Following the Committee's announcement of an inquiry into the National Biological Standards Laboratory it was subsequently advertised and a number of submissions received. However, the calling of the 1987 Federal election delayed the commencement of the inquiry. When the Sixteenth Public Accounts Committee was formed it decided to continue with the inquiry but to expand the terms of reference to include other aspects of the therapeutic goods evaluation and testing function of the Department of Community Services and Health.

1.16 The Chairman announced the inquiry into Therapeutic Goods Evaluation and Testing in January 1988. The terms of reference included such aspects of the function as:

- legislative backing for the program;
- evaluation, testing and monitoring of drugs and devices;
- effectiveness of inspections of manufacturers;
- structure of the Therapeutics Division;
- liaison with States, industry, professionals and consumers; and
- adequacy of resources.

1.17 The detailed terms of reference can be found at Attachment A. During the course of the inquiry the Committee found that the focus of the inquiry varied according to the issues and concerns that arose during the taking of evidence.

1.18 The Committee has throughout the inquiry examined the therapeutic goods program as a whole. As the goal of the

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7. Joint Committee of Public Accounts, Report 273, Response to Report 240, Report of the Auditor-General - March 1984, Canberra, AGPS, 1987, p 2.

Department is to safeguard the Australian community in relation to the quality, safety and effectiveness of therapeutic goods, the Committee is of the view that particular aspects, such as drug evaluation, cannot be examined in isolation.

1.19 In examining the program, the Committee has taken a broad view of therapeutic goods and included not only pharmaceutical drugs and medical devices but proprietary goods and herbal and natural products in the review. The Committee has considered that it was important to receive a broad range of views on the matters under review. To that end, the inquiry was widely advertised and major associations and representative bodies were invited to contribute to the inquiry. However, in this Report the Committee has concentrated on reporting its findings in relation to pharmaceutical drugs and medical devices.

1.20 The Committee has received some 80 submissions from parties as varied as the Department of Community Services and Health, State and Territory health authorities, industry, professional and consumer bodies, manufacturers of therapeutic products, staff associations and individuals.

1.21 The Committee held fourteen public hearings during the course of the inquiry, two days of which were held in both Sydney and Melbourne. The remainder were held in Canberra. The Committee also carried out inspections of the National Biological Standards Laboratory's facilities in Canberra and Melbourne, the site of the proposed new building in Symonston, ACT, and the Drug Evaluation and Evaluation Support Branches in Phillip, ACT.

1.22 The Committee held informal discussions with a large pharmaceutical manufacturer and inspected the premises during its normal operations. The Committee also met with representatives of the Pharmaceutical Society of Australia at their headquarters in the ACT.

1.23 A list of the organisations and individuals that provided written submissions plus details of the Committee's hearings in terms of dates, witnesses and organisations represented, if applicable, are at Attachments B and C. A summary of recommendations made by the Committee can be found at Attachment D.

Chapter 2

PROGRAM FRAMEWORK

Therapeutics Division

2.1 The Therapeutics Division has responsibility for fulfilling the Commonwealth's objective of ensuring the quality, safety and effectiveness of therapeutic goods on the Australian market.

2.2 The Division comprises five branches:

- Drug Evaluation Branch
- Evaluation Support Branch
- Pharmaceutical Laboratories Branch
- Biological Laboratories Branch
- Medical Devices and Dental Products Branch.

2.3 The last three branches are known as the National Biological Standards Laboratory (NBSL). Until 1984 the NBSL had a separate identity as a Division within the Department. The principal functions of each Branch are as indicated below.

2.4 *Drug Evaluation Branch*

This Branch is responsible for the evaluation of the clinical, toxicity and pharmaceutical chemistry aspects of general marketing and clinical trial applications for drugs. The Branch also provides support for the Australian Drug Evaluation Committee (ADEC).

2.5 *Evaluation Support Branch*

The Evaluation Support Branch provides co-ordination and clerical and administrative support to the Drug Evaluation Branch. It also monitors the safety of marketed medicines in Australia, administers controls over the import and export of therapeutic substances and administers the drug education policy of the Division. The Branch also provides support for the Adverse Drug Reactions Advisory Committee.

2.6 *Pharmaceutical Laboratories Branch*

The laboratory-based sections of the Branch test samples of therapeutic goods and carry out applied research as well as providing scientific and technical advice and training. Other functions include the regular inspections of manufacturers of therapeutic goods in Australia to assess the competence of the companies to manufacture various categories of therapeutic goods. Recalls of therapeutic substances and devices are co-ordinated by this Branch. This Branch also provides support for the Therapeutic Goods Committee (TGC).

2.7 *Biological Laboratories Branch*

This Branch aims to ensure that selected human and veterinary vaccines and related immunobiological products are safe and effective and that pharmaceuticals, biologicals and medical devices are of satisfactory microbiological quality. The Branch also supplies other NBSL laboratories with healthy laboratory animals for essential experimental use.

2.8 *Medical Devices and Dental Products Branch*

The Branch carries out evaluation of a limited number of medical devices plus problem investigation and testing. The Branch maintains the National Register of Therapeutic Goods, controls the importation of designated categories of devices and provides support for the Therapeutic Device Evaluation Committee (TDEC). In addition, the Branch operates a voluntary program in conjunction with the dental and allied professions to ensure the quality, safety and efficacy of dental products.

Comment

2.9 In conducting the inquiry the Committee was anxious to obtain an understanding of all aspects of the Division's operations and the interaction between the various branches.

2.10 During the inquiry the Committee became aware that whilst particular groupings of branches of the Division may liaise closely and identify as a unit, the Division as a whole did not always appear to do so. The Committee believes that interaction is necessary in order to achieve the objectives and obligations of the therapeutic goods program. A lack of co-ordination in its approach to the therapeutic goods function was evident during the public hearings, particularly the latter series of hearings.

2.11 The Committee is of the view that the therapeutics program must be considered as a whole. Whilst the evaluation function, particularly drug evaluation, would appear to take prominence within the Division, the Committee believes this is only the beginning of the process. The Committee shares the PSB Review's findings that the five branches have yet to achieve the necessary integration.[1]

2.12 Evaluation has a very necessary and vital role of keeping unsafe products from the Australian market. The post-marketing surveillance functions of inspections and testing are also important to ensure the continued safety of products and to also ensure that those evaluated products are as effective as the evaluation process determined. The recall procedure is the final recourse if all else fails.

Advisory committees

2.13 A number of advisory committees have been established to advise the Secretary or Minister in relation to particular aspects of the therapeutic goods program. Functions and membership of the committees are as indicated below.

2.14 *Australian Drug Evaluation Committee*

The Australian Drug Evaluation Committee (ADEC) is a statutory committee constituted under the Therapeutic Goods Act 1966 with the function of advising the Minister on matters pertaining to the use of therapeutic substances within Australia. The Committee was formed in 1963 at the same time as the drug evaluation function commenced in Australia.

2.15 ADEC provides the ultimate level of advice to the Minister on the outcome of the evaluation of therapeutic

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1. PSB Review, op cit, p ii

substances in Australia. The functions of the Committee, which consists of eight expert members, are outlined in the Therapeutic Goods Regulations.

2.16 The Adverse Drug Reactions Advisory Committee (ADRAC)is a specialist sub-committee of ADEC. ADEC has solicited reports of suspected adverse reactions to drugs in Australia since 1964. In 1970 ADRAC was established to administer the reporting scheme. The Committee reviews all Australian reports of adverse drug reactions and is particularly concerned with all suspected reactions to new drugs, all suspected drug interactions and reactions to other drugs which are suspected of significantly affecting management of a patient.

2.17 *NBSL Advisory Committee*

The NBSL Advisory Committee is an independent expert committee which oversights the operation of the National Biological Standards Laboratory. It was established in 1986 as a result of the Ross Inquiry into Commonwealth Laboratories.

2.18 The Advisory Committee regularly reviews the objectives of the Laboratory and has the task of developing operational guidelines and associated performance indicators to assist management in the efficient operation of the NBSL.

2.19 The Committee's terms of reference were approved at its first meeting in 1986. It has a membership of seven: three expert members, the Division Head, an Australian Government Analytical Laboratory representative, a Department of Primary Industries and Energy representative and a staff representative.

2.20 *Therapeutic Device Evaluation Committee*

The Therapeutic Device Evaluation Committee (TDEC) was established as a statutory committee under the Therapeutic Goods Regulations in November 1987. The Committee reports directly to the Minister.

2.21 Its terms of reference are to evaluate therapeutic devices and any other therapeutic good as referred by the Minister or which the Committee thinks should be evaluated. The Committee also advises the Minister regarding the import, production (if in Australia) and distribution of evaluated products. TDEC also consists of seven expert members.

2.22 *Therapeutic Goods Committee*

The Therapeutic Goods Committee (TGC) is a statutory committee established in 1987 under the Therapeutic Goods Regulations. The TGC has taken over the role and responsibilities previously assumed by the Therapeutic Goods Advisory Committee and the Therapeutic Goods Standards Committee.

2.23 The TGC's terms of reference require it to consider any matter referred to it by the Minister in relation to the administration of the Therapeutic Goods Act and to advise the Minister in relation to those matters, plus the results of its considerations and inquiries into standards, labelling and packaging of therapeutic goods. The Committee has ten members, six of whom are expert members, one consumer representative, one device manufacturer, one pharmaceutical manufacturer and one representative from the Department of Primary Industries and Energy.

Comment

2.24 The Committee met with the Chairmen of the Therapeutic Goods Committee and the Therapeutic Device Evaluation Committee, the former acting Chairman of the NBSL Advisory Committee and the Chairman and two members of the Australian Drug Evaluation Committee.

2.25 The Committee supports the use of independent advisory committees to provide advice either to the Minister or the Secretary of the Department. The Committee, however, is concerned that some functions of the therapeutic goods program may not be covered by independent advice.

2.26 One area of concern is the NBSL Advisory Committee and its sphere of reference. Both the Committee and the Department were somewhat unsure as to whether functions of NBSL other than laboratory functions such as inspections and recalls were included. Both groups of witnesses referred to the establishment of the Committee following a recommendation of the Ross Committee which implied restriction to laboratory functions only.[2] As the NBSL's functions are now wider than laboratory only, this should be reflected in the Advisory Committee's operations.

2.27 The Committee notes that an accepted method of advising the Minister is to provide a copy of minutes of meetings.[3] Whilst this may be acceptable for routine matters, the Committee believes that for more important matters advice should be made in a direct and explicit manner.

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2. Minutes of Evidence, op cit, pp 389-94, 2215-6
3. Ibid, p 2219

2.28 The Department stated that, in relation to a particular matter in the minutes of ADEC, by putting the minutes to the Minister, he 'in effect', approved the matter.[4]

2.29 The Committee was also concerned to hear evidence that the Therapeutic Goods Committee forwarded advice through the Departmental Secretary to the Minister. The Committee believes that such advice should be forwarded directly to the Minister, with a copy to the Secretary for his information if considered appropriate.[5]

2.30 In additional information provided to the Committee, the Department advised that the first meeting of the TGC was held on 3 February 1988 and the minutes were provided to the Minister on 22 June 1988. The minutes of the second meeting held on 4 August 1988 were sent to the Minister on 3 November 1988.[6] The Committee was somewhat surprised that it took 3-4 months for the minutes to be provided to the Minister.

2.31 The Committee recommends that:

- The Department of Community Services and Health review the terms of reference of the independent advisory committees and review the activities of such committees and their inter-relationships to ensure that coverage of the therapeutic goods program is comprehensive and without duplication. Each Committee, in its separate terms of reference, should give priority to those therapeutic goods which entail a high community risk.

- The Therapeutic Device Evaluation Committee, the Australian Drug Evaluation Committee and the Therapeutic Goods Committee should provide explicit advice direct to the Minister.

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4. Ibid, p 2047
5. Ibid, pp 1070, 1081
6. PAC file 1987/6 B(21)

Legislation

2.32 A recurring theme throughout the inquiry has been the lack of uniform, national legislation in the therapeutic goods area. The need for such legislation was recognised as far back as 1966 when Commonwealth and State Health Ministers formed a working party to examine such a proposal.

2.33 Current Commonwealth powers are restricted and several pieces of legislation are relied upon to exercise the existing powers:

- Customs (Prohibited Imports) Regulations - regulates the import into Australia of drugs or active ingredients for drugs
- Therapeutics Goods Act 1966 - sets standards for therapeutic goods that are imported, subject of interstate trade, on the Pharmaceutical Benefits Schedule list or supplied to Commonwealth agencies; establishes the National Register of Therapeutic Goods
- Therapeutic Goods Regulations - establishes the Australian Drug Evaluation Committee, Therapeutic Device Evaluation Committee and the Therapeutic Goods Committee.

2.34 State and Territory legislation is the basis for control over local manufacture, distribution and sale of therapeutic goods. The various pieces of legislation are not uniform across Australia.

2.35 All witnesses to the inquiry have been critical of the current legislative framework for regulating therapeutic goods in Australia. The Department of Community Services and Health in its submission stated:

> Virtually all advanced nations use nation-wide legislation to regulate therapeutic goods (including pharmaceuticals, vaccines, diagnostics and therapeutic devices), whereas Australia at present has an overlapping and in some cases ineffective patchwork of Commonwealth, State and Territory legislation.[7]

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7. Minutes of Evidence, op cit, p 76

2.36 The PSB Review strongly supported the proposal for uniform national legislation. It recommended that Commonwealth legislation should be drafted urgently with a view to consultation with the States and industry before the passage of the legislation in the Autumn 1988 Sittings of the Parliament.

2.37 The Review recommended that the draft legislation should include provision for:

- registration of pharmaceuticals and therapeutic devices;
- licensing and inspection of manufacturers and wholesalers;
- uniform application of standards to imported and locally produced goods;
- application of uniform testing procedures; and
- an adequate appeal mechanism.[8]

2.38 The Committee supports this recommendation.

2.39 The Committee has heard evidence relating to consultation in the lead-up to new legislation, delays in the introduction of the legislation plus the need for more specific information in particular areas.

2.40 In the Department's submission to the inquiry dated March 1988 it stated that 'extensive liaison with representatives of the therapeutic goods industry and consumer organisations' had taken place in developing a draft bill. Consultation with the States was continuing following discussions in 1986 at the Health Ministers' Advisory Council and the National Therapeutic Goods Committee and in 1987 at the Health Ministers' conference.[9]

2.41 When giving evidence in March 1988 the Department indicated that a draft bill had been completed in December 1987 but further consultation at officer level was required, with a number of major matters requiring agreement prior to introduction to the Parliament of the draft bill. At that time the Department

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8. PSB Review, op cit, p xvi, recommendation 45
9. Minutes of Evidence, op cit, p 76

indicated that the draft legislation would be ready for the Budget Sittings 1988, not the Autumn Sittings 1988 as previously anticipated.[10]

2.42 The Committee, however, was disturbed to hear evidence from the States, industry groups and consumer groups that consultation has not been as extensive as the Department had indicated in its submission and evidence. Most groups were aware of the proposal in principle, but had had no detailed discussions or consultation with the Department. In particular, industry and consumer groups were aware of proposals but were concerned at the lengthening timetable for further consultation and eventual introduction into the Parliament.

2.43 The States have been involved in some broad consultation, but were not aware of details. For example, the South Australian experience is as follows:

> MR RUDDOCK - But the Commonwealth legislation is going to provide quite a different framework, is it not? It will take this matter out of your hands, will it not?
>
> Mr Davis - That we do not know. We have some detail about the legislative proposals we know through national committees - the National Co-ordination Committee on Therapeutic Goods. But we have nothing such as a Bill to look at which would help us to mirror what our regulations need to be in accordance with, or in addition to, the Commonwealth legislation.[11]

2.44 NSW made the following comments:

> CHAIRMAN - You, at this stage, do not have more than what I think you referred to as an outline of the Commonwealth legislation?
>
> Mr Mewes - Yes, of the actual specific legislation. We were provided at the last National Therapeutic Goods Committee meeting with what was virtually an upgraded version of what I had seen on several occasions and it was a rough concept of a licensing program, but certainly no details.

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10. Ibid, pp 160, 163
11. Ibid, p 1852

CHAIRMAN - What have you been told by the Commonwealth as to the likely date of passage of the legislation?

Mr Mewes - It was for next year, I think, with an effective ----

Mr Martin - It will be presented to Parliament in 1989.

CHAIRMAN - Before that you would anticipate a fairly thorough consultation process, and New South Wales would play a major role.

Mr Mewes - We would hope so, yes.

CHAIRMAN - Certainly, it is not imminent.

