The Parliament of the Commonwealth of Australia

House of Representatives
Standing Committee on Community Affairs

PRESCRIBED HEALTH

A Report on the Prescription and Supply of Drugs

PART I - Regulation and the Pharmaceutical Industry

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TERMS OF REFERENCE

The House of Representatives Standing Committee on Community Affairs is to inquire into and report to the Parliament on:

i) current legislative and regulatory controls and professional practices which influence the prescribing, retailing, supply and consumption of pharmaceuticals;

ii) the responsibilities and standards which should apply to the distribution, promotion and marketing of pharmaceuticals; and

iii) the range and quality of information and education on appropriate drug use as opposed to commercial promotion and marketing.

ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
ACA	Australian Consumers' Association
ACI	Approved Consumer Information
ADEC	Australian Drug Evaluation Committee
AFAO	Australian Federation of AIDS Organisations
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
AMA	Australian Medical Association
ANF	Australian National Formulary
APAC	Australian Pharmaceutical Advisory Council
APB	Australian Publishers Bureau
APMA	Australian Pharmaceutical Manufacturers Association
ARTG	Australian Register of Therapeutic Goods
ASCEPT	Australasian Society of Clinical and Experimental Pharmacologists & Toxicologists
BNF	British National Formulary
CHATN	Community HIV/AIDS Trial Network
CHF	Consumers' Health Forum of Australia
CTN	Clinical Trials Notification Scheme
CTX	Clinical Trials Exemption Scheme
DHHCS	Commonwealth Department of Health, Housing & Community Services
DITAC	Commonwealth Department of Industry, Technology & Commerce
DPSC	Drugs & Poisons Schedule Committee
DRS	Doctors Reform Society
DUSC	Drug Utilisation SubCommittee
EC	European Community
FBCA	Federal Bureau of Consumer Affairs
GMP	Good Manufacturing Practice, Code of
HIC	Health Insurance Commission
IEC	Institutional Ethics Committee
MaLAM	Medical Lobby for Appropriate Marketing

MCA	Media Council of Australia
MEC	Medicines Evaluation Committee
MIMS	Monthly Index of Medical Specialties
MSD	Merck, Sharp & Dohme (Australia)
NCCTG	National Coordinating Committee on Therapeutic Goods
NCE	New Chemical Entities
NFA	Nutritional Foods Association
NHMRC	National Health & Medical Research Council
NPDA	National Pharmaceutical Distributors Association
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBRT	Pharmaceutical Benefits Remuneration Tribunal
PBS	Pharmaceutical Benefits Scheme
PEAC	Pharmaceutical Education Advisory Committee
PGA	Pharmacy Guild of Australia
PHARM	Pharmaceutical Health & Rational Use of Medicines Working Party
PI	Product Information
PIPA	Product Information on Pharmaceuticals in Australia
PMAA	Proprietary Medicines Association of Australia
PMAC	Proprietary Medicines Advisory Committee
PPI	Patient Package Inserts
PSA	Pharmaceutical Society of Australia
PSWA	Pharmaceutical Society of Western Australia
RACP	Royal Australasian College of Physicians
R&D	Research and Development
SACOA	South Australian Council on the Ageing
SUSDP	Standard for the Unform Scheduling of Drugs & Poisons
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TMEC	Traditional Medicines Evaluation Committee
TPC	Trade Practices Commission
VDUAC	Victorian Drug Usage Advisory Committee

RECOMMENDATIONS

CHAPTER 2 - The Regulatory Framework

1 The Committee recommends the amendment of Schedule 1 of the Standard for the Uniform Scheduling of Drugs and Poisons to include therapeutic and non therapeutic poisons that should be readily available to the public with no restrictions except mandatory warnings or safety directions. **(para 2.28)**

2 The Committee recommends that, given the potency of many Schedule 3 drugs and the administrative difficulty of differentiating between different drugs in this class, the blanket prohibition on advertising all Schedule 3 drugs to the public should remain. **(para 2.41)**

3 The Committee recommends that it be mandatory for generic names to be placed on labels one point size larger and using the same type face, font and colour as the name and placed immediately above the brand name. **(para 2.48)**

4 The Committee recommends that, in accordance with the Pharmaceutical Society of Australia's Policy statement 23.4, manufacturers should aim to have:

(a) a total area of not less than 70mm x 50mm available to the pharmacist on which to apply the dispensing label; and

(b) essential data on storage conditions, drug name, batch number and expiry date placed close together to facilitate over-labelling by pharmacists without obscuring part of this information.

(para 2.51)

5 The Committee recommends that both the Therapeutic Goods Administration and the National Health and Medical Research Council give greater consideration to simplifying the warning statements that appear on medicine labels. **(para 2.57)**

6 The Committee recommends that all pharmacists instructions be written in Plain English. **(para 2.59)**

7 The Committee recommends that the National Health and Medical Research Council examine the possibility of including a cautionary note on packages of

unscheduled and Schedule 2 & 3 drugs advising older people to consult a pharmacist or doctor on appropriate dosage rates for their age, weight and state of health. **(para 2.64)**

8 The Committee recommends that the membership and operations of the Medicines Evaluation Committee be finalised as a matter of urgency. **(para 2.91)**

9 The Committee considers that the Traditional Medicines Evaluation Committee is an appropriately constituted body to evaluate traditional products that are being evaluated for registering on the Australian Therapeutic Goods Register and recommends that it continue as an important source of expert advice for the Department of Health, Housing and Community Services. **(para 2.96)**

10 The Committee recommends that the Therapeutic Goods Administration (TGA) continues to evaluate all grandfather drugs to ensure that they meet the required safety, quality and, where appropriate, efficacy standards of the Therapeutic Goods Act and thus anticipate any potential safety or quality problems before they occur. The Committee also recommends that this area of drug evaluation be examined in the overall review of the TGA currently being undertaken. **(para 2.101)**

11 The Committee recommends that the Australian Drug Evaluation Committee produce a list of the small number of generic drugs containing active ingredients with known or potential bioequivalence problems. The drugs on this list should be noted in the Pharmaceutical Benefits Book, either as a separate appendix or with a cautionary note placed beside each individual entry. Such a note could advise that a patient stabilised on one brand should not be changed to another without appropriate monitoring. **(para 2.120)**

CHAPTER 3 - The Pharmaceutical Benefits Scheme

12 The Committee recommends that the Pharmaceutical Benefits Advisory Committee (PBAC) meets four times per year to consider listing of drugs as the most efficient way of ensuring that delays in the listing process are minimised. Furthermore the Committee recommends that PBAC, if necessary, sit for longer than two days at each meeting to ensure that submission backlogs do not develop. **(para 3.49)**

13 The Committee recommends that the Pharmaceutical Benefits Advisory Committee, when considering a particular drug which has specific relevance

to a specialist area of clinical treatment, ensures that a nominated representative with expertise in a specialised area of therapeutics, practical experience of drug committees, a current clinical practice and recruited through specialist associations be consulted during the process of evaluation. **(para 3.54)**

14 The Committee recommends that the Government review the current membership of the Pharmaceutical Benefits Advisory Committee with a view to increasing the level of available specialists in drug use on the Committee. This can be effected by appropriate amendments to s101(1)&(2) of the National Health Act. Formal mechanisms should also be established to coordinate the listing process between State and Federal Governments in an effort to standardise drug lists and derive more precise guidelines for listing on the Pharmaceutical Benefits Scheme. **(para 3.55)**

15 The Committee recommends that the Pharmaceutical Benefits Advisory Committee invites manufacturers of breakthrough drugs for life threatening conditions to submit the drugs for Pharmaceutical Benefits Scheme listing once they have received marketing approval from the Australian Drug Evaluation Committee. **(para 3.59)**

16 The Committee recommends that a cost-effectiveness sub-committee of PBAC be established through which health economists and industry representatives could review economic submissions and make recommendations to PBAC. **(para 3.77)**

CHAPTER 4 - The Pharmaceutical Industry

17 The Committee recommends that pharmaceutical companies, in making applications for listing new products on the Pharmaceutical Benefits Scheme, provide the Pharmaceutical Benefits Pricing Authority with pricing information which includes the amount to be spent on promotional activities as part of the submission for determining the price of the product. This information should also give a breakdown of the proportion of promotional expenditure devoted to independent medical education as the Committee would like to encourage a greater proportion of financial resources to be spent on educational, as opposed to brand product, promotional advertising. **(para 4.12)**

18 The Committee supports the promulgation of ethical principles to guide professional organisations in their dealings with the industry and recommends that guidelines similar to those prepared by the Royal Australasian College of Physicians be developed by the Australian Medical Association and other specialist colleges. **(para 4.19)**

19 The Committee recommends that guidelines based on the Association of the British Pharmaceutical Industry code and Royal Australasian College of Physicians guidelines be included in the Australian Pharmaceutical Manufacturers of Australia Code of Conduct for industry sponsored trials and functions. Adoption of such guidelines would reduce the potential for pharmaceutical companies being accused of unethical behaviour in the promotion of their products. **(para 4.34)**

20 The Committee recommends that a representative from a peak consumer health group with the appropriate background be included on the Australian Pharmaceutical Manufacturers Association Complaints Subcommittee. **(para 4.42)**

21 The Committee recommends that a representative of the Department of Health, Housing and Community Services be given observer status on the Complaints Subcommittee, given the shared interest in this matter by the Department, which administers the Therapeutic Goods Act, and the Australian Pharmaceutical Manufacturers Association. **(para 4.43)**

22 The Committee recommends that Sections 10.2 & 10.3 of the Australian Pharmaceutical Manufacturers Association's Code of Conduct be replaced with the following:

"10.2 If the subcommittee, after making such further inquiry as is necessary or desirable, forms the opinion that a breach of the code has occurred, it shall inform the Chief Executive Officer of the breach and the reasons and of the form of Sanction to be applied to the Member, as provided for under Section 11 of the code.

10.3 If the subcommittee considers that no breach has occurred, it will so advise the Chief Executive Officer and the parties to the complaint shall be so advised".

(para 4.45)

23 The Committee recommends that the Code be amended to empower the Complaints Subcommittee to require corrective advertising and/or to impose a fine on a member company found to be in breach of the Code. No upper or lower limit should be placed on the fine but the amount of the fine should reflect the gravity of the offence. Furthermore, the Committee recommends that fines should be significantly increased for repeated offences by the same manufacturer. **(para 4.51)**

24 The Committee recommends that Section 11.2 of the Australian Pharmaceutical Manufacturers Association's Code be amended to provide that

member companies found to have breached the Code be required to submit a draft of any retraction statement or corrective advertisement to the Subcommittee for approval. If the Subcommittee is not satisfied with the format, size or wording of the statement it may redraft the statement. The Subcommittee should be able to determine the mode and method of publication. **(para 4.54)**

25 The Committee recommends that corrective letters should be sent on Australian Pharmaceutical Manufacturers Association stationery, at the offending company's expense, to encourage doctors to read retraction statements. **(para 4.55)**

26 The Committee recommends that the Australian Pharmaceutical Manufacturers Association (APMA) Code be amended by the inclusion of a statement that should a company refuse to comply with a sanction imposed by the Complaints Subcommittee or refuse to have a complaint heard by the Complaints Subcommittee then the Chief Executive Officer may either refer the matter to the Department of Health, Housing and Community Services or institute legal proceedings on behalf of the APMA. **(para 4.56)**

27 The Committee recommends that the Australian Pharmaceutical Manufacturers Association develop a comprehensive publicity program including, but not restricted to, immediate steps to publish in various widely read medical journals, articles on the Code and its requirements. **(para 4.62)**

28 The Committee recommends that the Australian Pharmaceutical Manufacturers Association consider funding a 008 telephone information line and publish its availability to medical practitioners via the various professional associations. The 008 information line would provide callers with general information on the APMA Code of Practice and complaint submission procedures. It is not envisaged that complaints could be lodged directly over the telephone. **(para 4.63)**

29 The Committee recommends that the Media Council of Australia further publicise the complaints procedures for the Therapeutic Goods Advertising Code to members of the public. **(para 4.70)**

30 The Committee recommends that the Proprietary Medicines Association of Australia (PMAA) amend its Code of Practice to allow the complaints handling mechanism to be applied to nonmember companies with their consent. Provision should also be made in the Code for the referral of complaints against non PMAA members to the Department of Health, Housing and Community Services or the Trade Practices Commission. **(para 4.73)**

31 The Committee recommends that the Proprietary Medicines Association of Australia amend its complaints handling mechanism to allow for an appeals process independent of the industry and that sanctions, other than those involving membership, be imposed directly by the complaints panel. It is further recommended that a representative from the consumer movement and the Department of Health, Housing and Community Services, at least, be included in a separate code administration committee. **(para 4.75)**

32 The Committee recommends that the Proprietary Medicines Association of Australia establish a monitoring committee, along the lines of the Australian Pharmaceutical Manufacturers Association Monitoring Subcommittee, to review advertisements by its members, and if necessary place the advertisements before the Complaints Panel. **(para 4.77)**

33 The Committee recommends that the Proprietary Medicines Association of Australia publicise the existence of its Code and complaint handling mechanism both in trade journals and directly to pharmacists. It is recommended that this occur on a regular basis. **(para 4.79)**

34 The Committee recommends that the Proprietary Medicines Association of Australia establish a 008 telephone information line and publicise it in trade journals and directly to pharmacists. **(para 4.80)**

35 The Committee recommends that the Nutritional Foods Association be required to report its progress towards developing a viable code for self regulation to the Trade Practices Commission on a six monthly basis. **(para 4.100)**

36 The Committee recommends that the classification of alternative medicine practitioners as "health professionals" for the purposes of Regulation 4 of the Therapeutic Goods Regulations be removed unless the Nutritional Foods Association can demonstrate to the Trade Practices Commission by 1 January 1994 that it has the resources, industry coverage and expertise to administer such a code effectively. **(para 4.101)**

37 The Committee recommends that Institutional Ethics Committees request that companies sponsoring drug trials should indicate if objections have been raised previously by the Therapeutic Goods Administration under a Clinical Trials Exemption Scheme application and provide details of any objections and further recommends that the National Health and Medical Research Council include in its note on clinical trials that companies provide information about an approach to another institutional ethics committee concerning the same clinical trial proposal and a requirement to submit a full record of that decision. **(para 4.116)**

38 The Committee recommends that the Factor F Scheme be continued, subject to a further analysis of the conclusions and recommendations made by the Bureau of Industry Economics in its report. **(para 4.128)**

CHAPTER 5 - Consumer Issues

39 The Committee recommends that the Therapeutic Goods Administration (TGA) be required to formally approve consumer information, to be termed Approved Consumer Information (ACI). ACI should be evaluated and approved in the same way that Product Information is. To this end, the Committee recommends that the TGA, in consultation with industry and peak consumer bodies, draws up an appropriate format for ACI, based on European Community guidelines. **(para 5.32)**

40 The Committee recommends that once the Therapeutic Goods Administration has evaluated the clinical details of Approved Consumer Information (ACI), they be forwarded to appropriate health education specialists to ensure that the ACI have been written in Plain English and are likely to be understood by non specialists. **(para 5.33)**

41 In order to increase availability of consumer information, the Committee recommends that Approved Consumer Information should be printed in a compendium available for purchase by the public. **(para 5.37)**

42 The Committee recommends that by 1 January 1994, Approved Consumer Information should be required for all new Schedule 3 drugs and variations to them approved after that date. All existing schedule 3 drugs should have ACI provided by 1 January 2004. **(para 5.41)**

CHAPTER 6 - A National Drug Strategy

43 The Committee recommends that the Department of Health, Housing and Community Services coordinates the preparation of an Australian National Formulary to provide drug information to prescribers and dispensers and furthermore that this be made available in computerised format for use by prescribers and dispensers as an independent database on drugs in Australia. **(para 6.19)**

Chapter 1

ESTABLISHMENT OF THE INQUIRY

INTRODUCTION

1.1 On 26 July 1989, the Minister for Housing and Aged Care, the Hon Peter Staples, MP, wrote to the then Chairman, Mr Neil O'Keefe, MP, referring an inquiry to the Committee. The specific terms of reference were for the Committee to inquire into and report to the Parliament on:

i) current legislative and regulatory controls and professional practices which influence the prescribing, retailing, supply and consumption of pharmaceuticals;

ii) the responsibilities and standards which should apply to the distribution, promotion and marketing of pharmaceuticals; and

iii) the range and quality of information and education on appropriate drug use as opposed to commercial promotion and marketing.

CONDUCT OF THE INQUIRY

1.2 The inquiry was advertised in the major metropolitan newspapers in August 1989. In addition, letters inviting submissions were sent to over 70 individuals and organisations likely to have an interest in the inquiry.

1.3 The calling of the general election in 1990 and subsequent dissolution of Parliament made it necessary to seek Ministerial approval to resume the inquiry

after the election. This was given by the Minister for Aged, Family and Health Services, the Hon Peter Staples, MP, on 20 June 1990. Interested parties and those who had already forwarded submissions were advised of the recommencement of the inquiry by the new Chairman of the Committee, Mr Harry Jenkins, MP, in July 1990.

1.4 The Committee has received over 130 submissions from individuals, organisations representing the pharmaceutical industry, the medical and pharmaceutical professions, State and Commonwealth government bodies and consumer groups. A list of all the submissions received by the Committee can be found at Appendix 1.

1.5 Because of the broad scope of the inquiry, the Committee determined that it would table three separate reports, each addressing selected aspects of the terms of reference. This, the first report, focuses on the current legislative and regulatory controls and the responsibilities and standards which should apply to the promotion and marketing of pharmaceuticals. The second report will address the professional practices which influence the prescribing of pharmaceuticals and the range and quality of information and education on appropriate drug use as opposed to commercial promotion and marketing. The final report will examine the current legislative and regulatory controls and professional practices which influence the distribution, retailing and supply of pharmaceuticals.

1.6 To assist its investigations for the first report, the Committee held public hearings in Adelaide, Brisbane, Hobart, Melbourne, Perth and twice in Canberra and Sydney. A list of witnesses who appeared before the Committee can be found at Appendix 2.

1.7 Inspections and informal discussions were also held at a number of centres. In Sydney the Committee visited the premises of Merck, Sharp & Dohme (Australia) Pty Ltd and held informal discussions with the Pharmaceutical Society of Australia (NSW Branch) Ltd. The Committee had two series of inspections in

Melbourne, visiting the Victorian College of Pharmacy, Royal Melbourne Hospital and several community pharmacies in October 1990 and Martin & Pleasance Pty Ltd, Sigma Co Ltd and the Commonwealth Serum Laboratories in April 1991. In Adelaide, the Committee visited the premises of F H Faulding & Co Ltd.

1.8 The Committee also held a workshop in Canberra on 30-31 July 1991. The workshop was attended by a number of individuals and representatives of organisations who had forwarded submissions to the Committee. In addition, representatives from academic institutions, professional bodies, consumer groups and Commonwealth government agencies were invited. Appendix 3 provides a list of workshop delegates.

1.9 The workshop provided Committee members with the opportunity to discuss in greater detail with those having a particular interest in the Committee's inquiry the major issues which had emerged and provided a forum for an exchange of views by all groups represented. It also assisted in shaping the Committee's approach to the inquiry and determining areas of priority.

PRELIMINARY OBSERVATIONS

1.10 Since this inquiry was first announced in 1989 there have been quite a few changes in the pharmaceutical environment which all have a bearing on this inquiry and on the general debate relating to rational drug use.

1.11 In addressing the pharmaceutical industry, the Committee is aware of other investigations which have been conducted covering part of the subject area of this inquiry; notably the review of the future of drug evaluation in Australia conducted by Professor Peter Baume, the Trade Practices Commission review of self-regulation of therapeutic goods and the Bureau of Industry Economics review of the Factor F Scheme. These investigations, where appropriate, have been taken into account and not duplicated in this Committee's inquiry.

1.12 Although the promulgation of the Therapeutic Goods Act and Regulations has already resulted in changes to the regulatory system, the full impact of these changes is not yet evident.

1.13 In other changes, the Federal Government has introduced a pensioner co-payment for drugs listed on the Pharmaceutical Benefits Scheme (PBS). This aims to make both prescribers and consumers more aware of the cost components in the provision of prescription drugs. The Government has further introduced a minimum pricing policy, which is intended to provide financial incentives to prescribe the lowest priced drug in a class of drugs approved for a particular indication, requiring the patient to pay the difference between the lowest priced brand name and the one prescribed.

1.14 Furthermore, the Government has, at the bureaucratic level, set up three bodies to provide a coordinated pharmaceutical education strategy, reporting through the Secretary of the Department of Health, Housing & Community Services (DHHCS) to the Minister. The three components of the strategy are the Australian Pharmaceutical Advisory Council (APAC), the Pharmaceutical Education Advisory Committee (PEAC) and the Pharmaceutical Health and the Rational use of Medicines (PHARM) working party.

1.15 The final development relates to a restructuring of pharmacy remuneration and a more efficient demographic distribution of pharmacies throughout Australia. The Government has entered into an agreement with the Pharmacy Guild of Australia (PGA) to achieve rationalisation in the distribution of pharmacies. As part of the overall package, the Pharmaceutical Benefits Remuneration Tribunal (PBRT), has also determined new remuneration levels for pharmacists. The effects of restructuring are presently being examined by the Senate Standing Committee on Community Affairs.

1.16 The overall level of activity involved in the examination of the supply, distribution and consumption of pharmaceuticals in Australia is an indication of the

importance of this area in economic, social and individual health terms. Whereas the pharmaceutical industry and the regulatory system have been subject to a range of reviews over recent years, this inquiry was established, in part, to identify and make observations on factors influencing the quality of drug use and to make recommendations for achieving a more informed and better balanced approach to medicines.

1.17 In conducting its investigations, the Committee became aware of the shortage of data which exists in the area of drug use in the community. There have been a series of developments which will enable much more specific comprehensive information to be provided on drug usage patterns, but much still remains to be done.

1.18 Some recent developments include the collection of drug usage statistics by the Health Insurance Commission (HIC) on the basis of prescriptions written for drugs for a value greater than $15.00, negotiations between the Government and the PGA to obtain access to prescription data under $15.00 and arrangements to provide the Drug Utilisation Sub-committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) with this information for analysis and publication. If these statistics were to be supplemented with hospital drug data it would be possible to have an overall picture of drug usage patterns throughout Australia. This would also assist in providing a better profile of the general health of the Australian community.

1.19 This report will deal with the regulatory framework including drug scheduling and drug evaluation and look at some of the changes brought about by the Therapeutic Goods Act and Regulations. There will also be some discussion of PBS, the role of the PBAC and the development of cost effectiveness as a key determinant in drug evaluation.

1.20 The report will also look at the pharmaceutical industry and its promotion and marketing strategies, discuss self-regulation of the industry and the

balance between regulation and the encouragement of research and development. This also leads to issues concerning consumer representation and consumer information.

1.21 Finally, the question of a national drug strategy and the need for an Australian National Formulary will be considered in this report.

1.22 In its concluding remarks, the Committee stresses the need for overall coordination of activities between industry, health professionals, consumer groups and regulatory agencies to ensure progress towards better health outcomes.

Chapter 2

THE REGULATORY FRAMEWORK

SCHEDULING OF DRUGS

Uniform drug schedules

2.1 The original Australian (drug) Schedules were based on the British Schedules of the Nineteenth Century and were intended as a dispensing guide for pharmacists. The Australian Schedules have now evolved to control the way drugs and poisons are distributed, prescribed, dispensed, advertised and marketed.

2.2 The Drugs and Poisons Schedule Committee (the Schedule Committee) is a subcommittee of the National Health and Medical Research Council's (NHMRC) Public Health Committee. The Schedule Committee is responsible for making recommendations, inter alia, regarding the scheduling classification of all drugs and poisons. The Schedule Committee includes a member from each State and Territory health authority with expertise in administering drugs and poisons legislation as well as experts on human, animal and agricultural drugs and poisons. This composition ensures a mix of experts and State representatives.

2.3 All States and Territories operate separate systems of poisons scheduling under local Poisons Acts or their equivalents. Although poisons schedules are basically similar throughout Australia, there are local variations relating to the number of schedules, their definition and their content. Through a continuing liaison process, the Schedule Committee works with State and Commonwealth authorities to recommend the placement of poisons in schedules and to promote uniform scheduling

throughout Australia. To this end, the NHMRC regularly produces the "Standard for the Uniform Scheduling of Drugs and Poisons" (SUSDP) as a guide for the States and Territories.

2.4 In the past, the States and Territories have adopted the NHMRC recommendations to varying degrees leading to inconsistencies between their drugs and poisons schedules. Not only have identical drugs been listed in different schedules, but the labelling and packaging requirements for drugs in the same schedules have also varied. The inefficiencies caused by these variations were well illustrated in comments by the National Pharmaceutical Distributors Association (NPDA):

> "we have to carry two products exactly the same but [with] different labelling because of scheduling. A product might be Schedule 3 in Queensland and Schedule 2 in New South Wales. We have to carry two lines; we have to make sure that we do not supply the wrong product to the wrong State". (NPDA: Transcript of evidence, p 205)

2.5 At its June 1990 meeting, the Australian Health Ministers' Conference reached agreement for all States to adopt the schedules for drugs and poisons contained in Standard No 5. This depended on the States and Territories agreeing to a common definition of the schedules (SUSDP No 5, part 1), establishing uniform packaging and labelling requirements so that products prepared in one State could be marketed in another (SUSDP No 5, parts 2 & 3) and agreeing to the uniform classification of the substances themselves (SUSDP No 5, part 4).

2.6 While the State and Territory Governments are committed to harmonising their standards, the adoption of the uniform schedules has occurred at varying rates. One obstacle has been that the States and Territories have different procedures for amending existing schedules. Some States can amend the schedules by Gazettal reference, while others require amendment to legislation in what has been described by the NHMRC as "a very complex situation". (NHMRC: Transcript of evidence, p 998)

2.7 The Committee has been told by the NHMRC that all States and Territories are in the process of adopting SUSDP No 5 or have recently adopted them, although some States are retaining minor amendments to meet local requirements. (NHMRC: Transcript of evidence, p 994-998)

2.8 Appendix 4 contains the latest classifications for poisons as determined in SUSDP No 5.

2.9 For the purposes of this inquiry, the Schedule Committee's most relevant function is to recommend the scheduling and rescheduling of pharmaceuticals, thereby determining whether, inter alia: they can be purchased without prescription (unscheduled, Schedule 2 or 3); require a doctor's prescription for purchase (Schedule 4 or 8); be advertised directly to the public (unscheduled or Schedule 2); or only advertised to health professionals (Schedules 3, 4 or 8).