Mr Mewes - No.[12]

2.45 When the ACT representative was asked if he was aware of timing of the new legislation, the following exchange took place:

CHAIRMAN - Could I ask you how up-to-date your information is about the imminence of those amendments? Are you briefed monthly about its progress or----

Mr Bugler - The last meeting of the co-ordinating committee was subsequent to the meeting of this Committee in May. My understanding there was that the Commonwealth was advanced with this proposal, quite advanced.

CHAIRMAN - What have you been told about the likely date of the amendments?

Mr Bugler - That has not been canvassed.

CHAIRMAN - Have you any idea at all when it might be?

Mr Bugler - I would hope that it would be, if not early next year, later next year.

CHAIRMAN - Have you got any direct basis for saying that? Have you been advised by any senior Commonwealth official of any likely date?

Mr Bugler - No.[13]

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12. Ibid, p 1767
13. Ibid, p 1653

2.46 The ever lengthening timetable for introduction of the legislation is of great concern to the Committee. As stated in Chapter 1 the lack of appropriate legislation was of concern to the Committee in 1985. However, this concern should in no way impede proper consultation with interested parties. The Committee believes that the draft bill should be made public as soon as possible and should be made available to those parties for comment. Adequate time should be allowed for proper debate.

2.47 It is now anticipated by the Department that the legislation will be introduced in the Budget Sittings 1989.[14]

2.48 During the course of this inquiry, the Committee has been advised by the Department of various dates for the introduction of the legislation into the Parliament. These are shown below.[15]

Form of advice	Date of advice	Proposed date for introduction of legislation
1st Response to PSB report	October 1987	Autumn Sittings 1988
Submission	March 1988	Autumn Sittings 1988 was earlier expectation but may be later
Hearing	March 1988	Budget Sittings 1988 but other legislative pressures may mean Autumn Sittings 1989
2nd response to PSB report	August 1988	Autumn Sittings 1989
Hearing	October 1988	Budget Sittings 1989

2.49 The Committee is extremely concerned that over a 12 month period, the timetable for introduction of the legislation into the Parliament extended by some 18 months.

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14. Ibid, p 2003
15. PAC files 1987/6 B(2) and B(10); Minutes of Evidence, op cit, pp 76, 163; PAC file 1987/6 A(2); Minutes of Evidence, op cit, p 2003

2.50 In order to facilitate consultation, the Department in late October 1988 circulated a discussion paper on the proposed new bill to the States, industry and consumer groups. This paper sought responses within three months. The Committee notes that the Department does not intend to seek approval to distribute the draft bill to interested parties other than State Governments prior to introduction in the Parliament. The Committee, confirming comments in paragraph 2.46, is of the view however that it should be distributed.

2.51 The Department has provided the Committee with a copy of the discussion paper circulated to interested parties. The Committee has not seen a draft bill for the proposed legislation.

2.52 The Committee notes that the Department, in comment on the consultative process in the discussion paper, now describes previous consultation with representatives of therapeutic goods industries and consumer organisations as 'preliminary', rather than 'extensive' as in the Department's March submission to the inquiry.[16] The Committee believes extensive consultation with all interested parties is essential.

2.53 The discussion paper states that establishment of a national regulatory system and the uniformity deriving from it will:

- overcome anomalies caused by differences in current controls over locally manufactured and imported goods;
- benefit the therapeutic goods industry and consumers in Australia by reducing costly and confusing differences in regulations between the States;
- apply uniform standards for the manufacture of therapeutic goods in Australia;
- enable a more comprehensive monitoring of therapeutic goods available in Australia, and more effective action in identifying and recalling faulty products;
- benefit the Australian pharmaceutical export industry by facilitating Commonwealth certification of products in accordance with the WHO Certification Scheme and by generally enabling Australiato maintain its reputation as a responsible exporter; and

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16. PAC file 1987/6 A(2), Minutes of Evidence, op cit, p 76

- facilitate Australia's access to international conventions and to bilateral and multilateral manufacturing inspection agreements. Such arrangements have the potential to streamline the evaluation of imported goods.[17]

2.54 This uniformity is to be achieved through the introduction of a national registration system for therapeutic goods, a national licensing system for Australian manufacturers of such goods and the uniform application of standards to therapeutic goods whether imported, exported or supplied within Australia.[18]

2.55 The Committee considers that the Department has not acted in a manner consistent with its repeatedly stated view that uniform national legislation is essential before controls over certain aspects of the therapeutic goods function can be effected. The major areas of concern include:

- the need for legislation to prevent, without government approval, the importation into and/or sale, in Australia, of therapeutic devices banned overseas;
- the lack of an enforceable national standard and machinery for the Commonwealth to ensure compliance with the Code of Good Manufacturing Practice (GMP);
- the absence of legislation in some States for licensing of manufacturers which has resulted in widely varying standards and practices;
- the lack of a national standard that may have prevented Australia from joining international forums which could facilitate Australian exports; and
- difficulties manufacturers encounter when exporting products due to Australia's difficulty in signing bilateral and multilateral inspection agreements.

2.56 A number of these matters directly affect public safety and it is for this reason that the Committee is particularly concerned with the continuing and lengthening delays in introducing a new bill to the Parliament.

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17. PAC file 1987/6 A(2)
18. Ibid

2.57 The Committee is particularly concerned as revenue measures contained in the proposal are linked with the provision of an improved service by the Division.

2.58 The Committee is of the view that lack of an enforceable national standard could be a major threat to public health in Australia, particularly in those States where there is no legislative backing to enforce the Code of GMP and manufacturers persistently flout that Code. The Committee recognises that most reputable firms willingly adhere to GMP at great cost.

2.59 The delay is particularly damning when the first moves towards uniform legislation occurred in 1966.

2.60 Notwithstanding this, the Committee is somewhat encouraged that progress is in fact being made towards the introduction of a bill for uniform national legislation following the distribution of the discussion paper. However, the lengthy delays to date make it imperative that all possible action should be taken by the Department to ensure that the draft bill is introduced into the Parliament as soon as possible following full consultation with all parties. This consultation should include all industry groups, including prescription, proprietary, health food and natural products peak bodies, pharmacist, medical and other professional bodies, consumer groups, manufacturers and State Governments.

2.61 In the intervening time, the Committee urges the Department to investigate whether it is possible to amend current legislation to tighten areas which are of concern or to close gaps that currently exist. The Committee, however, determined not to make recommendations in this area to ensure no further excuse for delay in implementing the principal recommendation.

2.62 In view of the long history of delay in preparing the legislation and the grave issues of public health and safety at stake the Committee proposes to take the unprecedented step of recalling the Department, independent of the Finance Minute process, within six months to examine progress towards the implementation of national legislation.

2.63 The Committee recommends that:

- The Department of Community Services and Health should ensure full consultation

with all interested parties including the States and industry and consumer groups and that urgent efforts be made to ensure introduction of the bill for uniform national legislation to control therapeutic goods into the Parliament in the Autumn Sittings 1989 with a commencement date no later than 1 January 1990.

. The Department of Community Services and Health prepare within six months a report on progress made towards having the legislation in place by the commencement date or earlier to enable a review by the Public Accounts Committee, independent of the Finance Minute process, to be undertaken.

National drug policy

2.64 The PSB Review briefly examined the formation of a National Drug Use Advisory Committee to provide expert advice to the Minister on actual prescription drug usage, the commissioning and evaluation of education campaigns, the problems of over-medication and drug abuse, and advertising and promotion. The Review did not consider the issue in detail nor make recommendations as the Department was likely to consider these matters in a proposed study of drug education.[19]

2.65 A national drug policy includes elements such as an examination of drug usage, education of professionals regarding prescribing patterns eg over or under medication of patients, education and informing the patient by campaigns through doctors, pharmacists and inclusion of patient information inserts with products sold, and a monitoring of advertising. These issues would mesh with the legislative and regulatory aspects of the evaluation and testing functions of the Department.

2.66 An ideal drug policy would involve the use of appropriate, cost-effective, safe and efficacious drugs with the end result of neither over or under treating the community. In addition, the financial cost to the government could be reduced.

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19. PSB Review, op cit, pp 104-5

2.67 The Committee believes that the therapeutic goods function is an essential element in ensuring public health and safety.

2.68 The PSB recommended that the Department, in its study of drug education, should include an examination of whether there is scope for a national advisory body on drug use policy.[20]

2.69 The Department has commissioned and had completed a report on drug education. The report was submitted to the Department on 31 May 1988, however, the report has not yet been released publicly. The Department advised it is yet to form a view on the report, partly as a result of four different areas of the Department having a direct involvement. There is no timetable for acting on the report.[21]

2.70 The Committee believes such a report should receive active and prompt consideration.

2.71 The Committee noted earlier in this Report that it views the Therapeutics Division as a whole entity interacting for the benefit of the Australian public. The Committee firmly believes that information on usage, an education policy for both practitioners and consumers and the monitoring of advertising are also essential elements in a therapeutics policy for Australia.

2.72 The Committee believes a national drug policy is essential for several reasons. First, a major aim would be to reduce inappropriate or excessive drug use within the community. Secondly, savings could occur in hospital and government drug costs. Thirdly, increased awareness by patients of the products being used and the effect they have.

2.73 The Committee also is of the view that the Department should encourage the activities of bodies such as the Pharmaceutical Society of Australia. In both formal and informal discussions with the Society the Committee was favourably impressed with its activities in regard to consumer education and information.

2.74 The Committee was surprised that the Department does not consult with the Society given that its members liaise directly with users on a daily basis regarding the use of drugs.[22]

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20. Ibid, p xiii, recommendation 31
21. Minutes of Evidence, op cit, p 2213
22. Ibid, p 747

2.75 The Committee believes that pharmacists are an essential element in efforts to increase user education. Pharmacies are located within each community and pharmacists can play an important role with day-to-day contact with consumers. The Society's current efforts in user education include the Self Care Program and a program for educating school children in the use of drugs and the effect a drug can have.

2.76 The Society, in evidence to the Committee, has indicated that there is a financial cost to the pharmacist in providing advice to users and suggests that the remuneration that is paid by the government could be changed.

2.77 The Society explained:

> The way the system is set up, the Pharmaceutical Benefits Scheme gives a subsidy to pharmacists to allow them to provide pharmaceutical goods to the community at a reduced cost. It is a piecework system; the amount of money that you get for each individual item is fixed by the Pharmaceutical Benefits Remuneration Tribunal and if you are a pharmacist the way to profit from the system is to dispense at the highest volume and the greatest frequency that you possibly can. If you maximise dispensing volume under the system the system rewards you.
>
> The important thing from our point of view is that if you take the time out to do these things, you get penalised.
>
> We have been saying, 'What you have to do is to look at the system, acknowledge the disincentives that it provides and try to build some incentives into it'...we have made submissions to the Pharmaceutical Benefits Remuneration Tribunal.[23]

2.78 The Committee, while in no way advocating an increase in public expenditure, believes a different basis of remuneration for pharmacists may be more in keeping with the profession of pharmacy and act in assisting in drug education.

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23. Ibid, p 740

2.79 The Committee recommends that:

- The Department of Community Services and Health actively pursue the development of a national drug policy. Extensive liaison should be undertaken with all interested parties.

- The Department of Community Services and Health provide, in the Finance Minute, its response to the Report on Drug Education, together with a timetable for implementing those recommendations it accepts.

- The Department of Community Services and Health explore ways in which pharmacists can contribute to consumer education and ways that pharmacists' reimbursement can be changed to acknowledge their contribution.

Chapter 3

DRUGS – GAINING MARKETING APPROVAL

Background

3.1 The initial step in ensuring the quality, safety and effectiveness of drugs and biological products on the Australian market is the evaluation process.

3.2 It is this process that was the subject of a major review in 1987 by the Public Service Board. The PSB Report, 'Review of Drug Evaluation Procedures', examined and made recommendations relating to the management of the drug evaluation and related functions of the then Department of Health.

3.3 As indicated in Chapter 1, the Committee took into account the PSB Review and its recommendations in this inquiry. The Review examined in some depth the evaluation procedures and made a number of detailed recommendations concerning the administration of the drug evaluation function. The Committee did not attempt to duplicate this and used the PSB Review as a starting point.

3.4 Prior to 1963 drugs were not evaluated before marketing. In 1958 the National Biological Standards Laboratory was established, but the Laboratory's functions were restricted to matters such as compliance with standards of purity.

3.5 In the 1960's it became evident that the effect of therapeutic substances on humans needed to be properly researched prior to sale to the general public. Simply, the evaluation process involves the examination by a regulatory authority of documentation relating to a drug's development including detailed results of clinical trials in humans.

3.6 In 1963 the Australian Drug Evaluation Committee (ADEC) was established under the Therapeutic Goods Regulations to oversee the process.

3.7 As previously indicated, the responsibility for pharmaceuticals does not rest entirely with the Commonwealth nor are State requirements uniform across Australia.

3.8 Under the Customs (Prohibited Imports) Regulations the Commonwealth has control over fully imported drugs and imported active ingredients by requiring the authority of the Secretary, Department of Community Services and Health, prior to import.

3.9 The Commonwealth also has control over products supplied to the Commonwealth, goods supplied under the Pharmaceutical Benefits Schedule and goods subject to interstate trade.

3.10 The Commonwealth does not have control over products manufactured from Australian ingredients which are not subject to interstate trade and are not on the Pharmaceutical Benefits Schedule.

3.11 It is proposed, however, that the new legislation will cover this category to ensure Commonwealth control over all products on the market.

3.12 Information on the number of drugs on the Australian market could not be provided by the Department. However, information on the number of drugs on the Pharmaceutical Benefits Schedule was available. There are some 600 different active substances of which there are 1 280 - odd forms and strengths. There are some 1 890 different brands of these forms and strengths.[1]

The evaluation process

3.13 Australia carries out comprehensive evaluations of all drugs over which it has control. It does not rely upon or use evaluation reports from overseas regulatory authorities. The drug evaluation process in Australia was recognised by all witnesses as being of a high standard and as having been successful in keeping unsafe drugs off the market.

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1. Minutes of Evidence, op cit, pp 108-9

3.14 The Department has issued guidelines known as NDF 4, 'Guidelines for preparing applications for the general marketing or clinical investigational use of a therapeutic substance'. These guidelines are currently under revision and are subject to discussion with the Australian Pharmaceutical Manufacturers Association (APMA). The draft revised guidelines are known as NDF 5.

3.15 The evaluation process for pharmaceuticals varies in its length and requirements for various types of marketing applications. The various types include new chemical entities, generics, new formulations and changed dosages. The general principles will be outlined and differences referred to later.

3.16 When seeking marketing approval for a new drug the manufacturer submits to the Department data in the following three groups:

- pharmaceutical chemistry
- toxicity studies (in animals)
- clinical studies (in humans)

3.17 Upon receipt, the data are considered by the Therapeutics Liaison Committee (an internal departmental committee) to assess if acceptable and in an appropriate form for evaluation. The data are then sent to the three relevant sections of the Drug Evaluation Branch for evaluation.

3.18 The Department advised that it is some six months after the distribution of data for evaluation that reports from the three evaluators are available.[2]

3.19 The Pharmaceutical Chemistry Evaluation Section has a two-year backlog in evaluations.[3] Drugs that are considered to be significant advances on other products available are given priority.

3.20 An overview of the three reports is prepared by a Medical Services Adviser which includes a recommendation on whether or not the data support marketing approval. The overview

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2. Ibid, p 138
3. Ibid, p 120

plus the three reports are then transmitted to ADEC. The Department has a target of 15 months for all applications to reach ADEC.[4]

3.21 ADEC meets six times a year to consider applications for marketing approval and the Department advised that the Committee rejects half of the applications.[5] Reasons for rejection vary and include lack of information, requests for clarification, or the unsuitability of the product for marketing in Australia. ADEC's recommendation can be subject to settlement of certain outstanding issues plus agreement, between the Department and manufacturer, on the product information document.

3.22 From application to final marketing approval the Department estimates it generally takes about two years.[6]

3.23 The Department does however fast-track certain applications if it can be shown that the drug is a major therapeutic advance on what is available. If several new formulations of a product are submitted for general marketing approval the Department stated that the first one would receive priority if it gives a major advantage over drugs currently approved. If it is not the first of a major group then there would be no priority.[7] The Department does not fast-track modifications to existing drugs generally, and in particular, it does not give priority to Australian developed modifications that may have export potential.

3.24 Application for marketing of a generic drug is not required to contain repeat studies in the animal toxicity area or the human clinical area. The data that are required are aimed at demonstrating that the new brand is equivalent to the original one. The two brands should be interchangeable.[8] Generics do not receive any priority through the system.