2.10 The Committee is satisfied that progress is being made towards the adoption of uniform drugs and poisons schedules throughout Australia and that many of the concerns raised in submissions when the Inquiry first commenced in 1989 have now been addressed.

Industry representation in scheduling process

2.11 The Committee is aware that the lack of a pharmaceutical industry representative on the Schedule Committee is an issue of concern for sections of the industry.

2.12 The Proprietary Medicines Association of Australia (PMAA) represents the manufacturers of non prescription drugs (unscheduled & Schedule 2 and 3 drugs) and has argued that the Schedule Committee has "failed to reflect a valid cross section of technical, commercial, industry and public opinion" resulting in "an unjustifiable degree of regulatory restriction without demonstrable consumer benefit". (PMAA:

Submission, p 247)

2.13 A related criticism of the Schedule Committee is that it conducts its activities in too much secrecy. The PMAA has called for " a full and open review of the poisons scheduling system" while the Australian Consumers' Association (ACA) and the Consumers' Health Forum (CHF) jointly recommend that the Schedule Committee "make public any decisions to change the status of a drug so that community/consumer organisations can inform the Committee of their views before final decisions are made". (ACA & CHF: Submission, p 1577)

2.14 In its defence, the Schedule Committee has pointed out that much of the information it uses to determine the placement of drugs within schedules is commercially sensitive and is provided in confidence to the Australian Drug Evaluation Committee (ADEC) by pharmaceutical manufacturers. This information is forwarded to the Schedule Committee by the pharmaceutical companies, via ADEC, on the understanding that it will remain confidential.

2.15 If scheduling decision making is to be totally open, then pharmaceutical manufacturers may be reluctant to provide the Schedule Committee with the same commercially sensitive information that ADEC is provided with. Manufacturers would have to provide separate, non sensitive information on which to make scheduling decisions. Such requests could reduce the detailed information the Schedule Committee has access to and add a further step to the drug evaluation process.

2.16 The Schedule Committee has pointed out that it is a committee of experts and that as such it might not be appropriate to have non expert representatives on it.

2.17 As the Schedule Committee does have access to commercially sensitive information, there may be some difficulty in finding an industry representative from one company (and thus, potential competitor) to sit in on meetings who is acceptable to companies submitting applications.

2.18 In an attempt to strike a compromise with its critics, the Schedule Committee, after consultation with the pharmaceutical industry, from 1992 plans to adopt a number of steps to improve its public accountability.

2.19 The Committee has been advised by the Chairman of the Schedule Committee that there will be, from its first meeting in 1992, a gazettal of its meeting agendas 30 days prior to the meetings and subsequently, gazettal of its recommendations and decisions concerning product scheduling.

2.20 In addition, it will be possible, from 1992 to lodge appeals against Schedule Committee recommendations with the Public Health Committee. (NHMRC: Transcript of evidence, p 999)

2.21 The Committee recognises the need for public accountability, but as the Schedule Committee needs access to the same commercially sensitive information provided to ADEC, the Committee accepts that a degree of confidentiality is required in the Schedule Committee's decision making process.

INDIVIDUAL SCHEDULES

Redefinition of Schedule 1

2.22 Schedule 1 poisons are defined as those "poisons of plant origin of such danger to health as to warrant their being available only from medical practitioners, pharmacists or veterinary surgeons". (SUSDP No 5)

2.23 The existence of Schedule 1 in its current form is an anachronism, as it now contains only five plant derivatives that have not been assigned to a more appropriate schedule. A list of these substances can be found at Appendix 5.

2.24 The Schedule Committee has produced an unpublished discussion paper calling for a redefinition of the Schedule 1 classification so as to broaden its use[1].

2.25 The above discussion paper suggests an option to redefine Schedule 1 as "Poisons for therapeutic use that should be readily available to the public with no restrictions except mandatory warnings or directions for use"[2]. Schedule 1 would thus be the first in a progression of increasingly strict controls for therapeutic poisons from Schedule 1 to 4.

2.26 Under this definition, Schedule 1 would contain those medicinal poisons that are considered to be safe for sale by supermarkets, health food stores or other shops, such as small low dose packs of aspirin and paracetamol, if labelled with appropriate directions for use or warning statements.

2.27 Alternatively, the discussion paper suggests that Schedule 1 could be used as a general schedule containing the medicinal poisons listed as described in the previous paragraphs, but also including such non therapeutic poisons as correction fluids, hair waving preparations and contact adhesives containing cyanoacrylic esters[3].

2.28 While conscious that its terms of reference do not allow a discussion of non therapeutic poisons schedules, **the Committee nevertheless recommends the amendment of Schedule 1 to include therapeutic and non therapeutic poisons that should be readily available to the public with no restrictions except mandatory warnings or safety directions.**

2.29 The Committee acknowledges that this recommendation would necessitate consequential amendments to the SUSDP by the NHMRC in cooperation

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1 "Schedule 1: A New Approach, A discussion paper for consideration by the Drugs & Poisons Schedule Committee".

2 ibid, p 2.

3 ibid, p 3.

with State authorities.

Deregulation of Schedule 2 & 3 drugs

2.30 During the inquiry, the Committee was made aware of arguments that restrictions on the sale of all Schedule 2 and most Schedule 3 drugs should be lifted so that consumers could have the convenience of being able to purchase them from a wider range of outlets. It was claimed that these drugs have wide margins of safety when used by the public in accordance with label directions, have often been on the market for a long time and that consumers are familiar with them. (PMAA: Submission, pp 218-220)

2.31 Queensland Health, however, has pointed out to the Committee that a number of Schedule 2 drugs have the potential to interact with a range of other drugs and foods and that it remains preferable that these drugs continue to be dispensed by a health professional. (Queensland Health: Transcript of evidence, p 869)

2.32 Similarly, the Pharmaceutical Society of Western Australia (PSWA) has argued before the Committee that information on both Schedule 2 & 3 drugs should be provided only by a medical practitioner or pharmacist who can counsel patients and advise them of any potential adverse reactions or precautions that should be taken. (PSWA: Transcript of evidence, pp 622 - 624)

2.33 The Committee is conscious of the importance of informed consumer choice with access to comprehensive information about the consequences of use and abuse of scheduled substances and does not believe that there should be a lifting of restrictions on the places of sale of Schedule 2 & 3 drugs.

Advertising of Schedule 3 drugs

2.34 Until 1979, Schedule 3 drugs could be advertised directly to the public. Since then, however, manufacturers of drugs in this schedule have been prohibited from advertising their products direct to the public. (Therapeutic Goods Regulations, Statutory Rules 394/1990, R 6(1)(e))

2.35 The PMAA agrees that it is appropriate that a number of Schedule 3 drugs, such as asthma treatments and insulin based products, should not be advertised directly to the public as their use should be preceded by a professional diagnosis and detailed instructions for use.

2.36 However, in evidence before the Committee, the PMAA stated that "there are a whole range of other products within Schedule 3 which could quite logically and sensibly be advertised to the public, where people could be aware of the availability". (PMAA: Transcript of evidence, p 165)

2.37 The PMAA believes that the advertising prohibition should be lifted for these drugs as "the public view advertising of medicinal preparations as a useful source of information and advice" and since there is "no evidence to suggest that people are inappropriately influenced by advertising to make inappropriate choices...". (PMAA: Submission, pp 229 - 230)

2.38 Furthermore, the PMAA believes that since the 1979 advertising prohibition and the resulting "ignorance of the availability of such preparations [Schedule 3 drugs], consumption shifted to less appropriate or less effective products for the condition". (PMAA: Submission, p 258)

2.39 The PMAA also argues that consumers have the right to know what products are available and that they should have the benefit of "responsible information" provided by manufacturers. (PMAA: Transcript of evidence, p 168)

2.40 The Committee remains concerned, however, that consumers will not be able to evaluate claims about the efficacy of competing brands of what are often potent drugs with potentially serious adverse reactions, interactions or contra indications.

2.41 **The Committee therefore recommends that, given the potency of many Schedule 3 drugs and the administrative difficulty of differentiating between different drugs in this class, the blanket prohibition on advertising all Schedule 3 drugs to the public should remain.**

LABELLING OF DRUGS

Package labels: generic v brand name

2.42 One contributing cause of accidental drug overdosing is the sale of identical drugs under different trade names. Patients tend to identify drugs by their trade names, which are prominently displayed, rather than by the generic, or chemical, names of the drugs which are also displayed, less prominently, on the package. Thus, patients seeing more than one doctor at a time can be prescribed and consume multiple doses of the same drug, under different trade names, without realising it. This problem is compounded when patients are prescribed drugs generically through hospitals but by manufacturer brand when seen by community doctors.

2.43 The South Australian Council on the Ageing (SACOA) told the Committee that:

> "One of the great dangers and the real problem is when people have drugs both under a brand name and under the generic name. I would strongly recommend that if a brand is dispensed the generic name should be on the label as well. ... It is essential otherwise people could be taking the same drug twice, particularly when there are different colours and different shapes and sizes". (SACOA: Transcript of evidence, p 495)

2.44 The Committee is aware that the generic name of a drug is already required to be printed on medication labels, but this is not a sufficient safeguard in itself to prevent confusion.

2.45 The Australian Medical Association (AMA), however, has also argued before the Committee that patients find it easier to remember the trade names of drugs rather than generic titles and that they "certainly tend to identify better with brand names". (AMA: Transcript of evidence, p 1084)

2.46 The Committee believes that patient confusion would be reduced if the generic names of drugs were displayed more prominently on standardised package labels.

2.47 The Australian Pharmaceutical Manufacturers Association (APMA) has commented that it has "no disagreement with the fact that the generic name of the active drug should always be on the label and consumers should be encouraged to read that... ". (APMA: Transcript of evidence, p 1026)

2.48 **Accordingly the Committee recommends that it be mandatory for generic names to be placed on labels one point size larger and using the same type face, font and colour as the name and placed immediately above the brand name.**

2.49 The related issue of generic prescribing will be addressed in the Committee's second report.

Labels: obscuring information

2.50 Further confusion in relation to labels occurs for many patients when the labels affixed by the manufacturer, detailing drug names (both brand and generic) and expiry date, are obscured by labels placed on containers by dispensing pharmacists. The Committee believes that manufacturers' labels should not be obscured by

pharmacists' labels.

2.51 **The Committee therefore recommends that, in accordance with the Pharmaceutical Society of Australia's Policy statement 23.4, manufacturers should aim to have:**

(a) **a total area of not less than 70mm x 50mm available to the pharmacist on which to apply the dispensing label; and**

(b) **essential data on storage conditions, drug name, batch number and expiry date placed close together to facilitate over-labelling by pharmacists without obscuring part of this information.**

2.52 The Committee also supports a suggestion by SACOA that patients be encouraged to write on drug labels in their own words, what the medication is for. (SACOA: Transcript of evidence, p 495) This practice may help patients, in particular those on multiple medications or from non English speaking backgrounds, to remember why they are taking a particular drug.

2.53 The related issue of the provision of Patient Package Inserts (PPI) and consumer information is discussed subsequently in Chapter 5.

Labels: cautionary warnings

2.54 Consumer groups have alerted the Committee to concerns that the cautionary statements required on medication packages may be unclear to members of the community. It has been argued that labels such as "Pharmacy only" or "Prescription only" may be clearer than "Supply without Prescription illegal". Little research has been done into the effectiveness of medicine warning labels, and what has been done indicates the need for improvements in their design and wording.

2.55 Currently both the NHMRC and DHHCS' Therapeutic Goods

Administration (TGA) are responsible for determining labelling warnings: NHMRC being responsible for specific warnings for specific drugs and the TGA being responsible for warnings for drug categories. Within the TGA, the Therapeutic Goods Committee's Subcommittee on General Requirements for Labels for Medicines is responsible for the Therapeutic Goods Order No 32 entitled "General Requirements for Labels for Therapeutic Goods" which lists labelling standards.

2.56 The Committee is aware of research already being conducted into the effectiveness of warning labels by the Preventive Strategies Panel of the NHMRC. Furthermore, the Committee is encouraged by the PMAA's involvement in and conduct of a seminar on consumer communication in October 1991[4].

2.57 **The Committee recommends that both the Therapeutic Goods Administration and the NHMRC give greater consideration to simplifying the warning statements that appear on medicine labels.**

2.58 Furthermore, the ACA and the CHF consider that the directions given by pharmacists on their labels could be more easily understood if they were written in Plain English. In their submission, the ACA and CHF give the following example:

"Standard Instruction

> One to be taken every eight hours, with or after food. Take at regular intervals. Complete the prescribed course unless otherwise directed. Warning: Avoid alcoholic drink.

Plain English Version

> One to be taken three times a day, with food. Space the doses evenly through the day. Keep taking this medicine until it is finished. Don't drink any alcohol". (ACA & CHF: Submission, p 1596)

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4 PMAA, "Communicate or Litigate: Proceedings of a Consumer Communications Seminar", October 1991.

2.59 **The Committee recommends that all pharmacists instructions be written in Plain English.**

Labels for non prescription drugs: dosage rates for the older population

2.60 It has become apparent in discussions with a number of witnesses that older people are far more likely to suffer adverse drug reactions and contra indications. While this is often the result of older people being on a greater number of medications, people's metabolisms change with age and manufacturers' recommended adult doses of self administered non prescription medications may not be appropriate or safe for the older population. This has been supported in evidence from SACOA and the PSWA.

2.61 As PSWA explained:

> "Most of the things you pick up in our pharmacies and in the supermarkets, where appropriate, are labelled for children but they have forgotten all about the elderly. In fact, their capacity to handle drugs and to eliminate them is totally different to that of a younger person. A frail elderly lady of 80 has perhaps a third of the capacity to handle drugs of a healthy young 25 year old, and yet there is no labelling whatsoever to warn people about that". (PSWA: Transcript of evidence, p 624)

2.62 The Committee appreciates the important role that pharmacists play in counselling patients on appropriate drug doses, particularly for Schedule 2 & 3 drugs, since correct dosage rates will vary from individual to individual. However, the Committee remains concerned that people purchasing unscheduled drugs from supermarkets and other non-pharmacy outlets may not receive such counselling and may not be aware that stated dosage rates for adults may not be appropriate for the older person.

2.63 Unfortunately, while drug packages for non prescription drugs contain

dosage rates for adults and children they do not list dosage rates for older people.

2.64 **Consequently, the Committee recommends that the National Health and Medical Research Council examine the possibility of including a cautionary note on packages of unscheduled and Schedule 2 & 3 drugs advising older people to consult a pharmacist or doctor on appropriate dosage rates for their age, weight and state of health.**

THERAPEUTIC GOODS ACT 1989 AND REGULATIONS

The Australian Register of Therapeutic Goods

2.65 The Therapeutic Goods Act 1989 ("The Act") and associated regulations came into operation on 15 February 1991 and were introduced to establish and maintain a national system of controls regulating the quality, safety and efficacy of therapeutic goods supplied within, or exported from, Australia for use in humans. The major parts of the Act cover the determination of safety and quality standards for Australian therapeutic goods, the establishment of an Australian Register of Therapeutic Goods ("The Australian Register") and the licensing requirements for manufacturers of therapeutic products in Australia.

2.66 All therapeutic products for import to, export from and marketing within Australia are required to be entered on the Australian Register in one of three categories: "Registered", "Listed" or "Exempt". Registered goods are evaluated for their quality, safety and efficacy whilst Listed goods are assessed for their quality and safety only.

2.67 The Media Council of Australia's (MCA) Therapeutic Goods Advertising Code Council has determined a range of medical conditions for which self diagnosis is inappropriate and where diagnosis and treatment should be carried out by a

registered medical practitioner. The MCA's Therapeutic Goods Advertising Code lists a range of such conditions and defines diagnostic claims for curing or alleviating such conditions as "prohibitions". The Therapeutic Goods Act has adopted an expanded range of prohibitions termed "Prohibited representations", which are defined in Schedule 2 of the Therapeutic Goods Regulations.

2.68 All drugs for which Prohibited representations are made, all drugs scheduled by the Schedule Committee (Schedules 1, 2, 3, 4 & 8), all new chemical entities and all products listed on the PBS are required to be Registered on the Australian Register. Prescription drugs (Schedule 4 & 8) and new chemical entities are evaluated by the Drug Evaluation Branch of the TGA and the Australian Drug Evaluation Committee (ADEC) before being approved for marketing. All non prescription drugs to be Registered are evaluated by either the Medicines Evaluation Committee (MEC) or the Traditional Medicines Evaluation Committee (TMEC). Schedule 3 of the Therapeutic Goods Regulations defines those products that are required to be Registered.

2.69 Listed goods are assessed by the TGA's Compliance Branch and are those of a less hazardous nature for which no Prohibited claims are made, such as most herbal, homoeopathic, vitamin and mineral products. Schedule 4 of the Therapeutic Goods Regulations defines those products that are required to be Listed.

2.70 Simple pharmaceutical formulations for external application and some classes of imported goods for private use do not require either Registration or Listing on the Australian Register and are classified as Exempt under the Act. Schedule 5 of the Therapeutic Goods Regulations defines those products that are classified as Exempt.

Code of Good Manufacturing Practice

2.71 The Australian Code of Good Manufacturing Practice (GMP) for

Medicinal Products was developed in 1969 to reflect agreed Government/industry standards for the manufacture of therapeutic products and is updated regularly to reflect new technologies and standards of manufacturing. Under the Therapeutic Goods Act, manufacturers of therapeutic products, with certain exceptions, are required to hold a licence which is granted if a manufacturer can demonstrate compliance with manufacturing standards including Codes of GMP during an inspection by officers of the Commonwealth GMP Audit and Licensing Section.

2.72 While major pharmaceutical manufacturers have been required to meet GMP standards of manufacture for many years, the passage of the Therapeutic Goods Act has meant that certain manufacturers, who previously were not required to comply with the Code of GMP are now obliged to do so. This has particularly affected the manufacturers of herbal and homoeopathic goods whose products utilise material of vegetable origin rather than the synthetic, reproducible materials from which other therapeutic drugs are made.

2.73 In March 1991, the Nutritional Foods Association (NFA) expressed concern that some of these manufacturers were finding compliance with the GMP Code difficult:

> "A number of companies ...that manufacture herbal products, for example, would not have had any interface with GMP... are ones that are now facing some difficulties in this area". (NFA: Transcript of evidence, p 236)

2.74 The TGA has advised that after subsequent discussion with the NFA, a dispensation has now been granted to the manufacturers of Listed and Exempt herbal and homoeopathic products for wholesale or retail supply so that they will not have to comply with the GMP Code in full until February 1993[5].

2.75 Furthermore, the GMP Auditing and Licensing Section, in consultation

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5 TGA, "Guidelines for Application of GMP to the Manufacture of Herbal Medicinal Products", 3rd Edition, 16 October 1991, para 1.2.

with the NFA, has developed special guidelines clarifying the application of the GMP Code for herbal manufacturers and citing a limited number of concessions that will be allowed, primarily, for herbal growers[6].

2.76 The Committee fully supports the application of the Code of GMP for the manufacture of all therapeutic products. The Committee also recognises the difficulties some small manufacturers of Listed and Exempt products may experience in attempting to apply the Code. The Committee believes that the dispensation described above represents a reasonable mechanism to assist producers of these products and balances the public's right to therapeutic goods manufactured to high standards of quality.

National Coordinating Committee on Therapeutic Goods

2.77 The Therapeutic Goods Act was designed to replace a range of Commonwealth, State and Territory legislation which had evolved sporadically, where the various responsibilities for drug regulation overlapped, were badly defined, contradictory or missing altogether. As a result, the Australian Health Ministers' Advisory Council established the National Coordinating Committee on Therapeutic Goods (the "National Coordinating Committee") to minimise the inefficiencies of the administrative arrangements then in existence.

2.78 The Therapeutic Goods Act and regulations, as Commonwealth law, take precedence where there are any inconsistencies with State or Territory legislation. Since there is so much overlapping legislation, Sub Section 6(3) of the Therapeutic Goods Act allows exemptions for 12 State and Territory Acts plus 11 sets of Regulations that will continue to operate until February 1993, thus giving the States and Territories time to harmonise their legislation and regulations with the Commonwealth Act (see Therapeutic Goods Regulations, R3).

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6 TGA, op cit.

2.79 Since passage of the Therapeutic Goods Act, the National Coordinating Committee's primary task has been to assist and coordinate the drafting of State and Territory legislation to complement the Commonwealth Act, remove any inconsistencies and ensure that no gaps emerge in the national regulatory system. This has been a slow and complex legal process touching on constitutional matters and Commonwealth/State relations.

2.80 Queensland Health believes that the National Coordinating Committee is:

> "a very useful forum to ascertain the developments that are being planned in the Commonwealth and other areas and to facilitate the harmonising of legislation .... it is a useful forum in terms of trying to optimise the similarity between legislation in the different states". (Queensland Health: Transcript of evidence, pp 880-881)

2.81 The Committee is aware of at least one example, namely the amendment of Victorian legislation to establish the Medicines Evaluation Committee, where the coordination of State and Commonwealth legislation is occurring with considerable delay. It appears that this type of problem is more widespread and that there will be further delays before a truly coordinated national system of regulation is operating.

2.82 The PMAA has commented:

> "Generally speaking, the move by the States to develop complementary legislation is slow, although there are signs of progress - greater in some States than others. If we are going to achieve the aim of consolidation and rectifying the duplication and the gaps through complementary legislation, then there has got to be a willingness to review thoroughly and also, if necessary, to repeal existing legislation. Certainly in that area there are no signs yet." (PMAA: Transcript of evidence, p 156).

2.83 Providing a State perspective, a spokesman for the Western Australian Health Department commented:

"I regard [the Therapeutic Goods Act] as an extremely valuable but very

complex piece of legislation. Western Australia will move to give complementarity to that as soon as some legal issues are resolved. There are one or two differing legal opinions amongst the States on what the States can and cannot do in the void left by the Act.... it is a technical legal problem." (Western Australian Health Department: Transcript of evidence, p 655)

2.84 The Committee supports the National Coordinating Committee's endeavours to coordinate the development of State and Territory legislation to complement the Therapeutic Goods Act and expresses its concern at the delays involved.

DRUG EVALUATION

Medicines Evaluation Committee

2.85 The Proprietary Medicines Advisory Committee (PMAC), was a Victorian Government committee that evaluated all non prescription drugs sold in Victoria under the Victoria Health Act 1958. Under Section 9 of the Commonwealth Therapeutic Goods Act, PMAC was contracted to operate on a national level and evaluate most non prescription products that are sponsored for Registration on the Australian Register. PMAC has been renamed MEC to reflect the Committee's new national responsibilities.

2.86 The formalisation of MEC's new role requires amendment to the Victorian Health Act 1958 and in October 1991 the National Coordinating Committee agreed that priority should be given to establish draft State legislation that would, inter alia, give MEC legal backing. The Committee is aware that the drafting and passage of legislation in each of the States and Territories to complement the Commonwealth Therapeutic Goods Act is a constitutionally and legally complex task.

2.87 The Committee views with concern the fact that, a year after the commencement of the Therapeutic Goods Act, there has been no legislation introduced to formalise the role of MEC, given that MEC is a key body in the national evaluation system.

2.88 MEC only evaluates those non prescription drugs that are to be Registered on the Australian Register. The vast majority of vitamin and herbal products are Listed and thus evaluated by the TGA's Compliance Branch rather than by MEC. However, the NFA, which represents the health foods, vitamin, mineral, herbal, homoeopathic and dietary supplements industry, expressed its concern that based on past experience, PMAC, now MEC, might not be "sympathetic" to those manufacturers who choose to have herbal and vitamin products Registered. As the then Executive Director of the NFA expressed it:

> "There is a concern felt by many of the manufacturer sponsor members within my industry that the PMAC, as it has been structured over a number of years, is not sympathetic towards vitamin and mineral supplements and at times is quite hostile". (NFA: Transcript of Evidence, p 229)

2.89 Notwithstanding that there is a nominee from the Victorian Chamber of Manufacturers on MEC, the NFA is concerned that the industry will not be sufficiently represented:

> "We still have a situation where we have an essentially Victorian committee which was developed primarily to look at pharmaceutical drugs but which will now be looking into the area of vitamin and mineral supplements and on which my industry has no representation at all.... if we were to be evaluated by a committee, we wanted more specific industry representation". (NFA: Transcript of evidence, pp 227-8)

2.90 Under the draft Victorian legislation, it is proposed that membership of MEC will be expanded to include an expert on traditional medicines manufacture and a nutritionist, even though the old PMAC membership will be retained as the nucleus.

2.91 **The Committee recommends that the membership and operations of the Medicines Evaluation Committee be finalised as a matter of urgency.**

Traditional Medicines Evaluation Committee

2.92 The Traditional Medicines Evaluation Committee (TMEC) evaluates products for Registration on the Australian Register whose efficacy is wholly or partly based on traditional use. These are primarily homoeopathic preparations or products with active ingredients of vegetable (herbal) origin and, for the purposes of the Therapeutic Goods Act, are defined in Regulation 2 of the Therapeutic Goods Regulations. TMEC is scheduled to meet at approximately 2 monthly intervals, subject to agenda items being in hand.

2.93 TMEC received only two submissions for registration in 1991, both of which were rejected, since most traditional or homoeopathic products are Listed and thus evaluated by the TGA's Compliance Branch. As a result, TMEC has met less frequently than expected although it has produced guidelines for registering herbal products which have been widely distributed[7]. TMEC's main function now is to provide expert advice on traditional medicines to DHHCS.

2.94 Despite the fact that TMEC has evaluated very few products, the NFA, as a representative body for the herbal and traditional medicines industry, supports the role and membership of TMEC:

> "We believe that the structure of the Traditional Medicines Evaluation Committee is more appropriate to the sort of products that it will be evaluating and we recognise that, in creating the committee, this is a major concession to the industry - recognition of the separate nature of our industry". (NFA: Transcript of evidence, p 228)

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[7] DHHCS, 'Guidelines for the Registration of Non-prescription Drugs - Appendix on Herbal Products", December 1991.