3.25 Minor applications such as a change in dose size do not require the same extensive evaluation process, although effort is made by the Department to process the application quickly. However, minor applications are still required to take their place in the queue.[9]

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4. Ibid, p 138
5. Ibid, p 139
6. Ibid, p 142
7. Ibid, p 126
8. Ibid, p 121
9. Ibid, p 126

Concerns and staffing

3.26 As previously indicated, the Committee has examined both the PSB 'Review of Drug Evaluation Procedures' Report and the two responses by the Department to that report.

3.27 The second Departmental response to the PSB Review was received by the Committee in August 1988, some 15 months after the PSB Review was completed. The Committee is somewhat concerned that the preface to that document refers to a recurring theme of inability to implement some recommendations owing to workloads, limited resources and difficulty in recruiting professional staff. The Department suggests that these problems may be overcome if some functions were relocated to a capital city with a much greater relevant labour market.[10]

3.28 The Committee will comment on the question of location of the drug evaluation function of the Department later in this Report. However, the Committee is of the view that a decision needs to be taken on this matter if this is a barrier to further improvements in the program.

3.29 The Committee is in general agreement with the PSB Review and its recommendations. The Committee notes that the Department has rejected several recommendations on the basis that they are not possible or based on misinformation.

3.30 The recommendations relating to functions other than drug evaluation will be examined elsewhere in this report.

3.31 The Committee believes that many of the concerns expressed to it during the course of the inquiry by the Australian Pharmaceutical Manufacturers Association (APMA), other professional bodies, manufacturers, consumer groups and individuals will be met when the implementation of the recommendations is completed. Many of the concerns expressed in this inquiry were expressed to the PSB Review.

3.32 Those concerns include:

- delays in the drug evaluation process;
- the system for determining priorities within the evaluation process;

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10. PAC file, 1987/6 A(2)

- a need for the exchange of information and evaluations with comparable overseas regulatory authorities;

- the introduction of a tracking system for marketing applications within the Department;

- a need for a more open information flow to companies, including more detail on decisions taken both by the Department and by ADEC and the stage the application has reached in the process;

- the desirability of companies examining evaluations prior to submission to ADEC;

- the introduction of target processing times with fees refunded if targets are not met;

- that priority has, in effect, been given to generic drugs by commencing evaluations prior to patent life of the original brand expiring; and

- the lack of uniform legislation.

3.33 The Committee sought Departmental comment on all these issues along with many others. The Committee is satisfied that the Department is endeavouring to implement the PSB Review recommendations and has a commitment to ensuring the highest standard of drug evaluation for the safety of the Australian public.

3.34 The Committee considers that the major difficulty facing the Department is resources. The Committee believes that the staff of the Drug Evaluation and Evaluation Support Branches are highly motivated and committed professionals but the delay in processing evaluations is indicative of the workload. A large number of evaluations are currently carried out by external evaluators.

3.35 The Committee is concerned that the solution to certain of the difficulties identified in this inquiry and the PSB Review were dependent upon resources which are not available. In addition to the concerns referred to in paragraph 3.32, other recommendations of the PSB Review which have yet to be finalised because of resourcing problems include:

- the trial of a new system for priority setting;

- a closer relationship with evaluators through feedback and training;

- the trial of industry expert reports; and
- the provision of evaluations to companies prior to their submission to ADEC.

3.36 The Committee notes that the current staffing of the Drug Evaluation Branch is 47 which includes secretarial staff.[11] During the hearing the Acting Head of that Branch stated that, in his opinion, some additional 30 staff would be required as the minimum necessary to perform the essential tasks. The Department advised that by the end of 1988-89 that the Branch could have a total of 50 staff within the current constraints.[12]

3.37 The Committee is particularly interested in the concept of sharing evaluations undertaken by other countries.

3.38 The PSB Review examined the possibility of exchanging evaluation reports with other drug regulatory agencies in comparable countries. It recommended that Australia should exchange evaluation reports with Sweden, and if possible Canada, with the long term view of sharing, with comparable countries, the heavy evaluation workload.[13]

3.39 The Committee fully supports this recommendation and notes that the Department is moving in this direction, particularly in respect of Sweden. The Committee believes it is essential that Australia should retain its high standards in drug evaluation but the exchange of properly researched and assessed evaluations with other countries maintaining a high and comparable standard should be encouraged.

3.40 The Committee also considers that over time, this could be extended from an exchange on a country to country, information only basis to a single international drug evaluation centre.

3.41 The Department has advised that it has no record of the concept of a centralised drug evaluation process having been listed on the World Health Assembly's agenda. The Department indicated that such a system could operate as a centralised process with each country, after a drug has been evaluated, then deciding whether to market it. In Australia ADEC would be able to put upon those evaluations its own assessment in the Australian community.[14]

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11. PAC file 1987/6 B(21)
12. Minutes of Evidence, op cit, p 2081
13. PSB Review, op cit, p viii, recommendation 8
14. Minutes of Evidence, op cit, pp 2066-7

3.42 The Committee recommends that:

- The Department of Community Services and Health report comprehensively in the Finance Minute on progress made in carrying out the recommendations of the Public Service Board Review of Drug Evaluation Procedures. If a recommendation is not to be or cannot be implemented then detailed reasons should be provided.

- The Department of Community Services and Health determine what resources are required in both the Drug Evaluation and Evaluation Support Branches to carry out the drug evaluation function in a more timely and efficient manner.

- The Department of Community Services and Health examine the issue of a centralised drug evaluation agency and advise in the Finance Minute what advantages and disadvantages the Department foresees with such a proposal.

- The Department of Community Services and Health consider the fast-track procedure for evaluating Australian developed modifications to drugs which are likely to have export potential.

Chapter 4

DEVICES AND DIAGNOSTIC PRODUCTS – GAINING MARKETING APPROVAL

Background

4.1 The evaluation process for medical devices on the Australian market is very different to that of drugs. Medical devices encompass any material, instrument, apparatus, machine, implement, contrivance, implant etc used in health care. They are distinguished from drugs by not achieving their principal intended purpose through chemical action within or on the human body.

4.2 Examples of therapeutic devices include many of an essential and critical nature eg heart valves and pacemakers, anaesthesia machines and associated equipment, kidney dialysis machines, cardiac resuscitators and heart-lung by-pass units. Other examples include equipment such as electrocardiograph machines, ultrasonic foetal monitors and x-ray units. Also included are items such as condoms, bandages and wheelchairs.

4.3 In 1984 the Minister for Health announced the therapeutic device program in response to community concerns about the number of devices coming onto the market as as result of technological advances and the increasing use of devices in health care.

4.4 The objective of the program is to ensure the quality, safety and efficacy of therapeutic devices. The Medical Devices and Dental Products Branch of the Department was created in February 1987 to carry out the program. The Branch absorbed the Australian Dental Standards Laboratory.

4.5 The Therapeutic Device Evaluation Committee (TDEC) advised the Committee that TDEC and the therapeutic goods program were established late by world standards. Australia was one of the last 'advanced' countries to set up regulatory processes for devices.[1]

4.6 The laboratory functions of the Medical Devices and Dental Products Branch are currently accommodated in Melbourne. The Branch Head and the Information and Secretariat Section are located in Canberra. It is envisaged that when the new NBSL building is completed in 1992 this Branch will relocate the balance of its functions to Canberra.[2]

4.7 The major elements of the therapeutic goods program are:

- register of devices (part of the National Register of Therapeutic Goods);
- pre-market evaluation;
- facility to test and investigate; and
- problem reporting and information dissemination scheme.[3]

Legislative controls

4.8 Legislative control over therapeutic devices supplied in Australia is through:

- Customs (Prohibited Import) Regulations. The Eighth Schedule of these Regulations specify six particular categories of goods that are prohibited for import except with the permission of the Secretary of the Department of Community Services and Health or other authorised officer.

- Therapeutic Goods Act 1966 and Therapeutic Goods Regulations. This legislation establishes the National Register of Therapeutic Goods and the Therapeutic Device Evaluation Committee.

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1. Minutes of Evidence, op cit, pp 822, 829
2. Ibid, p 42
3. Therapeutic Device Bulletin, No 1, May 1987, Department of Community Services and Health

4.9 The Department has very limited legislative powers over the supply of therapeutic devices in Australia. The only power is over the importation of a limited number of categories of therapeutic devices.

4.10 The Eighth Schedule of the Customs (Prohibited Imports) Regulations list the following categories of goods for which authorisation to import is required:

- Drug infusion systems;
- Implantable cardiac pacemakers, implantable defibrillators and implantable cardioverters and accessories for such;
- Intra-ocular lenses;
- Intra-uterine contraceptive devices;
- Prosthetic heart valves; and
- Insulin syringes that bear the word 'insulin'.

4.11 Only the first five of the above categories of devices require pre-market evaluation, that is, are subject to any assessment as to safety and effectiveness prior to import into Australia. All other categories of device do not require evaluation.[4] (The Department indicated there is some small requirement for insulin syringes.)

4.12 The Department advised that there was also some legislative backing for examination of therapeutic substances which are products that are put into the body and are considered a material, such as a collagen or bone cement. Goods for which a Therapeutic Goods Order is applicable, such as condoms and surgical sutures, are tested against those standards.[5]

4.13 The legislative backing of the Customs (Prohibited Imports) Regulations does not extend to products manufactured in Australia. There is no requirement that locally produced devices which fall into the five categories should be evaluated. However, through co-operation with local industry and industry bodies, the Department has been subjecting local and imported products to the same requirements.[6]

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4. Minutes of Evidence, op cit, p 2182
5. Ibid, p 2184
6. Ibid, p 2183

National Register of Therapeutic Goods

4.14 Under the Therapeutic Goods Act and Regulations the Secretary of the Department, in order to compile and maintain the National Register of Therapeutic Goods, may, by serving notice, require a manufacturer or supplier to register devices it manufactures or supplies. Information including the name of the product, the manufacturer and the identity and address of the person responsible for the quality and safety of goods in Australia is to be supplied. Certain product details are also required. (The Register also contains similar information on other therapeutic goods.)

4.15 The Register assists the Department in identifying and dealing with hazard alerts, recalls and complaints. It should be noted that the Department, in its Notice No 4, Notification of Therapeutic Devices, states in bold print:

> It must be stressed that the Register is only a list. No approval or controls are required or implied for devices to be included on the Register.[7]

4.16 The Department stated in evidence that there are some 3 000 categories of medical devices and some 24 000 different products on the National Register of Therapeutic Goods.[8] Some 84% of devices on the Australian market are imported.[9]

4.17 Only five of the 3 000 registered categories of device are evaluated. Of the 24 000 products on the Register the Head of the Medical Devices and Dental Products Branch of the Department estimated that fewer than 1 000 would be subject to evaluation. The vast majority are not.[10]

4.18 The Department however is not completely confident that it is aware of all companies or individuals either importing into or manufacturing in Australia. The Department stated:

> The onus under the current Therapeutic Goods Act is on us to find the company and tell it

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7. Notice No 4, Notification of Therapeutic Devices, National Register of Therapeutic Goods
8. Minutes of Evidence, op cit, p 2183
9. Ibid, p 2167
10. Ibid, p 2183

> that it needs to register...So there are bound to be a fair few ad hoc and small importers that we do not know about.[11]

4.19 The Committee believes the same statement would also apply to Australian manufacturers.

4.20 It is proposed that the new legislation will put the onus on the manufacturer rather than the Commonwealth for the required information to be entered on the Register. The Department has advised that the new legislation will also extend controls to locally produced goods.[12]

4.21 Under the proposed legislation it will be an offence to supply, import or export products that are not entered on the Register or that have not been made exempt. However, there will not necessarily be any additional evaluations of the products apart from the extension of controls over the designated categories to locally manufactured goods.

4.22 The Committee considers that the Register is an essential element in the Commonwealth's controls over therapeutic goods (both drugs and devices), particularly following the introduction of the proposed legislation. Every effort should be made by the Department to ensure the Register's completeness and accuracy.

4.23 The Committee acknowledges the concerns of the Australian Medical Devices and Diagnostics Association Incorporated (AMDADA) which stated that past experience has shown that increasing regulation leads to an increase in costs to both the suppliers and the government. In particular, AMDADA stated that the cost of the notification of products to the National Register of Therapeutic Goods has been in the order of tens of thousands of dollars and that further resources will continue to be expended by both industry and government in updating the Register.[13]

4.24 However, the Committee believes that the existence of such a Register can only benefit consumers and industry alike when reacting to issues such as hazard alerts, recalls and complaints.

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11. Ibid, p 2184
12. Ibid, pp 2183-4
13. Ibid, p 1010

Evaluation

4.25 As previously indicated only certain imported devices are legally required to be evaluated prior to supply to the Australian market. Locally manufactured devices of the same category are not required by law to be evaluated, but co-operation with local industry ensures that they are.

4.26 Prior to the establishment of the Medical Devices and Dental Products Branch in February 1987 some medical devices were evaluated. These were medical materials or products considered to be devices but which fell into the category of therapeutic substances eg medicated IUDs, certain tissue materials, certain materials inserted into the eye during surgery and some electrical devices. These evaluations had been carried out by the Drug Evaluation Branch of the Department since 1970.

4.27 The formal evaluation program which extended to areas outside therapeutic substances came into effect in February 1987.[14] The Department has issued guidelines, DG1 'Guidelines for preparing applications for the general marketing or clinical investigational use of designated therapeutic devices'.

4.28 The lack of import controls over the vast majority of devices that enter Australia each year is of major concern to the Committee. As previously indicated, some 84% of devices on the Australian market are imported.

4.29 As it is legally possible to import devices into Australia that are banned overseas, the Committee sought the Department's advice as to whether any device had been the subject of such a prohibition overseas.

4.30 The Department advised the Committee of eight examples. They included:

- intra aortic balloon - used inside an artery to clear blockages or expand it to improve the blood flow; and
- programmable ventilator - used for anaesthesia and the ventilation of patients.[15]

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14. Ibid, pp 2181-2
15. Ibid, pp 2192-4

4.31 In its written advice concerning the above two examples, the Department stated they were:

> ...examples of a medical device whose importation should and could have been prevented if there were adequate resources and legislative backing.[16]

4.32 The Department advised that it became aware of the problems with these two devices as a consequence of monitoring USA Food and Drug Administration activities and then checking whether such products have been imported into Australia.[17] However, other countries do not publish information in the same manner as the USA, which means Australian authorities do not necessarily become aware of problems in other countries.[18]

4.33 One control over the importation of products into Australia comes not from Australia but from the USA. The export controls in that country require that if the product is not acceptable for sale in the USA, then specific approval from the regulatory agency in the importing country is required.[19]

4.34 The Department advised in July 1988 that it had given approval for the importation of a number of devices which were not approved for general marketing in the USA.[20] The Department was able to subsequently advise the Committee that in relation to the two previously mentioned devices, no record of such a letter had been found.[21]

4.35 The Department further advised however that TDEC had recently resolved that the Department was not to permit the importation of devices that were known to be unsafe. One difficulty the Department saw was that until the product is actually in Australia, the Department has legally 'little ground' to take action. Once in Australia the Trade Practices Act can come into force through the recall process.[22]

4.36 The Committee is very concerned that, given the method by which the Department obtains information about products, plus the unavailability of such information from some countries, a number of unsafe devices have been and could be on the market in

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16. PAC file 1987/6 B(15)(3)
17. Minutes of Evidence, op cit, p 2194
18. Ibid, p 2195
19. Ibid, p 2199-2200
20. Ibid, p 2200
21. PAC file 1987/6 B(21)
22. Minutes of Evidence, op cit, p 2200

Australia. There is no obligation on the importer to disclose such information.

4.37 The Committee recognises that a requirement for such disclosure will not necessarily prevent problems arising when devices are in use or detect them when they occur. However, it is one means whereby the almost totally free market can be regulated for the benefit of the Australian public.

4.38 The Committee has put to both TDEC and the Department the question of whether interim measures could be taken by amending the Customs (Prohibited Imports) Regulations to prevent the importation into Australia of devices banned overseas.

4.39 The Committee notes that the submission from TDEC referred to its view that the sale of products deemed unsafe by international authorities should be restricted. The submission stated, referring to TDEC minutes of December 1987:

> Accordingly, on a for comment basis, TDEC propose that the sale/importation of devices identified as unsafe by other regulatory bodies should be restricted to the maximum extent possible under current legislation, subject to manufacturers successfully arguing, on a case by case basis, that the restriction should not stand.[23]

4.40 During May 1988 the Committee took evidence from the Chairman and Secretary of TDEC. The Secretary of TDEC is also Head of the Medical Devices and Dental Products Branch of the Department. At that hearing TDEC's views were sought:

> CHAIRMAN - I cannot see why there is not a system whereby there is a requirement that a person wishing to import has to certify that a device is not the subject of prohibition from sale in the United States, Canada, or whatever other jurisdictions we choose. Why cannot that be done by regulation tomorrow?
>
> Dr Beech - I suppose it could be. We would be relying on the person who is importing the goods to make that declaration and to be aware of the facts and if we found out later we would take some sort of legal action.