2.95 Furthermore, the NFA believes that TMEC "is comprised of people that do in fact have knowledge of and experience and some degree of background in herbal medicine and traditional medicines". (NFA: Transcript of evidence, p 228)

2.96 The Committee considers that the Traditional Medicines Evaluation Committee is an appropriately constituted body to evaluate traditional products that are being evaluated for registering on the Australian Therapeutic Goods Register and recommends that it continue as an important source of expert advice for the Department of Health, Housing and Community Services.

"Grandfather" drugs

2.97 The Therapeutic Goods Act is not retrospective and under Section 66 of the Act, products that were legally on the national market or for sale in individual States at the time of the commencement of the legislation were automatically Listed or Registered on the National Register by the TGA following application from the sponsor. These drugs are known as "Grandfather" products.

2.98 Many grandfather products have only been examined to a level sufficient to determine whether the product should be Listed or Registered on the Australian Register, the annual registration charge that should apply and to check or create the unique registration number and Australian Register name for the product.

2.99 The TGA is now reviewing the information it holds on grandfather products, but nonetheless, many of these products that were marketed in individual States under local legislation have not had to meet the safety, quality and efficacy criteria that are now required nationally under the Therapeutic Goods Act. As the TGA stated:

> "You have to realise that with the [Therapeutic Goods] Act only having come into effect in February [1991] and the grandfathering process that virtually automatically adopted all the products in the marketplace at

that time, that they have not been subject to any review, at this point, on a product by product basis. Inevitably there would be a number of those that have carried forward from the pre legislation market which we would possibly not approve of under the present situation and which may not comply. But we will be attempting to monitor the marketplace and gradually pick up those that do not comply". (DHHCS: Transcript of evidence, p 992)

2.100 The principal area of concern lies with non prescription products, as prescription drugs and PBS items were already fully evaluated on a national basis by ADEC and PBAC before the implementation of the Therapeutic Goods Act. DHHCS has advised that in early 1992 it will be assessing the standards of manufacture of imported products and the safety and quality standards of goods now on the Australian Register but previously rejected for marketing in Victoria by the Victorian PMAC prior to passage of the Act. (refer para 2.85)

2.101 The Committee is aware that the TGA can withdraw from the Australian Register, and hence remove from the market, any product at any time if there are concerns about its safety or quality. **Nonetheless, the Committee recommends that the Therapeutic Goods Administration (TGA) continues to evaluate all grandfather drugs to ensure that they meet the required safety, quality and, where appropriate, efficacy standards of the Therapeutic Goods Act and thus anticipate any potential safety or quality problems before they occur. The Committee also recommends that this area of drug evaluation be examined in the overall review of the TGA currently being undertaken.**

2.102 Approval to market a drug in Australia is granted at the discretion of the Minister for Health, Housing and Community Services. In practice, an application from a company for a new patent of drug to be given marketing approval will go, together with the supporting test reports, through the TGA's Drug Evaluation Branch to ADEC, an independent statutory body, which will then make a recommendation to the Minister. An application for a generic drug to be given marketing approval will, together with the proof of its buyer and therapeutic equivalence, be considered wholly within the Department's Evaluation Branch.

Drug evaluation post Baume

2.103 The report on the future of drug evaluation in Australia commissioned by the Minister for Aged, Family and Health Services, the Hon Peter Staples, MP, under the authorship of Professor Peter Baume was released in July 1991 ("The Baume Report"). This report was the culmination of a series of earlier reviews of the drug evaluation system.

2.104 Previous reports such as the Ralph Report, the Industries Assistance Commission Report and the Public Accounts Committee Report looked at pharmaceutical manufacturing issues. The Australian National Council on AIDS Report looked at delays in the establishment of clinical trials and new treatments and a report by the Public Service Board looked specifically at the evaluation process. However, the Baume Report entitled "A Question of Balance" had the benefit of having very precise terms of reference which were designed to look specifically at the evaluation process within Australia as well as to bring Australia into the broader regulatory framework, acknowledging the trend towards greater regulatory harmonisation.

2.105 Responses to the Baume Report have been universally favourable. The APMA in evidence to the Committee, stated:

> "We are very supportive of the Baume Report. We see it as a major step forward in drug evaluation, not only in Australia, but internationally. We have stated that publicly. We are very strongly supportive of the principle. I guess now it remains to be seen how the practice will occur because the proof will be in the implementation of those recommendations". (APMA: Transcript of evidence, p 1021)

2.106 In the same way that the manufacturers support the Baume Report, favourable comments have also been received from other major interest groups. The Royal Australasian College of Physicians (RACP), in evidence to the Committee stated:

"The College strongly supports the Baume Report and is very pleased to see that it has been implemented as quickly as it was suggested it should be in the report". (RACP: Transcript of evidence, p 1174)

2.107 Consumer groups such as the Australian Federation of AIDS Organisations (AFAO) have also given support to the main thrust of the Baume Report's recommendations. AFAO is:

"... generally satisfied with Baume's Report ... the main problems we do have with the report are its ongoing implementation: at the moment it is a book sitting on a shelf. We have not really seen any direct consequences of the report at this time". (AFAO: Transcript of evidence, pp 1047-1048)

2.108 In response to questions relating to the implementation of the recommendations in the Baume Report, DHHCS informed the Committee that a task force had been set up to specifically address the Baume recommendations. This task force reports to the Minister on a monthly basis and progress is monitored by the Secretary of the Department.

2.109 When questioned about the lack of industry representatives on the task force, the Department did not feel that industry representation was appropriate. However, if the implementation process is to work effectively it has to be seen to be a public process with full access to information concerning adherence to the time frame set out in the report.

2.110 In order to meet some of the concerns which have been expressed regarding the lack of an industry representative on the Baume implementation task force and questions about whether the Baume recommendations had been implemented according to the time table, an external review group has been set up with responsibility for auditing the implementation process. This three member review group which includes industry and consumer representation will examine the implementation process midway through 1992. This will greatly assist in the public

accountability of the implementation process.

2.111 Another critical factor relating to the successful implementation of recommendations for the Baume Inquiry is the appointment of a national manager for the TGA. The appointment of the national manager was made in December 1991 and the Committee hopes that the appointment will enable necessary administrative and organisational changes to be made in order to ensure the outcomes suggested in the Baume Report.

Generic drugs

2.112 When a company introduces a new drug onto the market it enjoys a monopoly on the sale of the drug as it is under patent, currently for 20 years. Once the patent expires, other manufacturers can copy the drug and market it under a different brand name, usually at cheaper prices. Such brands are called "generic" drugs.

2.113 Before a generic drug can be marketed in Australia it has to pass the stringent bioavailability and bioequivalence standards set by the TGA in the "Guideline for Bioavailability and Bioequivalence Studies" and in the "Requirements of Bioavailability and Bioequivalence Studies for Various Types of Application". Bioavailability relates to the rate and extent of absorption of a drug in the body following administration. A bioequivalence trial of two products compares the rate and extent of absorption of the products when tested in a panel of human subjects[8]. A drug is required to conform to the bioequivalence standards set for the brand name product in the same dosage form before it can be marketed in Australia as a generic equivalent.

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[8] Thomas, J, "The Bioequivalence debate and Minimum Pricing Policy of PBS", The Australian Journal of Pharmacy, 71, Dec 1990, 967- 970, p 968.

2.114 The only differences between original drugs and their generic equivalents should be in the excipients, that is the colouring dyes, flavouring and inactive fillers used in manufacturing. These differences should not affect the bioequivalence of the active ingredients.

2.115 The APMA has argued however, that bioequivalence does not guarantee effective clinical therapeutic equivalence:

> "The fact that two products contain the same quantity of the same active ingredient does not mean that the patient will respond to them in identical ways, either because of the means of manufacture or because of the inactive ingredients that are contained in it. There can be quite wide clinical and therapeutic differences in response to products that are considered to be generically equivalent". (APMA: Transcript of evidence, p 1027)

2.116 The Committee is aware that there is debate over the therapeutic equivalence of generic brands. As one commentator described:

> "It must also be said that at times there appears to be a case of self interest in the arguments put by both industry and government to support the point of view taken by each, with perhaps not the scientific detachment which might be expected"[9].

2.117 There are, however, a small number of drugs where a minute difference in the bioavailability of their active ingredients can have the potential to lead to pharmacological or therapeutic variations. For these drugs, patients may react differently to different brands even though the drugs have passed the standard bioequivalence tests. In these cases, alternative brands are either not available in Australia, exempted from the Minimum Pricing Policy or a cautionary note is placed in the Pharmaceutical Benefits Book. Examples of these drugs include warfarin (an anti coagulant), (APMA: Transcript of evidence, p 1026 - 1031), digoxin (a heart

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9 Thomas, J, op cit, p 969.

stimulant), phenytoin (an anti-epileptic drug) and theophylline (a bronchodilator).[10]

2.118 The United States Food and Drug Administration regularly produces the "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations" (the FDA List) which provides a current list of prescription drugs that have been approved for marketing in the US. It also contains therapeutic equivalence evaluations for generic drugs.

2.119 The FDA List includes a code that highlights the names of generic drugs that contain active ingredients with a range of known bioequivalence problems.

2.120 **The Committee recommends that the Australian Drug Evaluation Committee produce a list of the small number of generic drugs containing active ingredients with known or potential bioequivalence problems. The drugs on this list should be noted in the Pharmaceutical Benefits Book, either as a separate appendix or with a cautionary note placed beside each individual entry. Such a note could advise that a patient stabilised on one brand should not be changed to another without appropriate monitoring.**

2.121 The related issue of generic prescribing will be addressed in the Committee's second report.

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[10] Upfal, J, The Australian Drug Guide (Schwartz & Wilkinson, 1991), p iv.

Chapter 3

THE PHARMACEUTICAL BENEFITS SCHEME

HISTORY AND DEVELOPMENT OF THE SCHEME

3.1 The Pharmaceutical Benefits Scheme (PBS) had its genesis in 1950 when, as part of the establishment of a national health scheme, the Menzies Government introduced a schedule of 139 "life saving and disease preventing" drugs which were made available free of charge to any person requiring them. The Commonwealth Government negotiated the price of drugs with manufacturers including a mark up of 33.3% reimbursement to pharmacists along with a dispensing fee. The authority for the supply of pharmaceutical benefits is derived from section 85 of the National Health Act 1953.

3.2 From 1959 the list of drugs available under the scheme was extended and conditions placed on their free availability. Initially a co-payment of 50 cents was required for non-pensioners. This was subsequently increased to $1.00 in 1971, $1.50 in 1975 and $2.50 in 1978.

3.3 Until 1990, pensioners and special beneficiaries received drugs prescribed from the list free of charge. However, in November 1990 co-payments for pensioners were introduced set at $2.50 per script, the same as other concessional users, with a safety net. Concurrently, co-payments for general users increased to $15.00 in 1991 and these co-payments are now indexed to CPI levels.

3.4 In an attempt to stem the increasing cost of the PBS the Government has, since 1985, made several changes to prescribing rules. These include; extending the life of prescriptions, including repeats, from 6 months to 12 months; increasing

the quantity of many drugs given from the one prescription but reducing the number of repeats allowed for other drugs; classifying more expensive medications as authority only drugs requiring special approval for use for limited indications and conducting education campaigns to make doctors and patients more aware of the cost of drugs and alternative therapies. These changes were intended to save money by reducing the number of times the Government would have to pay the pharmacist dispensing fee and to discourage doctors from prescribing expensive drugs when cheaper drugs or alternative therapies might be available.

3.5 In July 1988, following the Premiers' Conference, responsibility for the administration of some pharmaceutical benefits programs was transferred to the States. These programs include pharmaceutical benefits for public hospitals, psychiatric institutions, nursing homes and Aboriginal health services. Also in 1988, 34 of the 53 expensive drugs which were authority listed were taken off the authority list after lobbying from many medical professionals who claimed there were no cheaper alternatives to these drugs.

3.6 It is recognised that the PBS is the fastest growing component of the health budget and that total PBS expenditure which was $1 billion in 1987/88 may approach $2 billion by the middle of this decade if the present trend continues, as the following table demonstrates:

Actual Expenditure 1978-79 to 1989-91 and Estimates 1991-92 to 1994-95 *

Year	Expenditure ($M)	Increase (% over previous yr)
1978-79	315.6	-
1979-80	323.1	2.4
1980-81	365.2	13.0
1981-82	458.9	25.7
1982-83	506.0	10.3
1983-84	572.8	13.2
1984-85	656.4	14.6
1985-86	729.3	11.1
1986-87	866.6	18.8
1987-88	1059.0	22.2
1988-89	1134.9	7.2
1989-90	1311.2	15.5
1990-91	1296.8	-1.1
1991-92	1327.0	2.3
1992-93	1410.3	6.3
1993-94	1560.5	10.7
1994-95	1750.6	12.2

* Supplied by the Department of Health, Housing and Community Services 10.12.91. Note - includes Veterans' Affairs, Factor F, Administration, Health Insurance Commission Administration expenses, Pharmacy Restructuring and Alternative Arrangements.

COST CONSIDERATIONS

3.7 The goals of the PBS as set out in the program performance statements of DHHCS for 1991-92 is "to enable access to necessary therapeutic substances at the lowest cost to Government and consumers consistent with reliable supply". As the number of drugs listed on the PBS has grown from 139 in 1950 to 529 in the current list (1013 items in different forms and strength), the Government has tried variously to achieve cost containment by looking at the factors influencing the increasing costs.

3.8 Since the PBS was introduced, the Government has kept the costs of drugs charged by manufacturers at a relatively low level. As the major purchaser of therapeutic drugs, the Australian Government has used its monopsony to dictate prices considerably below those in more competitive markets[1].

3.9 The introduction of co-payments is another attempt to influence the consumption of prescription drugs. One of the difficulties with this approach is that consumers rely on the prescribing patterns of their doctors and price incentives can only work if consumers are aware of prices and can communicate resistance to more expensive brands to the prescribing doctor. This leads into the area of rational prescribing and will be dealt with in the second report on this inquiry.

3.10 A third means of reducing expenditure on the PBS involves the costs of distribution. In an agreement reached on 6 December 1990 between the Commonwealth and the Pharmacy Guild of Australia, a remuneration and restructure package for approved pharmacists involved pharmacy closures and amalgamations and rationalised the geographical distribution of pharmacies. The Pharmacy Restructuring Authority was established to facilitate this process of restructuring and an evaluation of this process is currently being undertaken by the Senate Standing Committee on Community Affairs.

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[1] Industries Assistance Commission report on Pharmaceutical Products, 4 April 1986, p 28.

3.11 Several factors have been cited as contributing to the increasing cost of the PBS. One of these is the ageing of the population. In 1986-87 pension use accounted for 59.3% of the PBS use. This increased to 67.9% in 1989-90 but according to a paper by the Parliamentary Research Service, the increase in the population over 65 years of age is possibly not the most significant factor in the increasing cost of the PBS[2].

3.12 According to this paper, the forward budget estimates of 1990-91 suggest that the pensioner proportion of PBS expenditure will remain relatively constant at about 67%. It is further argued that most of the increase has been due in recent years to "prescription drift". More expensive drugs are coming onto the PBS lists and doctors are increasingly prescribing these. The Government has consequently been turning its attention to ways of influencing a more rational approach to medicines on the part of prescribers.

3.13 As referred to earlier, one of the problems is the lack of precise price information for consumers. The final responsibility for the volume and composition of prescribing must lie with the medical profession and any successful shift in the cost of the PBS must eventually confront doctors to take financial responsibility for their actions.

3.14 In the British National Health Service, doctors are given a fixed annual drug budget. This provides a strong incentive to find the cheapest drug possible or to use non-drug alternatives. In Australia, this raises questions concerning the right of doctors to make clinical judgements about appropriate therapy and treatment and raises other issues about the way medicine is practiced. These issues will be explored in greater detail the next part of the Committee's inquiry.

3.15 The Committee does not have sufficient information to determine precisely the factors contributing to increased consumption levels of drugs and hence

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[2] Pharmaceutical Benefits Scheme and the Pharmaceutical Industry, Education, Welfare Research Group, Parliamentary Research Service, 20 September 1990.

increased costs to the PBS. This may include the expectation on the part of patients that a prescription forms an essential part of a consultation. Another factor is that prescribers use prescriptions as a way of terminating consultations.

3.16 The fact remains that the continuing trend for greater reliance on pharmaceutical solutions to health problems is part of a complex set of interactions between individuals and professional clinical groups. As more accurate data collection about the behaviour of patients and doctors becomes available it should be possible to determine with more precision some of the driving forces behind this increasing consumption trend and to propose realistic solutions.

3.17 This has already commenced with the work of the Health Insurance Commission in gathering data on prescribing patterns and co-operating with the Drug Utilisation Sub-committee of the PBAC. This will be developed in the next report and links in with the promotion of better health strategies overall.

Role of the PBS

3.18 If, as stated earlier, the role of the PBS is to provide equitable access to safe, high quality pharmaceuticals to all Australians and to limit budgetary costs to Government, some balance has to be reached between these two objectives. In addition the Government's aim of encouraging the development of an Australian pharmaceutical industry has to be taken into account. This will be dealt with in the next Chapter of this report.

3.19 The Committee, in discussions with representative organisations of the medical profession has taken evidence about an essential drug list and whether or not the Australian Pharmaceutical Schedule is appropriate for the needs of the Australian population.

3.20 Competing claims have been made about the nature of the scheduled list

of drugs on the PBS. Some witnesses have claimed that the list is too broad and encompasses too many drugs. It is argued that a more efficient list would approximate the essential list of drugs of the World Health Organisation.

3.21 In evidence taken in Brisbane from a Senior Lecturer in General Practice, a case was put for "a collapsed version of the PBS. I would argue that much has happened ..... that the PBS should perhaps have only two, or at the most, three non-steroidal anti-inflammatories, and perhaps four or five anti-hypertensives, not 15 or 20 or whatever there are." (Dr Copeman: Transcript of evidence, p 809)

3.22 The argument continues that the drugs not listed should still be available on the private prescription market. The witness went on to state that "the automatic licensing of every new non-steroidal anti-inflammatory and every new anti-hypertensive - which still seems to be occurring - should not occur quite so much. If they do license a new one that does seem to be really good and worth its weight in gold, then maybe they should cull a few of the older ones and use that financial muscle to keep prices down and increase the competition amongst the companies." (Dr Copeman: Transcript of evidence, p 809)

3.23 Similarly, the Federal Bureau of Consumer Affairs (FBCA) claims that Australia should introduce a limited essential drug list. The argument, by the Bureau, is that consumers are at an information disadvantage under the present scheme. There is not enough objective information provided about the range of drugs available, increasing dependency on doctors to make choices on behalf of patients.

3.24 On the other hand, other medical specialists in evidence to the Committee have argued for increasing the numbers of drugs available on the PBS. The argument used to support this case is that the greater the choice of drugs, the more scope there is for prescribers to stabilise patients on drugs which suit individual requirements and minimise side effects.

3.25 Other examples where drugs used in combination for cancer therapy may not all be available through the PBS and therefore limit the ability of the prescriber to exercise proper judgement about the best therapeutic combination of drugs without financial disadvantage to patients have been raised.

3.26 The question of equity has also been highlighted by AFAO who, in arguing for timely availability of new drugs for potentially life threatening illnesses say that such drugs should be available under the PBS at the earliest opportunity, thus maintaining the spirit of the original PBS which was to provide essential life saving drugs to the general community at an affordable level.

3.27 The Committee endorses the view that the PBS should be a list of cost effective drugs based on the individual health care needs of the Australian community. No system of subsidisation will satisfy the requirements of all medical specialisations, but in order to retain confidence in the PBS and to reduce confusion about the competing objectives of equity of access and cost containment, the Government has to develop clearer guidelines for listing. This will be assisted by the introduction of cost-effectiveness analysis by the PBAC (refer paras 3.68 - 3.79).

3.28 The Committee is aware that the minimum pricing policy has had some impact on prescribing habits within a category of similar drugs where subsidy is only provided for the lowest priced brand name. It remains to be seen whether this mechanism is an effective means of promoting long term rational prescribing and assisting in keeping overall costs down.

Other cost control mechanisms

3.29 Another means by which the Government influences prescribing and indirectly consumption of pharmaceuticals is by the use of the authority listing process, which restricts access to certain drugs under certain conditions. At present, there are 78 separate drugs or 145 separate pharmaceutical benefit items listed on

authority. It has been alleged that this is a crude form of cost containment and not an efficient way of providing universal access to drugs for the general community[3].

3.30 Another recent attempt at introducing equity and cost effectiveness under the PBS was the conduct of a consensus conference held in October 1991 which brought together specialists to look at the formulation of guidelines and advice to the PBAC in the use of new expensive medications in the area of lipid lowering drugs. This initiative is to be commended as another way of better informing the PBAC in its decision making.

State hospital budgets

3.31 The PBS is essentially a community-based scheme for providing access to drugs. One of the criteria used by the PBAC for not listing a drug is that it is a specialist drug best used in institutional settings. In this case according to DHHCS:

> "It will not be listed on the PBS but it will be funded under section 100 of the National Health Act, whereby the funding will be provided direct to the States who, in turn, will provide the drug to the patient. ..... the Commonwealth will still be subsidising the cost of the drug for that community phase of the treatment, but will be doing so in such a way that ongoing specialist supervision is maintained through the State hospital system". (DHHCS: Transcript of evidence, p 963)

3.32 The question of State hospital costs and Federal responsibility for providing funds for treatment, including drugs, is currently being looked at as part of the Macklin Review. The Committee will await the findings of this review before making any further comment. However, the Committee feels strongly that individual patients should not be penalised in any shifts in funding support and notes that new administrative arrangements have been put into place to guarantee a common Commonwealth/State safety net for pharmaceutical drugs.

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[3]Access Economics, "Evaluation of the PBS", Business Council Bulletin, April 1989.

LISTING DRUGS ON THE PBS

The Pharmaceutical Benefits Advisory Committee

3.33 As described earlier in this Chapter, once a drug has been approved for marketing in Australia by ADEC, its manufacturer has the option of applying to have the drug listed for subsidy on the PBS. This application must be submitted to the Pharmaceutical Benefits Advisory Committee (PBAC) of the PBS. PBAC is responsible for advising the Minister which drugs, and in which forms and dosages, should be listed on the PBS. PBAC, whose membership and functions are defined in Section 101 of the National Health Act 1953, is responsible for adding or deleting drugs on the PBS and any restrictions to be placed on the prescription of PBS drugs.

3.34 PBAC currently meets in February, June and October each year for two day meetings to consider applications for PBS listing. Sponsors are required to forward their submissions for listing at least one month before each meeting. Assuming that a drug is approved for listing on the PBS, a formal submission is then forwarded to the Minister for approval; a price for the drug is negotiated between the manufacturer and the Pharmaceutical Benefits Pricing Authority (PBPA); a formal physical assay of the drug is conducted and enquires are made to ensure that the manufacturer has sufficient stocks of the drug available. The details of the drug and the details under which it can be prescribed on the PBS are then printed in the next edition of the "Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners" (the "PBS Book"). The PBS Book is updated and published every four months with supplements appearing every two months.

3.35 It can thus take four to six months from lodgement of a submission with PBAC to the time that inclusion of the drug on the PBS is detailed in the PBS Book, which, in effect, is when true market access is provided.

The Pharmaceutical Benefits Pricing Authority

3.36 PBPA is responsible for securing a "reliable supply of PBS items at the lowest cost to the Australian taxpayers and consumers" (PBPA, Annual Report 1990-1991, p 3). The two main criteria used for determining the price of pharmaceutical products listed on the PBS are gross profit margins and the comparative prices of products that are considered by PBAC to have a similar therapeutic effect (PBPA, Annual Report 1990-1991, p 3). This involves reviewing prices of drugs already on the PBS and those that have just been approved for listing by PBAC. PBPA has five members; a chairman, an industry nominee, a consumer nominee and a nominee from both the Department of Industry, Technology & Commerce (DITAC) and DHHCS.

3.37 PBPA is also responsible for the Pharmaceutical Industry Development Scheme (Factor F) which requires PBPA, when pricing drugs, to take into account the level of activity being undertaken in Australia by the sponsoring company including new investment, production, research and development. This is discussed in Chapter 4.

3.38 During price negotiations, PBPA receives advice from PBAC on the relative therapeutic value of the drug being submitted and whether prices can be justified on the grounds of better therapeutic outcomes. The discussions between PBPA and manufacturers have been described as follows:

> "The amount of negotiation can depend on the advice of the [PBPA]. If there is a situation where you have got one drug equivalent to another and the Pricing Authority says, 'The price is that', then there is practically no negotiation to be undertaken. It is the sort of situation of take it or leave it. But there are other situations in which the person to negotiate is given room to move, and that is where the detailed negotiation comes about." (DHHCS: Transcript of evidence, pp 981 - 982)

3.39 PBPA is aware that compromise is needed:

> "our objective is to keep the price as low as possible while maintaining access. We do not want to set it so low that no manufacturer wants to list" (DHHCS: Transcript of evidence, p 983).

3.40 On occasions, manufacturers show no interest in receiving PBS listing for their drugs, particularly if the drugs are unique or highly specialised. In referring to drug costs, the PBAC Secretary commented:

> "To get on to the PBS those costs need to be looked at by the Pharmaceutical Benefits Pricing Authority. In some cases, [the manufacturers] realise they would be required to drop their price and they are not prepared to even ask for listing or to decline invitations to listing even". (DHHCS: Transcript of evidence, p 958)

3.41 In such cases, the manufacturer can negotiate for a partial Government subsidy for the drug under the Special Pharmaceutical Benefits provisions whereby the PBS partially subsidises the drug, forcing the patient to pay a portion of the cost (for example Bleomycin, a drug used to treat Hodgkins' disease and Clomiphene Citrate, used by patients undergoing in-vitro fertilisation). Alternatively, the manufacturer can place the drug on the private prescription market, when there is no PBS subsidy at all and the patient is forced to pay the full cost of the drug.

3.42 The implications of drug prices and activity in Australia by the pharmaceutical industry is discussed in detail in Chapter Four.