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23. Ibid, p 826

CHAIRMAN - It is not only the potential civil liability but there would be - as there well ought to be - potential criminal liability. This is an area that does not need to wait what could be a year or longer for national legislation. This is a problem which could be addressed...

Dr Beech - The onus could be put on the importer to make that sort of declaration. That would be quite possible.

Dr Hughes - The Committee has looked at this and it is as major a concern for us as it is for you. We are not so bold as to tell you how to make the law, but we would be grateful that those devices be prohibited to the maximum extent that they are prohibited by law, and if the law can be changed in order to do that we would support any moves in that direction. It may well be that another form of designated device is one that has been deemed unsafe elsewhere.

CHAIRMAN - Yes, and one of your duties under the terms of reference is to furnish advice to the Minister relating to the importation of devices.

Dr Beech - That is the difference between the devices and the drug area at the moment in that in the drug area generally everything is screened. In the devices area only specific categories are screened, the rest are not. The only other thing that that importer may have to do currently, other than just bringing it through Customs and paying the tariff, is that if he has been served a notice requiring him to register products on the national register of therapeutic goods then he would have to register it on the national register of therapeutic goods.[24]

4.41 At that hearing the proposition put by the Committee was considered feasible. When that evidence was given the Committee was expecting the legislation to be introduced in the Autumn Sittings 1988 at the latest, with a possibility of the Budget Sittings 1988.

4.42 When the same proposition was put to the Department, including the Head of the Medical Devices and Dental Products Branch, some six months later in November 1988, the Committee was

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24. Ibid, pp 857-8

surprised to hear that there had been no consideration of the proposal, either following on from the Committee's hearing or as a result of the TDEC minute:

> CHAIRMAN - Mr Roche, if your Minister said to you, `I want to stop the importation of medical devices that are prohibited' - let us assume we have a little definition which will satisfy the Minister of what we want to stop - `and I want that done as quickly as we can humanly do it as a department'...how quickly can we get that prohibition in force through the Customs regulations, assuming that we have a definition that is going to be acceptable?
>
> Mr Roche - I could not say at this stage without looking at the detail of it. As Dr Beech has said, we have 3 000 categories of device alone which have somehow got to be adequately prescribed in the regulations. I am not sure how long it would take us to do that effectively. That, I presume, just gets you to the stage of a prohibition. Then we need to introduce some sort of screening process on top of that.
>
> ...
>
> CHAIRMAN - How long would it take if I wanted to introduce - however unreasonable it might be - an outright prohibition on the import of medical devices which are banned in another country overseas?
>
> ...
>
> Mr Roche - I think it would be a significant task, Mr Chairman. I could not put an estimate on it.
>
> Mr Pflaum - If it was by their declaration, I think it could be done fairly quickly. I was searching for an analogy in my own mind and the closest analogy I could come up with was the Chernobyl disaster and imported food.
>
> ...
>
> CHAIRMAN - You see, one thing you could do is you could prohibit unless the federal Department of Health gave its approval. So at least then the onus, the obligation, the

responsibility, the legal prohibition is in place. We have done our bit as a country and as a government and as a department to protect the public interest. That is what I would argue. Why cannot we do that?

Mr Roche - It already applies in respect of drugs. You cannot import them without our approval.

Dr Beech - You are basically putting devices on the same basis as drugs. That is what you are saying. That is what it means, because drugs at the moment have that prohibition, so you are putting devices into the category.

...

CHAIRMAN - We impose that prohibition unless the Department of Health consents. If it is banned overseas, it is prohibited from being sold here unless the Department of Health says otherwise. That seems to me to be fundamental. If someone has a product that he wants to sell here you have the issue of examining where the prohibitions are overseas and whether, on balance, it should be imported. But at least you know about it. Again the Department's attention is focused on the problem.

...

Mr Pflaum - If I may say so, Mr Chairman, I think it is quite unrealistic a proposition but it could be done in that space of time, which is what I said. But what we would, effectively, be doing is keeping devices out of the country-----

CHAIRMAN - But banned overseas.

Mr Pflaum - Which are banned somewhere overseas - in one country at least, somewhere overseas.

...

CHAIRMAN - The problem that you are advancing, Mr Pflaum, is that it is better to have open slather, open season, free market, no regulation, import what you want no matter what happens elsewhere in the world, than to have a system where your Department is placed

on notice about problem areas. That really is all I am advocating. I am just speechless that you are resisting this. I am just amazed - I am just amazed.

Mr Roche - Mr Chairman, I think you are misrepresenting the departmental position.

CHAIRMAN - Set us straight.

Mr Roche - The departmental position is that we are trying to do a proper, professional job of evaluation on priority items, and we have looked at the ones that we consider to be the most significant from a therapeutic point of view. What you are suggesting is that we should engage in what would be a very large administrative effort to cover the field in a way that is not going to be totally effective. We know that many of the problems that arise with devices can arise after the product has actually passed the import barrier and it is actually in the country. That occurs for reasons that we have already discussed - recall of a particular batch; product approved, batch recalled.[25]

4.43 The Committee views the lack of consideration of a proposal to restrict in Australia the sale of products that have been assessed as unsafe by overseas authorities as most serious. This is particularly so as it appears that the suggestion has been on the agenda for discussion since at least December 1987 at a TDEC meeting, the Ministerial advisory body.

4.44 The Committee notes AMDADA's concerns regarding the need to look at the reasons a product was banned overseas if import control is used as a means to regulate industry. The Association's preference for the Register to be used as the point of control is also noted.[26] However, the Committee is of the view that as the Register, both currently and in the future, imposes little control or assurance over the safety and effectiveness of medical devices, apart from the five designated categories, it cannot be used for control purposes. One benefit the Register will have in the future is ensuring manufacturers compliance with the Code of GMP, because of the licensing system.

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25. Ibid, pp 2203-7
26. Ibid, pp 1043-5

4.45 The Committee recommends that:

. The Department of Community Services and Health urgently consider and implement means by which improved control can be exercised over devices entering Australia:

- Determine if there are any further devices on the Australian market that have been subject to regulatory action by comparable overseas authorities.

- Examine its records to determine whether any letters have been issued to USA companies to authorise import into Australia of devices that have been subject to regulatory action in the USA with a view to reviewing the authorised devices in Australia.

- That companies be required to advise the Department if a device marketed in Australia has been the subject of regulatory action by a comparable overseas authority. Marketing approval should only be given if the Department is satisfied the product is safe.

These measures should be examined as an interim measure pending passage of the proposed legislation as well as a requirement after that.

Extension of designated categories

4.46 The issue of what or whether other medical devices should be evaluated is a question that has concerned the Committee. Accordingly the Committee has put it to a number of witnesses including the Department, TDEC and AMDADA.

4.47 The Department advised the Committee that it has engaged a consultant to compile a statistical database to be used in developing priorities for evaluation of devices. This model aims to be a systematic framework which the Department can use to work out the most critical of the devices requiring attention. It is expected that this will be completed in late 1988.[27]

4.48 Both the Department and the Therapeutic Device Evaluation Committee gave evidence that there are additional devices that should require evaluation before marketing and that this evaluation should be extended by legislation to cover both imported products and locally produced goods.

4.49 The Department currently believes that 'there are fairly obvious areas' of devices that should be examined from a public health point of view. These include:

- equipment for maintaining the cardiovascular system;
- anaesthetic and ventilation equipment;
- certain implanted products;
- products that apply a direct current to the body; and
- devices made of biological products.

4.50 The Department advised that the selection of the above examples followed analyses done on problems reported both in Australia and the USA, where some of those items appear as major causes of death and/or injury. Other witnesses have given similar evidence.[28]

4.51 It has been stated by several witnesses that many of the problems with devices occur after the product has been supplied and when in use and those problems would not necessarily become apparent during evaluation. AMDADA suggested that evaluation procedures will only detect fundamental safety or efficacy problems but will not detect inherent design faults or prevent inappropriate modification or utilisation of the device by the user. Inadequate care in maintenance and use are also factors.[29]

4.52 AMDADA also suggested that ongoing analysis should be carried out to assess whether, following the introduction of pre-marketing evaluation for particular categories of devices,

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27. Ibid, pp 860, 2186
28. Ibid, pp 867-8, 2186-7
29. Ibid, p 1012

the incidence of problems due to the products themselves rather than the surgical or other procedures associated with them declines.[30]

4.53 The Committee acknowledges the need for persons using devices to stay up-to-date to avoid user error or failure error. If such an analysis shows such an error, then an appropriate education program should be devised.

4.54 The Committee acknowledges that the selection of five categories of device to be designated as requiring evaluation is, given the scarce resources available to the Department, a responsible approach. The Committee also accepts that it is impractical and would not be beneficial to the public for every device to be evaluated.

4.55 The Committee believes the Department should review its list of designated devices requiring marketing approval before supply to the Australian market on the basis of what is desirable for public health and safety. The statistical model, data from overseas regulatory authorities and data from Australian experience to date should all be used.

4.56 If this list of devices is greater than resources would allow, then the Committee is strongly of the view that the Department should reconsider the resource allocation within the Department. The Committee believes that these issues are ones that the advisory committees should be bringing to the Minister's attention.

4.57 The Committee recommends that:

- The Department of Community Services and Health review its list of designated devices requiring marketing approval before supply to the Australian market on the basis of what is desirable for public health and safety. The statistical model, data from overseas regulatory authorities and data from Australian experience to date should be used.

- If this list of devices is greater than resources would allow, the Department of Community Services and Health should

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30. Ibid, p 1011

> reconsider the resource allocation within the Department. The advisory committees should draw the Minister's attention to these issues.

Delays in the process

4.58 In common with the drug evaluation process, delays in the evaluation and approval process for devices have been referred to. AMDADA, whilst agreeing with the approach of selecting certain categories of critical devices for pre-market evaluation, stated that its members have indicated a general concern regarding the timeliness of approvals, particularly in relation to intra-ocular lenses and drug infusion devices. AMDADA suggested that this could be due to a lack of staff and/or expertise and also uncertainty regarding the depth of data required by the Department.[31]

4.59 The Department has since advised the Committee that there were some delays in the middle of the year while procedures were being developed but evaluation times are now substantially reduced.[32]

4.60 TDEC did not consider that there have been unreasonable delays due to the targeting of particular groups of devices. However, it was stated that the question of resources means that:

> ...we are having some difficulty moving from an embryonic program...to an operational program.[33]

4.61 The Secretary to TDEC went on to state that the Branch was at a 'very critical phase now'.[34]

4.62 One option that could be examined is the greater use of overseas evaluations by Australian evaluators. The Chairman of TDEC indicated that the Committee is interested in developing international evaluation procedures or at least co-operative ones in order to streamline activities and make the best use of resources.[35]

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31. Ibid, p 1011
32. PAC file 1987/6 B(21)
33. Minutes of Evidence, op cit, pp 861-2
34. Ibid, p 864
35. Ibid, p 861

4.63 The use of overseas evaluation procedures by the Department is generally supported by witnesses in order to reduce the time and resources spent by the Department in carrying out its tasks with the effect of evaluating devices more quickly.

4.64 Another option that has been advanced is that the Department could encourage a university or industrial group to conduct a research project rather than evaluate a product itself.[36]

4.65 The Committee supports the Department making effective use of evaluations from comparable overseas countries.

4.66 The Committee recommends that:

- **The Department of Community Services and Health make effective use of evaluations from comparable overseas countries in the Australian device evaluation program.**

Diagnostic products

4.67 Diagnostic products are used to determine the existence of particular conditions in order to determine whether medical treatment is necessary. Examples of in-vitro diagnostic products include AIDS virus tests and pregnancy tests. There is also an increasing number of self-diagnostic kits on the Australian market including urine tests used by diabetics, a kit to test for blood in faeces as an indicator for early signs of bowel cancer, pregnancy and ovulation kits. Other types of self-diagnosis units available are units to measure blood pressure and lung capacity.

4.68 This third category of products, as distinct from drugs and devices, is an area of increasing productivity overseas, but the Department advised the Committee that 'we presently have little or no resources devoted to this activity here'.[37]

4.69 The Committee is concerned that, despite the Department's comments that in-vitro diagnostics are an increasingly large group of products which can sometimes be therapeutically significant, the proposed legislation will exempt from registration or listing most in-vitro diagnostic products.

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36. Ibid, p 1055
37. Ibid, p 2188

4.70 The Committee was further concerned to find that the Department had not yet determined what products would be registered or listed, despite the discussion paper on the legislation being made available in October 1988 for comment. When questioned, the Department stated that AIDS and glucose tests were examples of the type of items that would probably not be exempt.[38]

4.71 The Committee believes that the availability and use of such self-diagnostic kits by the public is an indication of an increasing awareness of the role of the individual in health care and should not be discouraged. The lack of evaluation of such kits, particularly those which may be used as an initial diagnostic tool in a potentially life-threatening illness, is of real concern. The Departmental witness stated:

> ...then there is this quite aggressive marketing to the public, and those kits which are being sold to the public are not being tested at the present time.[39]

4.72 The Committee recommends that:

- The Department of Community Services and Health should review comparable overseas literature and procedures to determine its own evaluation procedures for diagnostic products.

- The Department of Community Services and Health examine the category of products known as diagnostics and determine which, if any, require immediate evaluation prior to introduction of the proposed legislation.

- The Department of Community Services and Health should determine whether diagnostic products fall into the drug, device or another category of therapeutic good and also whether Australian Drug Evaluation Committee or Therapeutic Device Evaluation Committee is the appropriate and relevant advisory committee.

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38. Ibid, pp 2189-90
39. Ibid, p 2191

Chapter 5

GOOD MANUFACTURING PRACTICE

Inspections

5.1 The Inspection Section, Pharmaceutical Laboratories Branch, carries out inspections of manufacturers of therapeutic goods in Australia. The Code of Good Manufacturing Practice (GMP) is the criteria against which the competence of companies to manufacture various categories of therapeutic goods is assessed.

5.2 There are two Codes of GMP, one for pharmaceutical manufacturers and one for manufacturers of sterile medical devices. These Codes were prepared by the Department in consultation with industry and the States. These Codes are internationally recognised as a means of regulating the quality of therapeutic goods for use in Australia and for export.

5.3 The Code sets out requirements relating to premises, equipment, personnel, documentation and quality control. The observance of these requirements is necessary through all stages of manufacture and handling if high quality production is to be consistently achieved and contamination, deterioration, errors, omissions and mix-ups avoided.

5.4 The majority of inspections of premises are carried out in conjunction with State health authorities.

5.5 The Department does not regularly inspect overseas manufacturing premises but when visiting overseas on other business will carry out inspections. There are currently some 2 700 overseas manufacturers on the Register and of these 44 have been inspected in seven countries.[1]

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1. PAC file 1987/6 B(21)

5.6 Under current legislation the Code has no legal standing and the Commonwealth has no authority to enforce the recommendations arising out of an inspection. All legislative backing for such action rests with the individual States and Territories. There is no uniformity amongst those jurisdictions. The Commonwealth's role is to ensure a uniform application and interpretation of GMP throughout Australia.

5.7 The Commonwealth does however have a final sanction in that it can delist products from the Pharmaceutical Benefits Schedule if the manufacturer is totally recalcitrant. This is not often used, although one manufacturer was delisted from December 1988.

5.8 As outlined in the Commonwealth's discussion paper on the proposed legislation, the Commonwealth will have power to enforce the recommendations of the GMP inspections and compliance with the Code will be one of the requirements for licensing of manufacturers.[2]

5.9 The Department advised the Committee that inspections will be carried out prior to a licence being given. However, inspections of established manufacturers carried out prior to introduction of the legislation will be used for licensing purposes if the standard is acceptable. The Department advised that all manufacturers who are currently considered to have critical deficiencies following GMP inspections will be inspected prior to a licence being issued.[3]

5.10 A number of the contributors and witnesses to the inquiry commented upon the inspections system and the uniform application of the standards.

5.11 Following that evidence, the Inspection Section appeared before the Committee. After hearing disturbing evidence concerning Commonwealth/State liaison in this area, the Committee sought specific submissions from all States and Territories on the matters raised by the Commonwealth. The Committee also heard evidence at public hearings from health authorities from the Australian Capital Territory, New South Wales, South Australia and Western Australia.