Delays in the PBS listing procedure

3.43 The APMA believes that the delay between the lodgement of an application for PBS listing and the time the details appear in the PBS Book is too long:

"One of the problems is ... that PBAC only meets three times a year. In our view it should meet more frequently ... But in addition to the need to meet more frequently, the process is one of the problems... Our view is that the process is too long, that there ought to be a method of ensuring that the printing process... is accelerated". (APMA: Transcript of evidence, pp 1031 -32)

3.44 The APMA recommends that more frequent meetings coupled with a more extensive use of the supplements to the PBS Book that are published every two months could meet many of the criticisms of PBAC. (APMA: Transcript of evidence, pp 1031 - 32)

3.45 AFAO has commented that it "would certainly support improved and more frequent meetings of PBAC as a way of trying to get the drugs accessed more readily" (AFAO: Transcript of evidence, 1051). AFAO has also recommended that appropriate performance indicators be devised for PBAC to ensure the timely evaluation of products for listing. (AFAO: Transcript of evidence, p 937)

3.46 DHHCS is aware of these complaints:

"We will have to see whether we need to schedule additional meetings [of the PBAC] or to have two or three-day meetings to make sure that the achievements brought about as a result of streamlining the drug approval process do not get delayed through the PBAC process. That is something we are certainly conscious of and will be looking at". (DHHCS: Transcript of evidence, 952)

3.47 In addition, the Department has examined the possibility of conducting the formal physical assay of drug samples at an earlier stage in the drug approval process.

3.48 DHHCS has pointed out, however, that delays do occur in the PBS listing processes because manufacturers do not have sufficient drug stocks to distribute prior to marketing. (DHHCS: Transcript of evidence, p 957)

3.49 **The Committee recommends that the Pharmaceutical Benefits Advisory Committee (PBAC) meets four times per year to consider listing of drugs as the most efficient way of ensuring that delays in the listing process are minimised. Furthermore the Committee recommends that PBAC, if necessary, sit for longer than two days at each meeting to ensure that submission backlogs do not develop.**

PBAC: membership base

3.50 AFAO has recommended that representation on PBAC be changed to include a doctor with clinical experience in the treatment of AIDS. (AFAO: Transcript of evidence, p 940)

3.51 PBAC currently comprises 6 medical practitioners nominated by the Minister from among 10 names submitted by the AMA, 1 pharmacist from among 3 nominated by the PGA and 1 DHHCS pharmacist (s 101 (1), National Health Act 1953). The Minister also has discretionary power to appoint a pharmacologist and up to 3 more medical practitioners, one of whom shall be nominated by the Doctors' Reform Society (ss 101(2), (2AA), National Health Act 1953). All these positions are filled at present and highlight the influence of the AMA over and above specialist colleges and other medical associations represented.

3.52 This raises questions about the adequacy of the mix of present membership on the PBAC. As currently constituted, the PBAC is essentially a generalist Committee, whereas State and hospital drug committees which determine drug lists for use in hospital settings, draw their membership base from specialist practitioners and experts in pharmacology, as well as from generalists. Some State committees, such as the Victorian Drug Usage Advisory Committee (VDUAC), have specific sub-committees composed largely of specialists from a particular discipline. These committees produce a limited list of drugs based on therapeutic need and have cost containment as a major objective.

3.53 The PBAC has commented that it "regularly consults with or seeks advice from specialists or specialist bodies in particular fields of medicine." (PBAC Submission, p 573) Furthermore, PBAC membership is picked on the basis that:

> "wherever possible we try and keep people who are out there practicing clinically to keep, if you like, [PBAC] very much at the forefront of what clinical practice is occurring in the community, in clinical settings". (DHHCS: Transcript of evidence, p 955)

3.54 The Committee notes that particular expertise is sought from specialists in particular fields of medicine when considering a specific drug category but considers that this should be more formalised. **Consequently, the Committee recommends that PBAC, when considering a particular drug which has specific relevance to a specialist area of clinical treatment, ensures that a nominated representative with expertise in a specialised area of therapeutics, practical experience of drug committees, a current clinical practice and recruited through specialist associations be consulted during the process of evaluation.**

3.55 **Furthermore, the Committee recommends that the Government review the current membership of the PBAC with a view to increasing the level of available specialists in drug use on the Committee. This can be effected by appropriate amendments to s101(1)&(2) of the National Health Act. Formal mechanisms should also be established to coordinate the listing process between State and Federal Governments in an effort to standardise drug lists and derive more precise guidelines for listing on the PBS.**

A more active role for PBAC

3.56 PBAC receives applications for the listing of drugs on the PBS from drug manufacturers and to a lesser extent, from individuals who request that particular drugs be listed.

3.57 AFAO has recommended that PBAC "should take a more pro-active role in soliciting applications from pharmaceutical companies" and that:

> "in the case of drugs for life-threatening conditions, PBAC and the Pharmaceutical Benefits Branch solicit an application from the pharmaceutical company if none has been received within 20 working days of ADEC approval". (AFAO: Transcript of evidence, p 938)

3.58 However as already mentioned, there is no incentive for manufacturers of some categories of specialist drugs to put in a submission for PBS listing, because the drugs are unique or will be used in the hospital setting:

> "from the drug company's point of view, sometimes it cannot be bothered putting in a submission. It knows that its drug is the best drug. It knows that it is a lot of work to put in a submission and that whatever happens, the patients are going to be treated with these drugs so why bother to put in a submission? ... The Company is still going to be paid for the drug, because it is going to come through the public hospital". (Dr van Hazel: Transcript of evidence, p 611)

3.59 The Committee is aware that PBAC cannot compel a manufacturer to lodge a submission for PBS listing, particularly when there is a price disagreement. **However, the Committee recommends that the Pharmaceutical Benefits Advisory Committee invites manufacturers of breakthrough drugs for life threatening conditions to submit the drugs for Pharmaceutical Benefits Scheme listing once they have received marketing approval from the Australian Drug Evaluation Committee.**

The PBS and State drug funding arrangements

3.60 As has been described in paras 3.31 and 3.32, the PBS is a community based scheme. While the PBS incorporates a wide range of drugs, it does not include many highly specialised drugs that are mainly used in hospitals or some injectable substances where the oral form is listed on the PBS. State public hospitals develop their own approved drug lists singularly or in conjunction with the

other public hospitals in their State and pay for these drugs through State health budgets. As Queensland Health explained:

> "There is a range of drugs which are commonly used for in-patients within hospital situations that would not appear on pharmaceutical benefits. Indeed, one of the determining parameters for items going on pharmaceutical benefits is that they are unlikely to be used in the hospital situation... in terms of absolute numbers there is probably a larger number [of drugs] on the standard [Queensland public hospital] list than there is on the pharmaceutical benefits list". (Queensland Health: Transcript of evidence, p 879)

3.61 However, the recent marketing approval given to some very expensive drugs has placed financial pressure on both the PBS and on State public hospital drug budgets. Both PBAC and PBPA have come under criticism for appearing to respond to this financial pressure by refusing to list highly expensive drugs on the PBS or by negotiating prices so low that manufacturers are disinclined to list their products. As one cancer specialist explained to the Committee:

> "The PBS is not succeeding by saying that it is being a tough negotiator and that it is not going to let [the manufacturers] get away with this price that they want, because then they go to the public hospital and the drug company gets any price... So the PBS is not succeeding by being a tough negotiator; it is just passing the buck to someone else". (Dr Van Hazel: Transcript of evidence, p 609)

3.62 Furthermore:

> "there certainly is a perception amongst the oncology fraternity that the PBAC was allowing financial considerations to influence its judgement. There was even a suggestion that it may be being leant on by Federal Government to try to ensure that the costs were borne by the States". (Royal Australasian College of Physicians: Transcript of evidence, p 1177)

3.63 In recognition that there needed to be at least a coordinated response to the rising cost to both the Commonwealth and States of pharmaceuticals, the Australian Health Ministers' Advisory Council (AHMAC) established a Working

Party on High Cost Drugs. As a result of the Working Party's recommendations, the Commonwealth, using its powers under s100 of the National Health Act is now negotiating cost sharing arrangements with the States for individual high cost drugs. For example, under an arrangement for the drug cyclosporin (an immune suppressant used for patients undergoing transplantation), the States pay for the use of the drug while the patient is in hospital and the Commonwealth meets the cost of the drug once the user becomes a hospital outpatient. Cyclosporin will not be listed on the PBS, although:

> "the Commonwealth will still be subsidising the cost of the drug for that community phase of the treatment, but will be doing so in such a way that ongoing specialist supervision is maintained through the State hospital system". (DHHCS: Transcript of evidence, p 963)

3.64 As a result of the recommendations of the Working Party on High Cost Drugs, an ongoing AHMAC Working Party on Highly Specialised Drugs has been established to, inter alia, select which drugs should be included in the funding arrangements for highly specialised drugs and negotiate national prices for them with manufacturers.

3.65 The Australasian Society of Clinical and Experimental Pharmacologists & Toxicologists (ASCEPT) sees such arrangements as a "breakthrough":

> "It is the first recognition that the provision of pharmaceuticals needs to be considered on a national scale and should transcend the bickering and cost shifting which result from the Commonwealth - State cost sharing arrangements on health. The AH&MAC Working Party report recognises for the first time the need to consider drugs provided through hospitals and through the Pharmaceutical Benefits Scheme as parts of a whole rather than separate entities". (ASCEPT: Transcript of evidence, p 1167)

3.66 Some confusion has arisen which is illustrated by the breakthrough lifesaving drug zidovudine (AZT), an antiviral drug which has been funded under special Medicare arrangements but which also falls into the category of a highly specialised drug and for the sake of consistency should be covered under the above

provisions. The Committee understands that consideration is presently being given by DHHCS to streamlining procedures in relation to highly specialised drugs. This should be done to overcome difficulties with consistency of application of standard principles and to better coordinate price negotiations with drug manufactures from a joint Federal/State perspective.

3.67 The Committee is concerned at allegations that PBAC and PBPA avoid listing drugs purely on the basis of their cost. However, the Committee is encouraged by the initiative of the AHMAC Working Party to coordinate cost sharing arrangements and believes that such an initiative will reduce complaints about the PBAC and PBPA's cost containment methods. Furthermore, the Committee believes that PBAC's initiative to require economic analyses of applications for PBS listing, as discussed in the next section of this Chapter, is an appropriate mechanism for seeking a more cost effective PBS.

COST EFFECTIVENESS

3.68 The Government, faced with the increasing cost of subsidising drugs on the PBS, has been forced to examine drugs on the grounds of economic efficiency as well as clinical efficacy. As a result, in August 1987 the Government amended the National Health Act 1953 to require PBAC to:

> "... give consideration to the effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations". (s101 (3A), National Health Act 1953)

3.69 PBAC will continue to base its decisions on the comparative clinical performance of drugs and their need within the community, but, in line with the Government direction above, will make increasing use of economic analyses in its evaluations.

3.70 The field of economic analysis is highly complex and there are several analytical methods for evaluating the cost effectiveness of pharmaceuticals. As a result, DHHCS has sought advice from external consultants and has, in consultation with the local industry, developed guidelines for including cost effectiveness analyses in submissions to PBAC for PBS listing[4]. As outlined by DHHCS:

> "We see [this] as simply part of a process of getting better value out of the health dollar... it is an iterative process, it is a consultative process. We have to start somewhere and this would allow us a base to enter into dialogue with the industry and to start to put in place some structures and processes, I guess, for looking at the cost of drugs in perhaps a more sophisticated way than we have been able to date". (DHHCS: Transcript of evidence, p 978)

Phased introduction of cost effectiveness analysis

3.71 DHHCS has introduced a requirement that all PBAC applications include an economic analysis by January 1993. Pharmaceutical companies have been encouraged to voluntarily submit economic analyses with their applications before that date. However, in the case of high cost/high use drugs PBAC is now likely to request such analyses if they have not been included in the original submission[5].

3.72 Australia is the first country in the world to require economic analyses from pharmaceutical companies as a basis for decisions regarding Government subsidisation of prescription drugs. This lead is now being followed in certain other countries, such as the Canadian Province of Ontario and is likely to form the basis for changes in the regulatory systems of other countries in the future. DHHCS has admitted that there are few people with the appropriate health economics skills in Australia:

"There is a learning curve for all involved; the industry, the Department,

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[4] DHHCS, "Draft Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee Including Submissions Involving Economic Analysis".

[5] ibid, p 1.

the PBAC and the academics that might be brought in as analysts to assist the industry. Certainly the shortage of skills in Australia is a notable feature of what we have to deal with". (DHHCS: Transcript of evidence, pp 977-978)

3.73 The external consultants used by DHHCS cautioned that:

"In view of the lack of expertise and trained personnel and because of the essentially experimental nature of some of the methods employed during economic analysis, it is important to recognise the need for commonsense and flexibility in the application of new requirements" [6]

3.74 The Pharmaceutical manufacturer Merck, Sharp & Dohme (Australia) Pty Ltd (MSD) has warned that the DHHCS draft economic analysis guidelines are "possibly the most stringent in the world" and that "it is doubtful whether or not companies or Government could meet the requirements of the guidelines in the short term"[7].

3.75 MSD suggests that PBAC should consider phasing in the level of analysis in addition to phasing in the requirement for analysis and that companies "should initially be given some flexibility in the preparation of PBAC submissions while expertise in the new area is being developed[8]."