5.12 The Committee has been most disturbed by the evidence given in relation to inspections. Several major issues have arisen:

- Claims by manufacturers that the Code of GMP is applied in a subjective manner;

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2. Ibid
3. Minutes of Evidence, op cit, pp 2006-7

- Differences in interpretation of the Code by State and Commonwealth inspectors;
- Differences in application of the Code between States;
- Variation in the strength of legislative backing for the Code between the States; and
- Lack of enforcement of the Commonwealth standard against manufacturers that do not comply with the Code of GMP.

5.13 In response to questions by the Committee, the Commonwealth provided its own statistics claiming that one-third of manufacturers in Australia had an unacceptable standard of production methods and quality assurance controls in accordance with the Code of GMP.

5.14 The Department defined an unacceptable standard of manufacture as:

> A grossly deficient standard of general compliance which includes a large number of minor and major deficiencies, and possibly some critical deficiencies, observed to persist over successive GMP inspections.[4]

5.15 The Department further defined minor, major and critical deficiencies as:

> The critical deficiency would be one that would or could cause harm to patients and a major deficiency would be one with the potential to cause harm indirectly to patients. The minor deficiency is a fairly minor deviation from good manufacturing practice or where quality assurance is not being followed.[5]

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4. PAC file 1987/6 B(16)(2)
5. Minutes of Evidence, op cit, p 1525

5.16 The following table was provided by the Commonwealth[6]:

Comparative Levels of Compliance with Codes of GMP
(based on GMP inspections 1986-1987)

compliance level	high	acceptable	unacceptable	total
State	no.*	no.*	no.*	no.*
NSW	11 (9%)	72 (56%)	45 (35%)	128
Vic	7 (11%)	34 (52%)	24 (37%)	65
Qld	0 -	13 (68%)	6 (32%)	19
SA	1 (10%)	5 (50%)	4 (40%)	10
WA	1 (8%)	6 (50%)	5 (42%)	12
Tas	0 -	2 (66%)	1 (33%)	3
ACT	0 -	0 -	3 (100%)	3
contract testing labs (all States)	4 (27%)	9 (60%)	2 (13%)	15
Totals	24 (9.4%)	141 (55.3%)	90 (35.3%)	255

* number of companies inspected

5.17 The Commonwealth Chief Inspector, in response to Committee questions, said that a manufacturer who is more likely to have an unacceptable standard of GMP could be described in the following terms:

> It is normally a small company run by an entrepreneurial type of person who tends to skimp on spending money, particularly on quality control and quality assurance...they tend to skimp on cleaning staff, and the factory is very dirty...Staff turnover does tend to be fairly high...[the products] tend to be the over-the-counter...medicines or vitamins...they are out there to make a fast buck. That is essentially what it is, without attending to proper good manufacturing practice.[7]

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6. PAC file 1987/6 B(16)(2)
7. Minutes of Evidence, op cit, p 1535

5.18 The number of manufacturers inspected by the Commonwealth is in the order 280-300. This includes public hospital pharmacies (except in NSW) which are inspected but not on a regular basis.[8]

5.19 The Department believes that it is aware of the majority of manufacturers in Australia. There is no requirement for manufacturers to notify the Department when beginning manufacture. The Department currently obtains information through its general activities in the industry, from other competing manufacturers, word of mouth and observing new products on the market. It will however be a requirement under the proposed legislation that manufacturers be licensed.[9]

5.20 In general, inspections are carried out on a joint Commonwealth/State basis although the states do conduct their own inspections. At the completion of an inspection the Commonwealth and State inspectors discuss the results of the inspections with the manufacturer. A report is later prepared by the Commonwealth on deficiencies found which is sent to the State authority for forwarding to the manufacturer.[10]

5.21 The major difficulty facing the Commonwealth is the lack of an enforceable national standard and varying or non-existent licensing systems within the States and Territories. The Commonwealth advised the following regarding licensing systems[11]:

Australian Capital Territory, Northern Territory, Queensland and Tasmania	- No licensing system
Western Australia & South Australia	- Licensing system only covers those products which are subject of a monograph in the British pharmacopoeia (devices and many products sold over-the-counter are not covered)

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8. Ibid, pp 1533-4
9. Ibid, pp 1543-5
10. Ibid. pp 1547-8
11. Ibid, pp 1550-1; PAC file 1987/6 B(16)(2)

New South Wales	- A comprehensive licensing system but it does not cover medical gases, bandages and dressings and medicated cosmetics
Victoria	- Licensing system relies upon the poisons schedule. Products such as vitamins, sterile injectables, and most over-the-counter products are not covered.

5.22 The Department advised the Committee that it applies the same standard of GMP regardless of the state in which the manufacturer is located, but that the Commonwealth does 'not get the backing of the legislation available in some of the states to enforce GMP standards'.[12] The Committee notes that circumstances vary widely across Australia. In some States and Territories there is no legislation under which GMP can be enforced, other States have inadequate legislation while others have comprehensive legislation but interpret and apply the Code differently to the Commonwealth.

5.23 During the inquiry the Committee heard evidence from manufacturers that there appeared to be double standards operating. For example, if a company could afford it, a higher standard of GMP was demanded while other organisations, such as sheltered workshops, manufacturing similar products, are not required to meet the same standards.[13]

5.24 When the Committee put to the Department the question of subjectivity and the uniform application of the Code, the Department stated that action on the report was taken by the States. However, there is no uniformity amongst the States, which have variable standards and variable legislation. The final outcome can be different between different jurisdictions but the actual report is uniform across those jurisdictions.[14]

5.25 The Department, however, acknowledged that the frequency of inspections does vary. The Inspection Section's objective is to inspect every manufacturer in Australia every 12 months. However, resources do not permit that and inspections have been categorised into six monthly (problem manufacturers),

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12. Minutes of Evidence, op cit, p 1527
13. Ibid, pp 402-10, 575
14. Ibid, p 185

12 monthly (run-of-the-mill manufacturers) and 18 monthly (`very good' manufacturers, mainly multinationals). The Department stated that:

> In practice, some of the 12 monthly inspections we may not get back to for 18 months and some of the 18 monthly inspections we would like to get back to we probably do not get back to for 24 or even 36 months.[15]

5.26 In addition to planned, announced inspections, there are also unannounced visits to problem manufacturers. The Commonwealth, however, claimed that some of the States give notice to the manufacturers when an unannounced inspection is planned thus not supporting the Commonwealth's intentions in this regard.[16]

5.27 The Committee heard a number of assertions from the Commonwealth regarding their liaison with state health authorities. The main concerns of the Inspection Section were that:

- There is generally a lack of co-operation from states regarding joint Commonwealth/State inspections of therapeutic goods manufacturers;
- State governments do not always take up Commonwealth recommendations with the manufacturer with the result that some major and critical deficiencies in manufacturing practice are not rectified; and
- State officers who accompany Commonwealth officers have no pharmaceutical production or quality control experience, with the exception of those from NSW.[17]

5.28 Following this evidence the Committee wrote to all State and Territory health authorities seeking comments. All responded. The Northern Territory advised that it does not have any manufacturers of therapeutic goods.

5.29 The Committee called for and heard evidence from the Australian Capital Territory, New South Wales, South Australian and Western Australian health authorities and appreciates the co-operation received from these State and Territory authorities.

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15. Ibid, p 1528
16. Ibid, p 1529
17. Ibid, pp 1547-8, 1552

ACT Community and Health Service

5.30 The Committee was concerned at the evidence given in relation to manufacturing standards in the ACT. This is particularly so as the Commonwealth has jurisdiction in the ACT, although responsibility for ACT health matters rests with the ACT Community and Health Service, part of the Arts, Sport, the Environment, Tourism and Territories portfolio, not the Department of Community Services and Health.

5.31 The ACT does not have legislation to licence manufacturers and as such there is no requirement for the manufacture or sale of therapeutic products to be notified to the ACT Community and Health Service. The ACT has a preliminary draft ordinance prepared but advised that it is unlikely that it will be made before the proposed new legislation is enacted.[18]

5.32 The Commonwealth stated that there is inadequate notification by the ACT of the existence of manufacturers in the ACT. It was also asserted that there is a lack of feedback to the Commonwealth regarding action taken by the Service.[19]

5.33 In response, the ACT Community and Health Service agreed that, whilst it was its policy to notify the Department of Community Services and Health of all known commercial manufacturers of therapeutic goods, it had never done so. However, the ACT has encouraged one manufacturer to approach the Department for an inspection.[20]

5.34 The Committee is concerned at the lack of co-ordination between two arms of the Commonwealth government. It was clear from the public hearing that there is a need for greater communication with the Department of Community Services and Health regarding manufacturers and their standards of GMP.

5.35 In particular the Committee was surprised to find that the witness regarded the current system of inspection and liaison with the Department as satisfactory despite certain identified weaknesses.[21]

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18. Ibid, p 1629
19. Ibid, pp 1543-4
20. Ibid, p 1651
21. Ibid, p 1653

NSW Department of Health

5.36 The Commonwealth has made a number of serious comments about the quality of manufacture within New South Wales.

5.37 In the Commonwealth's view, 35% of NSW manufacturers do not comply with current GMP, despite a licensing system. In 1987-88, 128 manufacturers were inspected and 45 were considered by the Commonwealth as unacceptable. Of the 45 unacceptable, 21 have persistent minor, major and critical deficiencies.[22]

5.38 The Commonwealth believes that NSW, whilst having a comprehensive licensing system, does not show a lower non-compliance rate with the Code of Good Manufacturing Practice than the States that do not have a licensing system. It was stated that the implementation of recommendations of the (Commonwealth) inspectors is not to an acceptable standard in NSW.[23]

5.39 The Commonwealth stated that the majority of problems that arise with NSW concern differences in interpretation of what constitutes an acceptable level of compliance with the Code of GMP. The Commonwealth asserts that NSW is often unwilling to accept the need for international standards of GMP `unless there is a demonstrable health risk'.[24]

5.40 The Commonwealth is of the view that NSW does not have the same standards as authorities overseas (knowledge gained through joint overseas inspections) nor those of the Commonwealth. The Commonwealth continued by stating:

> They regard our standard of GMP as too high.[25]

5.41 The Commonwealth is of the view that to participate in overseas agreements and to facilitate exports Australian GMP standards must be comparable with other developed countries.[26] It is also the view of the Commonwealth that NSW tends to be very parochial and protective of local industry.[27]

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22. Ibid, p 1730; PAC file 1987/6 B(16)(2)
23. Ibid
24. Ibid
25. Minutes of Evidence, op cit, p 1555
26. Ibid, pp 2126, 2132
27. Ibid, p 1554

5.42 The Commonwealth provided the Committee with correspondence from a recognised overseas regulatory authority to the effect that, with one or two exceptions, the standards of manufacture are more than a decade behind those of Western Europe.[28] NSW takes the opposite view and considers that the NSW standard is as good as many countries, and better than some, provided that good practices in manufacture are not confused with the excellence of the premises.[29]

5.43 The NSW Department of Health does not agree with the views put by the Commonwealth. NSW emphasises that it is the State inspectors who carry legal responsibility for the enforcement of the Code of GMP and therefore need to ensure that Commonwealth recommendations are substantial and defensible under the (NSW) Therapeutic Goods and Cosmetics Act.[30]

5.44 In respect of NSW's response in relation to Commonwealth recommendations for disciplinary action, the Commonwealth stated that there is often a difference of opinion although both health authorities do agree on certain cases. It is generally a matter of interpretation.[31]

5.45 The NSW officials told the Committee that its inspection and licensing program is based on a spirit of helpful co-operation rather than an adversarial approach to doing things.[32]

5.46 NSW advised the Committee that of the 144 companies licensed to manufacture substances or devices over the period January 1986 - August 1988, it considered 43 as needing a `concentrated effort from both Commonwealth and State inspections to lift the level of compliance'. Of this 43 there is a core group of 31 that were also on the Commonwealth's list. Of those 31, six had ceased production or held licences that were inoperative.

5.47 NSW is of the view that the remaining 25 is of concern. This is some 17% of companies, a lower figure than the Commonwealth's 45 of 128 companies.[33]

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28. PAC file 1987/6 B(16)(2)
29. Minutes of Evidence, op cit, p 1726
30. Ibid, p 1687
31. Ibid, p 731
32. Ibid, p 1746
33. Ibid, p 1749-50

5.48 When addressing the question of varying interpretations of the Code of GMP, NSW stated:

> I think there are very few instances...in which the Commonwealth and State inspectors disagree on the nature or extent of deficiencies in compliance with the Code in the case of the particular company. What sometimes does occur, however, is a difference of opinion as to what should be done to effect a correction of those deficiencies...As the licensing authority is New South Wales, that decision must rest with New South Wales, as it stands at the moment.[3]

5.49 Compliance with the Code of GMP is a condition of a licence to manufacture therapeutic goods in NSW. If a company is deemed not to comply, then grounds exist for suspension and cancellation of the licence.[35]

5.50 However, whilst this option exists, NSW believes that cancellation or suspension should be used as a last resort when other corrective measures have failed whereas the Commonwealth may suggest that the action be more immediate. NSW uses exhortation, persuasion, encouragement and education as the thrust of its system.[36]

5.51 Certain activities, such as bandage manufacture, do not need to be licensed.[37]

5.52 The Committee acknowledges that NSW has a comprehensive licensing system and notes the Department of Community Services and Health shares this view. The Committee is particularly concerned at comments regarding the standard of GMP in NSW due to the very large percentage of Australian manufacturers that operate from that State, and also the large number of major companies.

5.53 The Committee believes that the major problems between the Commonwealth and NSW are interpretation and assessment of the type and strength of action to be taken. The Commonwealth would appear to take a more aggressive role than NSW in upholding the Code.

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34. Ibid, p 1755-6
35. Ibid, p 1758-9
36. Ibid, p 1765-7
37. Ibid, p 1770

5.54 NSW appears to view compliance with GMP from a slightly different angle, preferring to encourage industry for a longer time prior to final sanctions coming into force.

5.55 The Committee notes that it is NSW that has to revoke or suspend a licence and defend such a sanction if the manufacturer objects and takes legal action.

5.56 The Committee acknowledges that NSW has in place a more comprehensive regulatory system than most other States and notes that its legislation has been used as a model by other, smaller States. The Committee also acknowledges that NSW has put in place a range of sanctions to be used against recalcitrant manufacturers and has in fact used certain sanctions. The Committee, however, notes that the interpretation of the Code of GMP varies between NSW and the Commonwealth inspectors as does the assessment of the type of action required. The Committee notes that both NSW and Commonwealth officials acknowledge such differences.

South Australian Health Commission

5.57 The Commonwealth, in written information to the Committee, stated that South Australia has tolerated for many years companies showing poor compliance with GMP and rarely suspends or revokes a manufacturer's licence. However one manufacturer has recently been persuaded to cease manufacture.[38]

5.58 The Commonwealth advised the Committee of three manufacturers who have poor compliance with GMP and have had persistent deficiencies since the early 1980s.[39]

5.59 The Committee was surprised to learn from the SA official that:

> There is no doubt that the three companies mentioned here do not comply with the standards of the Commonwealth inspecting officers. Whether it is true to say that they do not comply entirely with the Code of GMP may be a matter for dispute and a bit of debate. These three companies are historical manufacturers in South Australia who, to my

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38. PAC file 1987/6 B(16)(2)
39. Minutes of Evidence, op cit, p 1848

> knowledge, were licensed to manufacture well before 1980; they were well established at that time, and since that time have continued because they have been based in this historical legislation situation where we do not have the power to withdraw a licence which has been granted for manufacture of therapeutic substances under the old drugs Act.
>
> ...
>
> The legislation, as it exists now and existed prior to 1980, is not effective, not valid, when it talks in terms of withdrawing licences that have been granted by the Central Board of Health to manufacture.[40]

5.60 The official also advised of a new Act which provides for licences and withdrawal of licences, the Controlled Substances Act 1984, but for which Regulations have been drafted to bring the Act into effect but have never been finalised.[41]

5.61 When the SA licensing procedures were described as a manufacturer gaining a licence for life, or perhaps 'a licence to kill', the SA official agreed.[42]

5.62 Of the eleven manufacturers operating in SA it is considered by that State that the Code of GMP is 'not entirely met by any of those companies'.[43] The official stated that SA has no evidence that any of the companies which have major and critical deficiencies are producing products injurious to health.[44]

5.63 The Committee was concerned to hear of one manufacturer (a sheltered workshop) of bandages and dressings that did not comply with GMP and subsequently ceased manufacture. What surprised the Committee was that although the manufacturer had government contracts and supplied SA's major hospitals, the SA health authorities responsible for licensing and GMP were not aware of its existence prior to advice by the Commonwealth.[45] The SA official stated:

> We would have to say that we do not know and we would not know until somebody complained about a product, or the Commonwealth

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40. Ibid, p 1851
41. Ibid, p 1852
42. Ibid, p 1856
43. Ibid, p 1859
44. Ibid, p 1865
45. Ibid, p 1869

> discovered a new name in manufacturing in interstate commerce, or it had come to notice by some other mechanism.[46]

5.64 SA stated in its submission that, in relation to the implementation of Commonwealth recommendations, as many of them as possible are taken up, but for economic reasons they cannot all be taken up at once. Liaison then takes place to establish priorities. It noted that the pharmaceutical industry in Australia is not highly profitable and that local industry needs to be encouraged for economic employment reasons consistent with adequate standards of pharmaceutical production being achieved.[47]

5.65 The Committee was most concerned at the evidence it heard from the SA Health Commission representative. He described an environment where, once given, a licence cannot be revoked regardless of how bad the manufacturer's practices. State Regulations have not been completed to give effect to certain licensing provisions and certain companies do not comply with the Code of GMP.

5.66 The Committee believes that this situation will continue until uniform national legislation is introduced by the Commonwealth and it serves to emphasise the importance and urgency of such legislation.

Western Australian Health Department

5.67 The Commonwealth advised the Committee that Western Australia has tolerated for some years several companies showing very poor compliance with GMP. Of the 12 manufacturers inspected in 1987-88, five were unacceptable. Of those five, two had persistent minor, major and critical deficiencies.[48]

5.68 The WA submission does acknowledge that States have generally failed to introduce the statutory licensing systems required to cover all forms of therapeutic goods manufacturing. However, WA does not support forcing companies out of business without risks that are demonstrable. It has taken the view that educating manufacturers as to what is appropriate is more effective than using punitive powers.

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46. Ibid, p 1870
47. Ibid, p 1747 b-c
48. PAC file 1987/6 B(16)(2); Minutes of Evidence, op cit, p 1960

5.69 WA concluded that the current system of inspections is probably as efficient as possible, given the level of resources available.

5.70 WA is expecting to proclaim legislation similar to that in NSW which will enable most manufacturers to be licensed. This legislation will give backing to enforcing the Code. Once the legislation is in place then each manufacturer will need to apply for licensing. The inspections will be used as a basis for licensing.

5.71 However, the Committee was surprised to learn that under current legislation, if a manufacturer does not comply with the Code of GMP and there are critical deficiencies, there are no powers to act against that manufacturer. The Western Australian Health Department only has power over dangerous products or if a product contains poison.[49]

5.72 The Committee was concerned at the evidence given by WA as it indicated some degree of complacency, even though the Code of GMP was recognised as an important mechanism for ensuring quality products.

Comment

5.73 The Committee has found the evidence relating to inspections of manufacturing premises and compliance with the Code of Good Manufacturing Practice to be amongst the most disturbing heard during the inquiry.

5.74 The Department, during the concluding hearings, commented:

> I should thank the Committee for being a forum where we could bring this to a focus; it has been very helpful to us as well. [50]

5.75 The Committee notes that the evidence from the Commonwealth and NSW is similar in that both authorities agree with the importance of the Code and that the current problems are a result of differing interpretation of the Code and how to implement recommendations arising from inspections.

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49. Minutes of Evidence, op cit, p 1983
50. Ibid, p 2105

5.76 The Committee also notes that the Department believes:

> Dr Graham:...the States, particularly New South Wales, seem to be taking a much more serious approach to their obligations under the licensing system.
>
> CHAIRMAN: How long would you say that has been going on?
>
> Dr Graham: Possibly since the publicity about the problems in the industry and certainly that did increase the communication with New South Wales.[51]

5.77 The Committee acknowledges that NSW has a more comprehensive licensing system than most other States. However, the importance of NSW in Australian manufacturing necessitates a common approach in ensuring a high standard of manufacture.

5.78 The Committee is equally concerned with the practices in SA and WA as it is not possible in either State to take action against manufacturers who do not comply, particularly those which have critical deficiencies.

5.79 The Committee strongly believes that, for reasons such as this, uniform legislation is essential.

5.80 The Committee is apprehensive about the interpretation and application of the Code following the introduction of the proposed new legislation. The Department stated, in response to a question concerning employment implications and the importance of industry to a State, that:

> We do envisage there is going to be some difficulty in enforcing the Code. I think we can visualise situations...where we are going to have difficulty, but that is the challenge before us.[52]

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51. Ibid, p 2124
52. Ibid, p 2008

5.81 It is of concern to the Committee that the discussion paper on the proposed legislation states that State and Territory officers will be authorised to carry out inspections and other duties on behalf of the Commonwealth.[53] This concern results from the obvious differences in interpretation and application of the Code.

5.82 The Committee is further concerned that the co-operation of the State and Territory governments will be needed to introduce complementary legislation to cover unincorporated bodies which manufacture and supply only within one state.[54] From the evidence the Committee has seen it is these smaller bodies that are more likely to have major or critical deficiencies in their practice.

5.83 The Committee recommends that:

- The Department of Community Services and Health increase its education program of both State and Territory good manufacturing practice inspectors and manufacturers.

- The Department of Community Services and Health enter into discussions with State and Territory governments with the aim of signing agreements regarding introducing complementary legislation to allow enforcement of the Code of Good Manufacturing Practice for unincorporated bodies that operate intra-state.

- The Department of Community Services and Health advise all manufacturers of the requirements under the proposed legislation and the need to comply to ensure licensing under the new legislation.

Overseas manufacturers

5.84 As previously stated, the vast majority of overseas manufacturers who supply goods in Australia are not inspected by

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53. PAC file 1987/6 A(2)
54. Ibid

Australian inspectors. Inspections are generally conducted if the inspector is overseas on other business, although there is a more regular program with New Zealand.

5.85 The PSB Review recommended that adherence of overseas manufacturers to a Code of GMP should be determined by either inspections by Australian inspectors on a cost-recovery basis or entering bilateral or multilateral inspector conventions.[55] The Department advises that one problem with a cost-recovery basis is having enough experienced inspectors to be able to carry out such inspections.[56]

5.86 In supplementary information to the Committee, NSW made the following observation:

> With respect to the question of unsafe goods it would be interesting to ascertain whether the Commonwealth can provide absolute assurance that the Australian public is not 'placed at unnecessary risk of receiving sub-standard and possibly unsafe therapeutic goods' which are imported from countries which do not achieve the standards of GMP applied in Australia.[57]

5.87 The Committee believes that NSW addresses a valid concern in relation to overseas manufacturers. If the Commonwealth is to impose and demand high standards from Australian manufacturers the same standard should be expected from overseas manufacturers.

5.88 The Department, in an attempt to assure itself regarding the quality of overseas manufacturing practice, is looking to enter into bilateral and multilateral agreements.

5.89 Australia has been holding discussions with the United Kingdom, United States of America, Canada and New Zealand regarding bilateral agreements. Discussions have not commenced with countries in South-East Asia.[58]

5.90 Australia also applied to join the Pharmaceutical Inspection Convention (PIC), a multilateral agreement which includes European and Scandinavian countries, in August 1987.[59] Under both those types of agreements Australia would be

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55. PSB Review, op cit, p xii recommendation 25
56. Minutes of Evidence, op cit, p 2128
57. PAC file 1987/6 B(17)(2)
58. Minutes of Evidence, op cit, pp 2128, 2130-1
59. Ibid, p 2129

exchanging inspection reports of an equal standard. In addition there would be regular meetings and flow of information between the countries.

5.91 Australia's application to join PIC has been rejected because of a lack of uniform legislation in relation to licensing of manufacturers and enforcement of GMP. PIC will only deal with a national body[60] and Australia currently has nine different State, Territory and Commonwealth health authorities.

5.92 Similar difficulties have been encountered with the bilateral discussions.[61]

5.93 The Department advised that it is very important to join PIC before 1992. After that date a barrier will be established which may prevent Australian goods entering the European market.[62]

5.94 There are no concluded agreements.[63]

5.95 In addition to products Australia imports under such agreements being accompanied by assurances as to quality, Australian exporters would also be advantaged for the same reason. An example was given of a company which could not conclude an export agreement with a British company because Australia is not signatory to an inspection agreement.[64]

5.96 The Committee is most concerned that Australia has not been in a position to enter agreements, either bilateral or multinational, due to the lack of national legislation.

5.97 This is possibly endangering the Australian public as well as reducing Australian companies' export opportunities.

5.98 Under the proposed legislation, overseas manufacturing practices will need to be acceptable.[65] The Committee views the entering into of agreements as the most desirable manner to do this.

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60. Ibid, p 2129; PAC file 1987/6 B(21)
61. Minutes of Evidence, op cit, p 2131
62. Ibid, p 2130
63. Ibid, p 2131
64. Ibid, p 2132
65. PAC file 1987/6 A(2)

5.99 The Committee recommends that:

- The Department of Community Services and Health pursue both bilateral and multilateral inspection agreement discussions with a view to concluding such agreements as soon as possible.

Use in evaluations and PBS listing

5.100 The PSB Review recommended that, pending passage of the new legislation, the Department should investigate whether attainment of GMP Standards should be a criterion for general marketing approval and Pharmaceutical Benefit Schedule (PBS) listing.[66]

5.101 The Committee agrees with the PSB Review that there is little communication between the Inspection Section and parts of the evaluation process.[67] The Department advised the Committee that inspectors' reports are passed to the evaluation sections. However, the majority of evaluated drugs are imported and therefore inspection reports are not available. Overseas manufacturers are being asked to demonstrate their compliance with GMP.

5.102 When asked if an application for general marketing for a new drug would be approved if the manufacturer had failed to comply with GMP in relation to their existing product range, the Department stated:

> I would hope not but it is something that we have not gone into extensively, and we need to. I think the reason is that most of the new drugs which we are considering have been manufactured overseas and not locally .... We are going to ask for certification from the company concerned that it has complied with good manufacturing practice.[68]

5.103 The Committee urges the Department to obtain and take into account Australian inspection reports and to seek copies of reports of overseas inspections when undertaking both drug and device evaluations.

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66. PSB Review, op cit, p xii, recommendation 26
67. Minutes of Evidence, op cit, p 91
68. Ibid, p 2117

5.104 The Department advised that in relation to PBS listing all manufacturers of items on that schedule have been advised that they will need to comply with the Code of GMP. The Department advised that it has had six companies which were under review and one company has in fact had all its products delisted.[69] This was subsequently the subject of a Government announcement which stated that twelve other manufacturers were under threat of delisting due to deficiencies in GMP.

5.105 The Committee totally supports such action. Whilst it is desirable that GMP be of an attainable standard prior to licensing under the new legislation, under the current inadequate legislation delisting from the PBS list is the only sanction available to the Commonwealth.

5.106 The Committee urges the Department to review its list of manufacturers showing critical deficiencies to determine if this action is applicable to other manufacturers.

5.107 The Committee recommends that:

- **The Department of Community Services and Health review its list of manufacturers showing critical deficiencies to determine if further delisting from the Pharmaceutical Benefits Schedule is warranted for any manufacturers.**

WHO Export Certification Scheme

5.108 Since 1976 Australia has been a signatory to the World Health Organisation's (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. The Commonwealth Department is the certifying authority for the Scheme.

5.109 The objectives of the Scheme are to provide a mechanism whereby an importing country can satisfy itself that the product has been registered for marketing in the exporting country, that the manufacturing premises are regularly inspected and conform to GMP and obtain details of such inspections.[70] There are some 120 countries which are signatories to the Scheme.[71]

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69. Ibid, p 2133
70. PAC file 1986/6 B(16)(2)
71. Minutes of Evidence, op cit, p 1559

5.110 An export certificate is issued only when requested by the exporting company. There is no obligation to ensure that every product exported has a certificate under the WHO Export Certification Scheme.

5.111 The certificates under this Scheme are issued by the Import Export Section Evaluation Support Branch after consulting with the Inspection Section regarding compliance with GMP.

5.112 The Committee was advised by the Department that similar certificates are issued by certain States, thus creating multiple systems of issuing export certificates.[72] These certificates are known as certificates of free sale, as they attest that the product is on free sale in a particular State. Some states also certify to GMP standards on occasions.

5.113 During public hearings the Committee heard that NSW and WA were currently issuing such certificates of free sale and that SA has previously done so but has ceased the practice.[73] The Committee is not aware of the practices of other States.

5.114 The Committee was advised by the NSW officials that NSW began issuing certificates of free sale at the request of exporting companies in 1973. The officials emphasised they were not certificates of export. However, they could be used for export.[74]

5.115 These certificates generally do not refer to GMP but may do. They state that the manufacturer is licensed in NSW and that the goods are on free sale.

5.116 NSW also advised that the Commonwealth was aware of this practice and had not asked for the issuing of certificates to cease.[75]

5.117 NSW has since advised the Committee that it has ceased issuing such certificates. NSW emphasised in later correspondence to the Committee (dated 1 November) that:

> It should be repeated that these certificates have been issued by NSW as a licensing authority (which the Commonwealth is not) for some 16 years with the full knowledge and

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72. Ibid, p 1558
73. Ibid, p 1866
74. Ibid, pp 1789-90
75. Ibid, pp 1789, 1791; PAC file 1987/6 B(17)(2)

> acceptance of the Commonwealth (so long as they were not described as certificates of export-which they were not) as a service to paying licence holders...Had the Commonwealth formally requested NSW not to issue these certificates, with reasons therefore, NSW would have obliged. Despite the fact that such a request has still not been made NSW has decided to no longer issue certificates of free sale except where they are sought for purely domestic purposes.[76]

5.118 The Committee is disturbed to find that, although the Commonwealth had been critical of the States, no request has been made to stop the practice.

5.119 WA also advised the Committee that it issued such certificates.[77] The WA official told the Committee that the certificates were not noted 'not for export' or other appropriate wording, although verbal advice to that effect is given. The Western Australian Health Department has since advised the Committee that future certificates will include words to the effect that it does not imply adherence with the Code of GMP and should not be so represented.[78]

5.120 The Committee is concerned that once a manufacturer has such a certificate, particularly if its standard of GMP is not adequate and would not receive a WHO Scheme certificate from the Commonwealth, it could use the state certificate for similar export purposes.

5.121 This then places the burden on the importing country to determine the status of certificates issued by various jurisdictions within Australia. Countries not familiar with Australia's system of decentralised government may not realise that States are not signatories to the WHO Scheme. This could jeopardise Australia's international reputation if there are gross breaches of GMP which are not disclosed.

5.122 The Committee notes that SA had previously ceased the practice of issuing certificates, and NSW has now done so when they could be used for export. The Committee believes that this a responsible approach to the issue.

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76. PAC file 1987/6 B(17)(2)
77. Minutes of Evidence, op cit, p 1970
78. PAC file 1987/6 B(18)

5.123 During the course of the inquiry the Department has been critical of the practice of some States to issue certificates of free sale. The Committee was therefore surprised when the Department advised the Committee at its last hearing that it had in fact issued nine such certificates this calendar year. The Department stated that it should not have occurred and has issued a written instruction that is not to continue.[79] The Committee was further surprised when advised:

> ...it is my understanding that in at least *some of these instances, whoever the actual* manufacturer was - the applicant or the contractor - they had not met GMP.[80]

5.124 The Committee has been provided with details of the nine instances and in at least one, GMP was not complied with. A notation on the applicant's letter by the Inspection Section states `certification is not recommended. The Company does not comply with current GMP'.[81]

5.125 Under the proposed legislation it is expected that it will be an offence for any body, other than the Commonwealth, to issue such a certificate or any other document intended to achieve the purpose of a WHO certificate. The Department admits that proving the intention of certificates of free sale will be difficult. The Acting Head of the Division stated:

> I guess there will always be a sort of dividing line as to when something purports to represent a certificate and when it does not.[82]

5.126 The Committee believes that only the Commonwealth should issue certificates that may be used for export and suggests that certificates issued by States included the words `not for export purposes'. This could be included in the proposed legislation.

5.127 In the interim period, formal written requests to each State asking them to include such wording is also recommended.

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79. Ibid, p 2121
80. Ibid, p 2123
81. PAC file 1987/6 B(21)
82. Minutes of Evidence, op cit, p 2013

5.128 The Committee recommends that:

. The Department of Community Services and Health urgently and formally write to all remaining State authorities asking them to cease the practice of issuing certificates of free sale, as South Australia had done.

Chapter 6

POST – MARKETING SURVEILLANCE

Background

6.1 Post-marketing surveillance of products comprises regular inspections of manufacturing premises, testing of products, recalls of unsafe products and collection and assessment of reports of adverse reactions. Inspections were discussed in Chapter 5. These measures apply to both drugs and devices although there are some differences. Monitoring of advertising and promotion of therapeutic goods is another aspect.

6.2 The Committee believes that these measures are as important for public health in Australia as the initial evaluation processes.

Testing

6.3 The Pharmaceutical Laboratories, Biological Laboratories and Medical Devices and Dental Products Branches all selectively test products on the market to ensure safety and efficacy. Factors that the Department considers when determining which samples will be taken for testing include whether the product is listed on the PBS, the form the good takes, history of complaints and reports from GMP inspections. The sampling program is orientated toward the prescription market. Testing of the vast majority of over-the-counter products is restricted to that following complaints or other identified need due to a lack of resources.[1]

6.4 All drugs that are evaluated and gain marketing approval are now tested at the completion of that process for compliance with the specifications agreed to during the evaluation process. Drugs on the PBS list are tested every two to three years.

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1. Minutes of Evidence, op cit, pp 180-1, 2140-1

6.5 Devices are not tested on a regular and routine basis although certain devices are tested to ensure compliance with Australian standards. The majority of testing of devices follows complaints received by the Department.

6.6 Other products such as vaccines and certain diagnostic reagents are tested as part of a regular sampling program.

6.7 Samples for testing are obtained for:

- routine testing of a new product after gaining marketing approval;
- regular testing of prescription drugs on the PBS;
- regular testing of certain devices to ensure compliance with Australian standards;
- quality alert purposes after GMP inspection; and
- testing of products following consumer complaints.

6.8 The Department advises that samples are generally taken from the production line or at the wholesale level. Stability testing at point of sale is not generally carried out as it cannot be determined at what stage problems, if identified, had occurred eg manufacture, wholesale, transport or retail level. In an attempt to solve this problem the Department will be storing part of the samples collected for later stability testing and then comparing the results against those obtained at the earlier testing.[2]

6.9 The Department stated in its Annual Report 1987-88 that the proportion of substandard products identified by laboratory testing was higher in 1987-88 than previously. The Department considers that this reflects better targeting of sampling of problem products.[3]

6.10 The Committee believes that the testing program is an integral part of the process for ensuring safe and effective products on the market. There would seem to be a differently developed strategy for testing drugs on the Australian market than medical devices and diagnostic products. This in part is due to the newness of the therapeutic device program and the Committee notes that testing is a component of that program. The

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2. Ibid, p 2141
3. Department of Community Services and Health Annual Report 1987-88, AGPS, Canberra, 1988, p 39

Committee is of the view that testing of devices and diagnostic products needs to be undertaken on a targeted basis where the device or diagnostic product is likely to have an effect on the user or where application has suggested difficulties. Complaints should also continue to be investigated.

6.11 The Committee supports the sanctions proposed to be included in the new legislation if tests on the product indicate that it is likely to be unsafe or ineffective. These may include recall of the product, modification of manufacturing methods, batch release, removal from the PBS listing and removal from the Register upon withdrawal of a product manufacturing licence.[4]

Recalls

6.12 Recalls of products can be instigated through a number of avenues:

- the manufacturer may advise the Department of a problem with a product;
- the Department will receive and investigate a complaint from either consumers or health professionals; and
- the Department will find a problem during its testing or inspection program.

6.13 Recalls of all therapeutic goods in Australia are co-ordinated by the Department's Recalls Section, Pharmaceutical Laboratories Branch. This section records and arranges the investigation of complaints and problems. Uniform recall procedures, agreed with industry, are currently under revision. Each State health authority also has a recalls co-ordinator.

6.14 Following identification of a problem or receipt of a complaint it may be referred to the testing laboratories or the Inspection Section if appropriate. Once a decision is taken, following the assessment of the problem, there are various levels of recall which depend on the stage it is instituted and its seriousness. The recall will be either at the wholesale, retail or consumer level.

6.15 Following a recall each manufacturer has to account to the Commonwealth or State co-ordinator for the recovery of the product, although in many cases certain amounts are unrecoverable

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4. PAC file 1987/6 A(2)

and untraceable. The Department does not have 100% certainty of full recovery of a product on the market. The obligation is on the manufacturer to prove that it has recovered as much as can be expected.[5]

6.16 The Committee was particularly interested in action taken following a decision that a consumer level recall is warranted. The Department advised that media releases are issued as soon as possible which may or may not be taken up by the media. Advertisements are also placed in newspapers by the manufacturer but this may not occur for several days.[6]

6.17 The Department does not monitor the media to assess how widely press releases relating to recalls are taken up.[7]

6.18 The Committee believes that the 008 phone number currently being introduced by the Department will be of benefit to the public in terms of providing more information on recalls.[8] The Committee considers that further initiatives to increase public awareness should be investigated.

6.19 The Committee recommends that:

- The Department of Community Services and Health monitor media outlets to assess to what extent media releases concerning consumer level recalls are given immediate and thorough publicity. If, following such a review, the extent of publicity is not adequate, the Department should determine whether advertisements could be placed more expeditiously and prominently.

- The Department of Community Services and Health investigate and institute other mechanisms whereby information concerning retail and consumer level recalls can be brought to public attention.

Adverse reactions

6.20 Adverse reactions to both drugs and devices are reported to the Department. For drugs, reports are channelled through the Adverse Drug Reactions Advisory Committee, a

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5. Minutes of Evidence, op cit, pp 2143-4
6. Ibid, p 2155
7. Ibid, p 2156
8. Ibid, p 2156

sub-committee of the Australian Drug Evaluation Committee. There is also another sub-committee, the Congenital Abnormalities Sub-committee which looks into adverse reactions that may result in birth defects. Reactions to devices are reported through the Therapeutic Device Problem Reporting Scheme.

6.21 The Committee has heard from some witnesses that reports of adverse drug reactions are not encouraged by consumers, particularly drug reactions. The Department acknowledges this but advised it does accept such reports. However, reports from consumers are generally not in the form required and do not include the clinical data necessary resulting in additional work by the Department to determine if in fact the problem is an adverse reaction.[9]

6.22 There is no required reporting of adverse reactions. The Department advises that the majority of countries have not made reporting mandatory. The Australian authorities believe the system is not intended to give a total picture of all adverse reactions in Australia but is an alerting system for the more serious and unexpected reactions.[10]

6.23 The Committee supports strongly the Department's action in accepting and analysing reports of adverse reactions of both drugs and devices. Whilst it agrees that mandatory reporting will not necessarily give greater information to the Department, the reporting facility should be more widely publicised to the public. The Committee accepts that this may result in a large increase in notifications to the Department but that such reports should be encouraged to go through medical practitioners or hospitals.

6.24 The Department should also strongly encourage health professionals, hospitals and other sources to report all adverse reactions.

6.25 The Committee recommends:

- **The Department of Community Services and Health encourage all possible reports of adverse reactions to therapeutic goods to be made to the Department.**

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9. Ibid, pp 2172-3
10. Ibid, p 2173

Advertising and Promotion

6.26 The PSB Review recommended that the Department, together with the Australian Pharmaceutical Manufacturers Association (APMA) and the Proprietary Association of Australia (PAA), should develop a new advertising code. In addition, a monitoring mechanism was to be developed, including the medical profession and consumers, to allow a two-year trial of the self-regulation to be undertaken.[11]

6.27 The Department advised that the two-year trial with industry is currently underway. In relation to prescription goods, the Department has two concerns regarding the APMA trial:

- its judgements may be a little uneven; and
- it is essentially a voluntary system.

6.28 The Department also advised that it does not have the resources to monitor the system, however in early 1989 the Department expects to be able to determine an appropriate assessment mechanism.[12]

6.29 Some advertisers offer inducements to prescribers, and other forms of promotion include offers of free equipment. The Department advises that it has had:

> ...a narrow role in advertising to date and I think we are still forming a view on that.[13]

6.30 The Committee is concerned that advertising which is either misleading by virtue of the context in which the advertisement is portrayed or has inducements offered to the prescriber continue to be published. The Committee has heard evidence as to other activities of drug companies such as free samples and free equipment. While the Committee acknowledges such activities are part of commercial business activities, it believes that there should be a monitoring of such activities by the Department and an assessment of their effect as part of the national drug policy as recommended in Chapter 2.

6.31 Whilst the Committee believes self-regulation is the most cost-effective method, it considers that there is a need for a certain level of monitoring by the Department, particularly in

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11. PSB Review, op cit, p xiv, recommendation 38
12. Minutes of Evidence, op cit, p 2210
13. Ibid, p 2211

the initial stages. The Committee believes that an extended monitoring mechanism needs to be established incorporating the medical profession and consumers as recommended by the PSB Review.

6.32 The Committee recommends that:

- The Department of Community Services and Health commence monitoring of advertising, both electronic and printed, to assess whether it complies with the guidelines.

- The Department of Community Services and Health should monitor the promotional activities of manufacturers as part of the national drug policy.

Chapter 7

A STATUTORY AUTHORITY AND CHARGES

Background

7.1 The Therapeutics Division is one of 10 Divisions within the Department of Community Services and Health. It is subject to all the normal public service requirements, regulations and constraints.

7.2 Prior to 1984 the NBSL was a separate Division of the then Department of Health and was recognised internationally. However, since becoming part of the Therapeutics Division some witnesses alleged that this identity has been subsumed into the Department of Community Services and Health's identity.

7.3 During the course of the inquiry, a number of witnesses supported the establishment of a statutory authority for the whole therapeutic function.

7.4 The PSB in its report recommended that the Department should work towards the establishment of a statutory authority with responsibility for the evaluation and post-marketing surveillance of therapeutic goods. This authority was to be located in a major state capital city.[1] Another recommendation was that the planned new laboratory building should include accommodation for all staff involved in drug evaluation and post-marketing surveillance.[2]

7.5 The Committee notes that in the 1988 Budget the Government announced that it is to provide $59.2m over 4 years for construction of an integrated laboratory complex for NBSL.[3] Construction is expected to begin in 1989-90 and the laboratories

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1. Review of Drug Evaluation Function, Recommendation 41, p xv
2. Ibid, Recommendation 35, p xiv
3. Budget Statements 1988-89, Budget Paper No 1, AGPS, Canberra, 1988, p 125

be fully occupied by 1992. The Public Works Committee has considered the proposal and, in an interim report to the Parliament in November 1988, indicated it will be recommending the construction of the laboratory complex.[4]

Statutory authority

7.6 The Committee notes that the Department, in response to the PSB Review, stated that a decision has been taken against co-location of the drug evaluation function and the laboratories in the new building. However, no decision has yet been taken on the issue of the establishment of a statutory authority.[5]

7.7 Many witnesses were in favour of the establishment of a statutory authority independent of the Department and public service constraints.

7.8 The Committee believes that the establishment of a statutory authority should be considered. The statutory authority would include all functions currently carried out by the Therapeutics Division. The following benefits could flow from such a body:

- freedom to negotiate appropriate salary packages to attract professional staff;
- increased independence and flexibility from government funding controls leading to greater certainty regarding the future;
- complete separation from the large number of other, and increasingly diversified, Departmental functions;
- greater identification as an entity and a higher public profile for the program and its crucial role in public health;
- directly responsible and accountable to the Minister with strict mechanisms for reporting to the Parliament;

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4. Parliamentary Standing Committee on Public Works, Interim Report relating to Construction of National Biological Standards Laboratory, Symonston, ACT, Fifteenth Report of 1988, AGPS, Canberra, 1988
5. PAC file 1987/6 A(2)

- more direct interaction with the community and a better relationship with professionals, particularly doctors, who currently have some antipathy towards dealing with the bureaucracy in general and the Department of Community Services and Health in particular; and

- greater possibility for staff interchanges with other laboratories and research bodies.

7.9 The Committee recommends that:

- **The Department of Community Services and Health consider the establishment of a statutory authority which includes the evaluation, testing and post-marketing surveillance functions. It should also have responsibility for developing the national drug policy.**

Location of the drug evaluation function

7.10 A number of evaluators employed by the Department are located in Sydney. This is because of the larger pool of professionals who can undertake evaluations and the proximity to university medical schools and large teaching hospitals. The Department advises that the location, either in whole or part, of the evaluation function, in a state capital city is under consideration.[6]

7.11 The Committee is of the view that the co-location of the drug evaluation and laboratory functions as proposed by the PSB Review may have advantages in that the communication and interaction that would develop would be beneficial to all parties. However, the Committee considers that the location of a sub-group of evaluators in a major capital city is a viable option particularly given the increasing use of technology. Given the difficulty in recruiting suitably qualified and experienced staff, it may be the only option.

7.12 The Committee will not be making recommendations in relation to the location of the function, however, the Committee believes that the question of location of the drug evaluation function should receive active consideration.

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6. PAC file 1987/6 A(2)

7.13 The Committee recommends that:

. The Department of Community Services and Health carries out comprehensive cost/benefit studies of :

  - Locating the drug evaluation function in a major capital city; and

  - Co-locating the drug evaluation and laboratory functions.

  The question of co-location of drug evaluation with laboratory functions should be reconsidered.

Fees

7.14 In the 1988 Budget the Government announced the introduction of a system of fees for the evaluation and quality control of therapeutic goods and charges for the registration of therapeutic goods. The measures will be introduced in 1989-90 and charges will be set to recover the costs of the therapeutic goods program. It is expected that $15m will be raised in 1989-90 and $20m in following years.[7]

7.15 The pattern and level of charges has yet to be determined but the Department will be conducting discussions with industry on the issue.

7.16 It has been acknowledged that the introduction of fees will need to be linked to an improved service, particularly in relation to response rates to applications for marketing of new products. During one hearing the Department quoted from the Minister for Housing and Aged Care's covering letter to the legislation discussion paper :

> In the recent Budget, the Government announced its intention of introducing charges which would cover the costs of therapeutic goods regulation...The Government acknowledges that the introduction of charges will need to be limited to an improved service, particularly in relation to response rates to applications for the marketing of new products.[8]

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7. 1988-89 Budget Paper No 1, op cit, pp 132 and 311
8. Minutes of Evidence, op cit, p 2079-80

7.17 A number of witnesses to the inquiry have been in favour of fees for evaluations if a better service results. One suggested that a substantial fee when submitting a marketing applications would have the added advantage of discouraging frivolous application.[9] The same witness also suggested that if evaluations were not completed within a pre-determined time-frame, the fee should be refundable.[10]

7.18 Another witness, a smaller manufacturer, stated that a large up-front fee may put young, high tech Australian companies at a disadvantage when compared to multinationals.[11]

7.19 It has also been suggested that the introduction of registration fees for all products, including existing products, is another form of taxation and may not be acceptable to industry.[12]

7.20 An overriding concern of witnesses was that the charging scheme should be performance-related not merely income generating.

7.21 The Committee recommends that a fair system of fees be introduced for:

- licensing of manufacturers;
- evaluation of all therapeutic goods that are required to be evaluated;
- entering of a good on the National Register of Therapeutic Goods (whether registered or listed); and
- fees for quality control, including inspection.

7.22 However, in framing such a fee structure the Committee stresses that, for evaluation or other costs, there should under no circumstances be cross-subsidisation by one category of goods in respect of any other.

7.23 Goods already on the market that only require registration should not be re-evaluated. Fees for inclusion on Register should not be substantial.

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9. Ibid, p 209
10. Ibid, p 252
11. Ibid, p 588
12. Ibid, p 251-2

7.24 The Committee is of the view that consideration will need to be given to sliding scales of fees for the various types of evaluations eg new chemical entities compared to generic drugs.

7.25 The Committee also expects that the fees will be levied on a user pays basis eg manufacturers with a poor history of compliance with GMP should be required to pay an incremental charge.

7.26 Whether or not a statutory authority is established the Committee considers it essential that the revenue raised by such measures should be directed towards enhancing the performance of the therapeutic goods program and not incorporated into the Consolidated Revenue Fund as general revenue.

7.27 The PSB Review recommended the introduction of trust fund accounting.[13] The Department advised that this will be considered when developing the fees policy. The Committee supports the PSB recommendation if a decision is taken against the establishment of a statutory authority.

7.28 Funding options range from a totally self-funded body to some level of government funding to totally government supported. The latter is not considered an option given the recent Government decision on fees, nor is it desirable.

7.29 The Committee believes that the government should provide funding for all or any functions, such as drug education and monitoring of advertising, which are outside the evaluation, testing and inspection functions.

7.30 The Committee recommends that:

- **The Department of Community Services and Health report in the Finance Minute on progress made in developing a fees policy.**

- **The Department of Community Services and Health, in developing a fee structure, should not allow cross-subsidisation for evaluation or other costs by one category of goods in respect of any other.**

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13. PSB Review, op cit, Recommendation 29, p xiii

- The Department of Community Services and Health, in considering the establishment of a statutory authority, concurrently develop a funding proposal for such a statutory authority.

R E Tickner, MP
Chairman
16 December 1988

Terms of reference

The Committee recognises the important role of the Department of Community Services and Health, and in particular the National Biological Standards Laboratory, in evaluating, registering and monitoring drugs and devices that are used by the Australian population. The important issues of public health and safety are raised by its work.

The Committee's inquiry will examine, report on and make recommendations relating to the efficiency and effectiveness with which the Department carries out its therapeutic goods evaluation and testing function.

Particular aspects that will be addressed include:

- the adequacy of resources provided to the function, and in particular the NBSL, and the efficient use of those resources, including staffing, equipment, facilities and accommodation;
- the evaluation and registration of drugs and devices;
- the coverage and frequency of testing of both drugs and devices both with and without standards;
- the effectiveness of inspections, including liaison between the Department and State Governments;
- the structure of NBSL and the need for a separate identity for NBSL;
- the relationship between the three branches of the Therapeutics Division of the Department of Community Services and Health that constitute the NBSL and the rest of that Division and the Department;
- relationships with State authorities;
- relationship with consumers and their advocates;
- the development of standards;
- the effectiveness of the Department's education role;
- uniform legislation; and
- the Register of Therapeutic Goods.

In examining the function, the Committee will take into account the recent review by the Public Service Board of the Drug Evaluation Branch of the then Department of Health and the Department's response thereto.

Submissions received

ACT Community and Health Service
Amersham Australia Pty Ltd
Association of Draughting Supervisory and Technical Employees
Australasian College of Physical Scientists in Medicine
Australian Association of Clinical Biochemists
Australian Consumers' Association
Australian Dental Association Incorporated
Australian Drug Evaluation Committee
Australian Medical Devices and Diagnostics Association Incorporated
Australian Natural Therapists Association Ltd
Australian & New Zealand Society of Nuclear Medicine
Australian & New Zealand Association of Physicians in Nuclear Medicine
Australian Nuclear Science and Technology Organisation
Australian Pharmaceutical Manufacturers Association Incorporated
Australian Veterinary Association Ltd
Biomedical Engineering Advisory Group
Bio Nova Neo Technics Pty Ltd
Biotechnology Aust Pty Ltd
Boucher & Muir Pty Ltd
Consumers' Health Forum of Australian Incorporated
Department of Community Services and Health, Victoria
Department of Industry, Technology and Commerce
ICI Australia Operations Pty Ltd
National Association of Testing Authorities, Australia
National Heart Foundation of Australia
NBSL Advisory Committee
NBSL GMP Inspection Section
NBSL Microbiology Section
Northern Territory Department of Health and Community Services
N. Stenning & Co Pty Ltd
Nutritional Foods Association of Australia
NSW Department of Health
Pharmacy Guild of Australia
Pharmaceutical Society of Australia
Professional Officers Association
Proprietary Association of Australia Incorporated
Queensland Department of Health
Public Interest Advocacy Centre
Royal North Shore Hospital, Electromedical Standards Laboratory
Society of Hospital Pharmacists of Australia
South Australian Chief Pharmacists' Conference
South Australian Health Commission
Tasmanian Health Service
Therapeutic Device Evaluation Committee
Therapeutic Goods Committee
UCB (Pakel) Pty Ltd
Victorian Department of Premier and Cabinet
Western Australian Health Department

Barron, H
Campbell, Prof K O
Curtin, Mr P
Dawson, Dr D
Devenish, Mrs C A
Evans, Dr D J
Hall, Dr R C
Harvey, Dr K
Howes, Dr D W
Mercieca, A
Russell, Dr W J
Sparkes, Mrs D J
Thick, Mr G F
Trianni, A
Whitten, W K
Wood, Mrs M

Some of the above departments, organisations and individuals have forwarded more than one submission to the Committee during the Inquiry.

In addition a number of confidential submissions have been considered by the Committee. Parts of some of the submissions listed above have been supplied on a confidential basis.

ATTACHMENT C

Conduct of the inquiry

List of hearings and witnesses

14 March 1988, Canberra

Department of Community Services and Health	Dr B C E Ashley Mr A J Ayres Dr D de Souza Dr A Glover Dr D T Graham Mr G A Hine Mr T M McPherson Dr A Proudfoot Mr J Withell
Observers	
Australian Audit Office Department of Finance	Mr P Farrelly Ms K Nienaber

30 March 1988, Melbourne

ICI Australia Operations Pty Ltd	Mr J V Plunkett Mr A J Shallcross
Australian College of Physical Scientists in Medicine	Dr J R Coles
NBSL Advisory Committee	Dr R G Bateman Dr G N Vaughan
Observers	
Australian Audit Office	Mr P Farrelly

31 March 1988, Melbourne

UCB (Pakcel) Pty Ltd	Mr W H Thomas
Victorian Medical Postgraduate Foundation	Dr K Harvey
Glaxo Australia Pty Ltd	Mr A Fox Mr I W Williams

Bio Nova Technics Pty Ltd	Dr G Roberts Mr R L Tuft
Observers	
Australian Audit Office	Mr P Farrelly Mr S Mitchell

11 April 1988, Canberra

Consumers' Health Forum	Dr J Braithwaite Mr R M G Brown Ms M L Sylvan
Pharmaceutical Society of Australia	Mr P W A Crothers
Private capacity	Dr D Howes
Observers	
Australian Audit Office Department of Finance	Mr P Farrelly Ms K Nienaber

18 April 1988, Canberra

National Heart Foundation of Australia	Dr R L Hodge
Observers	
Australian Audit Office	Mr P Farrelly

11 May 1988, Sydney

Therapeutic Devices Evaluation Committee	Dr D R Beech Dr C F Hughes
Biomedical Engineering Advisory Group (NSW)	Mr L M Knuckey Mr S T Scahill
National Association of Testing Authorities, Australia	Mr J A Gilmore
Australian Drug Evaluation Committee	Prof M J Eadie Prof W J Louis Dr M L Mashford
Observers	
Australian Audit Office	Mr P Farrelly

12 May 1988, Sydney

Australian Medical Devices and Diagnostics Association	Mr T J Harwood Dr J E Hirshorn Mr T B Jones
Therapeutic Goods Committee	Mr R D Munro Dr G N Vaughan
Proprietary Association of Australia	Mr J Pentecost Mr D Sutherland
Australian Consumers Association	Ms Y S Kwok
Public Interest Advocacy Centre	Mr M W Hogan Ms A M E Nanson
Australian Pharmaceutical Manufacturers Association	Mr K D Bell Ms P A Davis Dr J E Hirshorn
Nutritional Foods Association of Australia	Mr P R Daffy Mr A J Morgan
Observers	
Australian Audit Office	Mr P Farrelly

16 May 1988, Canberra

Department of Community Services and Health, Inspection Section	Dr D T Graham Mr W F Jones Mr R W Tribe
Observers	
Australian Audit Office	Mr P Farrelly

12 September 1988, Canberra

ACT Community and Health Service	Mr V F Bugler
Public Interest Advocacy Centre	Mr M W Hogan
Australian Consumers Association	Ms Y S Kwok
New South Wales Department of Health	Mr J F Martin Mr B T Mewes
Observers	
Australian Audit Office Department of Finance	Mr P Farrelly Ms K Nienaber

13 September 1988, Canberra

Australian Federation of Consumer Organisation	Mr R M Brown
South Australian Health Commission	Mr J L Davis
Consumers' Health Forum	Dr K J Harvey Ms Y S Kwok Ms M L Sylvan
Proprietary Association of Australia	Mr J Pentecost Mr D Sutherland
Observers	
Australian Audit Office	Mr P Farrelly
Department of Finance	Ms K Nienaber

29 September 1988, Canberra

Health Department of Western Australia	Mr M Patterson
Observers	
Australian Audit Office	Mr P Farrelly
Department of Finance	Ms K Nienaber

19 October 1988, Canberra

Department of Community Services and Health	Dr A I Adams Dr B C E Ashley Dr D T Graham Dr J McEwen Mr T M McPherson Mr P T Pflaum Mr M J Roche Mr R Tribe Mr J Withell
Observers	
Australian Audit Office	Mr P Farrelly
Department of Finance	Ms K Nienaber

20 October 1988, Canberra

Department of Community Services and Health	Dr A I Adams Dr B C E Ashley Dr D R Beech Dr D T Graham Dr J McEwen

	Mr T M McPherson
	Mr P T Pflaum
	Mr M J Roche
	Mr R Tribe
	Mr J Withell
Observers	
Australian Audit Office	Mrs A Hazell
Department of Finance	Ms K Nienaber

3 November 1988, Canberra

Department of Community Services and Health	Dr B C E Ashley
	Dr D R Beech
	Dr D T Graham
	Dr J McEwen
	Mr T M McPherson
	Mr P T Pflaum
	Mr M J Roche
	Mr R Tribe
	Mr J Withell
Observers	
Australian Audit Office	Mr P Farrelly
Department of Finance	Ms K Nienaber

Summary of recommendations

The Committee has made a number of recommendations which are listed below, cross-referenced to their location in the text. The Committee's analysis in the text should be referred to when considering these recommendations.

The Committee recommends that:

Legislation

- The Department of Community Services and Health should ensure full consultation with all interested parties including the States and industry and consumer groups and that urgent efforts be made to ensure introduction of the bill for uniform national legislation to control therapeutic goods into the Parliament in the Autumn sittings 1989 with a commencement date no later than 1 January 1990. (paragraph 2.63)

- The Department of Community Services and Health prepare within 6 months a report on progress made towards having the legislation in place by the commencement date or earlier to enable a review by the Public Accounts Committee, independent of the Finance Minute process, to be undertaken. (paragraph 2.63)

Medical Devices

- The Department of Community Services and Health urgently consider and implement means by which improved control can be exercised over devices entering Australia:

  - Determine if there are any further devices on the Australian market that have been subject to regulatory action by comparable overseas authorities.

- Examine its records to determine whether any letters have been issued to USA companies to authorise import into Australia of devices that have been subject to regulatory action in the USA with a view to reviewing the authorised devices in Australia.

- That companies be required to advise the Department if a device marketed in Australia has been the subject of regulatory action by a comparable overseas authority. Marketing approval should only be given if the Department is satisfied the product is safe.

These measures should be examined as an interim measure pending passage of the proposed legislation as well as a requirement after that. (paragraph 4.45)

The Department of Community Services and Health review its list of designated devices requiring marketing approval before supply to the Australian market on the basis of what is desirable for public health and safety. The statistical model, data from overseas regulatory authorities and data from Australian experience to date should be used. (paragraph 4.57)

If this list of devices is greater than resources would allow, the Department of Community Services and Health should reconsider the resource allocation within the Department. The advisory committees should draw the Minister's attention to these issues. (paragraph 4.57)

The Department of Community Services and Health make effective use of evaluations from comparable overseas countries in the Australian device evaluation program. (paragraph 4.66)

Good Manufacturing Practice

- The Department of Community Services and Health review its list of manufacturers showing critical deficiencies to determine if further delisting from the Pharmaceutical Benefits Schedule is warranted for any manufacturers. (paragraph 5.107)

- The Department of Community Services and Health increase its education program of both State and Territory good manufacturing practice inspectors and manufacturers. (paragraph 5.83)

- The Department of Community Services and Health enter into discussions with State and Territory governments with the aim of signing agreements regarding introduction of complementary legislation to allow enforcement of the Code of Good Manufacturing Practice for unincorporated bodies that operate intra-State. (paragraph 5.83)

- The Department of Community Services and Health advise all manufacturers of the requirements under the proposed legislation and the need to comply to ensure licensing under the new legislation. (paragraph 5.83)

- The Department of Commmunity Services and Health pursue both bilateral and multilateral inspection agreement discussions with a view to concluding such agreements as soon as possible. (paragraph 5.99)

Export Certificates

- The Department of Community Services and Health urgently formally write to all remaining State authorities urging them to cease the practice of issuing certificates of free sale as South Australia had done. (paragraph 5.129)

Diagnostic Products

- The Department of Community Services and Health should review comparable overseas literature and procedures to determine its own evaluation procedures for diagnostic products. (paragraph 4.72)

- The Department of Community Services and Health examine the category of products known as diagnostics and determine which, if any, require immediate evaluation prior to introduction of the proposed legislation. (paragraph 4.72)

- The Department of Community Services and Health should determine whether diagnostic products fall into the drug, device or another category of therapeutic good and also whether Australian Drug Evaluation Committee or Therapeutic Device Evaluation Committee is the appropriate and relevant advisory committee. (paragraph 4.72)

Drug Evaluations

- The Department of Community Services and Health report comprehensively in the Finance Minute on progress made in carrying out the recommendations of the Public Service Board Review of Drug Evaluation Procedures. If a recommendation is not to be or cannot be implemented then detailed reasons should be provided. (paragraph 3.42)

- The Department of Community Services and Health determine what resources are required in both the Drug Evaluation and Evaluation Support Branches to carry out the drug evaluation function in a more timely and efficient manner. (paragraph 3.42)

- The Department of Community Services and Health examine the issue of a centralised drug evaluation agency and advise in the Finance Minute what advantages and disadvantages the Department foresees with such a proposal. (paragraph 3.42)

- The Department of Community Services and Health consider the fast-track procedure for evaluating Australian developed modifications to drugs which are likely to have export potential. (paragraph 3.42)

National Drug Policy

- The Department of Community Services and Health actively pursue the development of a national drug policy. Extensive liaison should be undertaken with all interested parties. (paragraph 2.79)

- The Department of Community Services and Health provide, in the Finance Minute, its response to the Report on Drug Education, together with a timetable for implementing those recommendations it accepts. (paragraph 2.79)

- The Department of Community Services and Health explore ways in which pharmacists can contribute to cosumer education and ways that pharmacists' reimbursement can be changed to acknowledge their contribution. (paragraph 2.79)

Advisory Committees

- The Department of Community Services and Health review the terms of reference of the independent advisory committees and review the activities of such committees and their inter-relationships to ensure that coverage of the therapeutic goods program is comprehensive and without duplication. Each committee in its separate terms of reference, should give priority to those therapeutic goods which entail a high community risk.(paragraph 2.31)

. The Therapeutic Device Evaluation Committee, the Australian Drug Evaluation Committee and the Therapeutic Goods Committee should provide explicit advice direct to the Minister. (paragraph 2.31)

Statutory Authority

. The Department of Community Services and Health consider the establishment of a statutory authority which includes the evaluation, testing and post-marketing surveillance functions. It should also have responsibility for developing the national drug policy (paragraph 7.9)

Location of drug evaluation function

. The Department of Community Services and Health carries out comprehensive cost/benefit studies of :

- Locating the drug evaluation function in a major capital city; and

- Co-locating the drug evaluation and laboratory functions.

The question of co-location of drug evaluation with laboratory functions should be reconsidered. (paragraph 7.13)

Fees

. The Department of Community Services and Health report in the Finance Minute on progress made in developing a fees policy. (paragraph 7.30)

. The Department of Community Services and Health, in developing a fee structure, should not allow cross-subsidation for evaluation or other costs by one category of goods in respect of any other. (paragraph 7.30)

- The Department of Community Services and Health, in considering the establishment a statutory authority, concurrently develop a funding proposal for such a statutory authority. (paragraph 7.30)

Recalls

- The Department of Community Services and Health monitor media outlets to assess to what extent media releases concerning consumer level recalls are given immediate and thorough publicity. If, following such a review, the extent of publicity is not adequate, the Department should determine whether advertisements could be placed more expeditiously and prominently. (paragraph 6.19)

- The Department of Community Services and Health investigate and institute other mechanisms whereby information concerning retail and consumer level recalls can be brought to public attention. (paragraph 6.19)

Adverse Reactions

- The Department of Community Services and Health encourage all possible reports of adverse reactions to therapeutic goods to be made to the Department. (paragraph 6.25)

Advertising and Promotion

- The Department of Community Services and Health commence monitoring of advertising, electronic and printed, to assess whether it complies with the guidelines. (paragraph 6.32)

- The Department of Community Services and Health should monitor the promotional activities of manufacturers as part of the national drug policy. (paragraph 6.32)