3.76 The APMA in a submission responding to the Department's draft guidelines makes a further suggestion that a cost-effectiveness sub-committee of PBAC be established to review economic submissions and make recommendations to PBAC[9].

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[6] Evans, D et al, "The Use of Economic Analysis as a Basis for Inclusion of Pharmaceutical Products on the Pharmaceutical Benefits Scheme", p 1.

[7] Letter to Committee Secretariat from MSD, 20 August 1991 containing "Submission by Merck Sharp & Dohme (Australia) Pty Ltd on Draft PBAC Cost-Effectiveness Guidelines", p 1 - 2.

[8] ibid, p 5.

[9] APMA response to DCSH draft guidelines, 11 December 1990.

3.77 **In view of earlier comments about the generalist nature of the Pharmaceutical Benefits Advisory Committee (PBAC) and the overall lack of experience of both industry and Government in cost effectiveness analysis, the Committee recommends that a cost-effectiveness sub-committee of PBAC be established through which health economists and industry representatives could review economic submissions and make recommendations to PBAC.**

3.78 In another effort to assist industry in this initial period, the Department of Health, Housing and Community Services has funded an academic clinician on a six month contract to be available to pharmaceutical companies to assist them prepare economic analyses before submission to the Pharmaceutical Benefits Advisory Committee. The Committee sees this appointment as significant.

3.79 The Committee fully supports the requirement that economic analyses be included in submissions to PBAC as a tool to determine the most appropriate drugs to be subsidised on the PBS. The Committee appreciates that Australia is at the forefront of this type of health economics and commends DHHCS for the consultative approach it has taken in developing the draft guidelines. However, the Committee also recognises that it is DHHCS' responsibility to ensure that Industry fully understands the guidelines and that the Department should use flexibility in its initial application of the new requirements whilst expertise grows in both Industry and Government.

A further delay in the listing process?

3.80 Industry has expressed concern that the economic analysis requirements will place an additional delay in the drug evaluation process. As detailed by MSD:

> "We are concerned at the potential for long delays in the evaluation of economic data, and hence delays in the PBS listing of products. The Government should give assurance to the Industry that the guidelines will not delay registration nor PBS listing of a new product and that cost

effectiveness studies will not become part of the requirements for registration trials"[10].

3.81 The Committee shares this concern and believes it incumbent on DHHCS to ensure that the introduction of the economic analysis requirement will not delay the consideration of submissions by PBAC.

[10] Letter to Committee Secretariat from MSD, op cit, p 3.

Chapter 4

THE PHARMACEUTICAL INDUSTRY

BACKGROUND

4.1 In the Bureau of Industry Economics' Report on the Pharmaceutical Industry released in November 1991, reference is made to the fact that the pharmaceutical industry in Australia is part of a global industry, characterised by high and increasing levels of research and development expenditure and high levels of regulation by Government. Government controls access to the market through the drug evaluation system and also controls the price of products in the market through the PBS.

4.2 Australia, with less than 2% of the global market, is not generally perceived as an attractive location for pharmaceutical activity[1]. The Australian pharmaceutical industry is dominated by the subsidiaries of multinational enterprises supplying 94% of the Australian market. Most pharmaceutical activity in Australia is concerned with the formulation and packaging of final products from largely imported active ingredients.

4.3 Against this background, the industry in Australia has a guaranteed market through subsidisation on the PBS, high quality medical services, along with the availability of skilled labour and proximity to expanding Asian markets. Australia also has strengths in medical research in bio-technology and despite its small population base, has the ability to participate reliably in multicentre trials of new drugs.

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1 Bureau of Industry Economics, Program Evaluation Report 11, The Pharmaceutical Industry: Impediments and Opportunities.

4.4 Due to the lack of major research and development activity in Australia, the industry concentrates a large proportion of its resources in the promotion and marketing of its products. These activities are regulated by the industry itself through the code of conduct of the APMA as well as control of electronic advertising through the Media Council of Australia (MCA). This is discussed in greater detail later in this Chapter.

Responsible corporate citizens

4.5 In section 9 of the APMA Code of Conduct, reference is made to members of the association being responsible corporate citizens[2]. The Committee has taken evidence from a range of witnesses who have questioned the promotional practices of some members of the association and whether or not there are effective ways of encouraging the industry to participate in health promotional activities without necessarily focusing specifically on particular brand name products. While it is recognised that individual companies, as well as the APMA, have a responsibility to their shareholders to maximise market share and increase profits, therapeutic substances carry a weight of ethical responsibilities with them which do not apply to other commercial products.

4.6 The Committee acknowledges that the industry does participate in and funds initiatives which are not drug specific and which assist in broadening the education base of medical practitioners. For example, MSD publish technical texts and manuals which assist in providing a range of reference sources for diagnosis and therapy for disease states. These include the Merck Manual and the Merck Manual of Geriatrics. This initiative in the area of professional educational references is commended.

4.7 Moreover, the industry participates in meetings to satisfy the particular

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2 Code of Conduct of the APMA, Edition 9, adopted 6 September 1990, p 40.

needs of specific groups such as rural doctors:

> "The isolation and the perpetuation of some of the vested interests that exist mean that alternatives have to be found for isolated regions and doctors. I think that is an important issue, and none of the meetings that the Rural Doctors Association have been able to hold would have been possible without the support of the drug companies in terms of their sponsorship. To date we have managed to sponsor three major annual conferences and about 13 regional conferences for rural doctors in New South Wales in the space of about 2 1/2 years." (AMA: Transcript of evidence, pp 1090-1091)

4.8 Pharmaceutical manufacturers also employ a range of strategies to promote and advertise their products to health professionals and the general community. These include advertising in professional journals, use of company detailers or drug representatives, sponsoring professional seminars and trade displays, funding of educational research facilities and provision of free product samples to doctors.

Advertising

4.9 Whereas advertising will be considered in greater detail in the next part of this Chapter, dealing with self regulation and the APMA Code of Conduct, the question of whether or not a ceiling should be placed on the amount of advertising undertaken by a company as a proportion of its sales volume has been discussed with several witnesses at public hearings. According to one witness, the promotional power of the industry was claimed to be:

> "about 15% of sales. People would argue over the amount but about $200 million is put into pharmaceutical promotion per annum; that is about $8 000 to $10 000 per doctor of incentive to try to influence the pen that writes the script. Against this megabucks of $200 million of promotion .... is something like mere hundreds of thousands of dollars put into independent education. So there is a total distortion, as I see it, of information out there which is due to the structural problem of Australia having left the volume of promotion relatively unrestrained." (Dr Harvey: Transcript of Evidence, p 421)

4.10 A possible solution to this has been suggested whereby as in Great Britain, only 10% of sales budget is allowed for promotion. Similarly, according to information provided at a public hearing, Egypt puts a tax on the pharmaceutical industry and channels it into independent education.

> "If the companies in the industry produce a good drug for the right indication, and the best of the innovative research based manufacturers do just that .... those companies would not suffer from their promotion being constrained .... The only ones that would suffer from the sort of structural redressing that I am talking about are those companies that make a profit by selling the wrong drugs for the wrong indications and using the power of marketing to convince the medical profession that this is to be done". (Dr Harvey: Transcript of evidence, p 424)

4.11 While it is recognised that individual companies operate in a very competitive marketplace, it must also be recognised that they have an obligation to encourage and assist in promoting better informed consumers, both prescribers and patients, and to create the best conditions for quality drug use in the community. For this reason, it is in the public interest for the industry to determine more precise guidelines about what proportion of their promotional budgets they spend on various promotional activities.

4.12 **The Committee therefore recommends that pharmaceutical companies, in making applications for listing new products on the Pharmaceutical Benefits Scheme, provide the Pharmaceutical Benefits Pricing Authority with pricing information which includes the amount to be spent on promotional activities as part of the submission for determining the price of the product. This information should also give a breakdown of the proportion of promotional expenditure devoted to independent medical education as the Committee would like to encourage a greater proportion of financial resources to be spent on educational, as opposed to brand product, promotional advertising.**

Company detailers

4.13 Company detailers, or medical representatives as they are called by the industry, are industry trained and increasingly recruited from the nursing profession. The Committee has been told that they tend to provide information to doctors which stress the advantages of a particular brand without having the necessary knowledge or inclination to provide a comparative assessment of that drug against others in the same therapeutic category. The APMA has recognised these criticisms and has established a program known as "MEDREP" to provide detailers with more comprehensive training.

4.14 A problem which has been highlighted to the Committee is that of the isolation of many GPs from sources of current information about new drugs. Company detailers obviously provide much needed information about new products on the market but there is some doubt about whether this is an appropriate way to educate doctors in a broad sense about the value of these products compared with other forms of treatment or drugs of competitors.

4.15 One solution to this which has been proposed to the Committee is the notion of academic detailing. This would involve independent pharmacists or doctors having responsibility for visiting GPs and specialists with a view to providing objective information about new drug therapy and alternative therapy from an independent base. This will be developed in greater detail in the next report on the inquiry which will deal specifically with the role and responsibilities of prescribers.

Other promotional activities

4.16 The pharmaceutical industry uses a range of other activities to promote products. These include the provision of free samples in the form of starter packs

for doctors, office stationery with company names and drug brand names on them, as well as other more expensive items such as computers. In evidence to the Committee a witness described it in the following terms:

> "everyone knows they bend the rules .... I do not know if you know about the Squibb story. They gave everybody a free computer, and that payola went up according to the cost of the product. .....They wanted to get it right into the market and they had the great idea to give everyone a free computer. They said, 'We are going to survey our drug and you can put all your results into the computer'. So we all got a computer and a printer and a monitor ..... They said, 'We are getting these computers back', but last year they sent out the letter saying 'Please sign this release and you can keep the computer'. (Doctors' Reform Society: Transcript of evidence, p 1203-1205)

4.17 The pharmaceutical industry does provide opportunities for doctors and other health professionals to meet together and to be briefed on the latest developments in a particular area of medicine. These seminars, dinners and symposia are usually heavily subsidised by the industry which often controls the program and content of the information provided. This is not to say that it is necessarily brand specific but highlights an important point raised at a public hearing. The AMA stated:

> "We believe that there is insufficient support for postgraduate medical education in this country and much of the activity is subsidised by pharmaceutical companies. There is concern within the profession that the bona fide education bodies are effectively bypassed in some of this post-graduate activity." (AMA: Transcript of evidence, p 1069)

4.18 The Committee is aware of the Guide to Ethical Principles in the Relationship between Physicians and the Pharmaceutical Industry published by the Royal Australasian College of Physicians (RACP), (refer to Appendix 6) which deals, among other things, with pharmaceutical industry sponsored travel and guidelines for the conduct of support at meetings. One problem with these guidelines is the qualitative assessment of what constitutes appropriateness and legitimacy of these activities. Ultimately, questions of ethical concern must be judged on an individual

basis in the absence of more precise guidelines.

4.19 **However, the Committee supports the promulgation of ethical principles to guide professional organisations in their dealings with the industry and recommends that guidelines similar to those prepared by the Royal Australasian College of Physicians be developed by the Australian Medical Association and other specialist colleges.**

4.20 It is important to stress that all professional bodies have a responsibility to conduct their activities in a way which reinforces public confidence in them. Any financially sponsored activities must be able to stand up to public scrutiny and there must be effective sanctions to prevent abuse or fraudulent misrepresentation. This is particularly the case where it involves public health issues.

ADVERTISING OF PRESCRIPTION PRODUCTS TO HEALTH PROFESSIONALS

4.21 Before 1987, the former Therapeutic Goods Compliance Branch precleared all promotional material for new prescription drugs and for new indications for established drugs. In June 1987 a Public Service Board Review of drug evaluation procedures recommended, among other things, that it was appropriate for the pharmaceutical industry to self regulate the advertising of pharmaceuticals to health professionals on a trial basis if advertising codes acceptable to the Government could be drafted[3]. As a result of this report, it was decided to allow the APMA to regulate advertising of prescription products for a 2 year trial period beginning in December 1987.

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[3] Commonwealth Public Service Board, Review of Drug Evaluation Procedures, June 1987, paras 4.234 - 4.236.

4.22 The APMA represents the manufacturers of prescription products. While its 51 member companies (as at March 1991) represent approximately 50% of registered pharmaceutical companies in Australia, it is estimated that sales by APMA members account for more than 88% of total industry sales of human use pharmaceuticals and in excess of 92% of National Health Service sales under the PBS. (APMA: Submission, p 1010)

4.23 Since its first publication in 1960, the APMA Code of Conduct has evolved through 9 editions to establish comprehensive standards for the promotion and advertising of prescription products to health professionals. The basic purpose of the Code is to ensure that pharmaceutical advertisements and promotional activities are neither misleading nor deceptive. Acceptance and observance of the Code is a condition of APMA membership and members must comply with both the letter and the spirit of the Code APMA[4].

4.24 In January 1990, the Minister for Consumer Affairs requested the Trade Practices Commission (TPC) to undertake a review of the existing self regulation arrangements dealing with advertising and promotion of therapeutic goods and in December 1991, the TPC produced a draft report on its findings. Much of the review involved assessing and commenting on the effectiveness of the APMA Code of Conduct, dealing with market problems, the effectiveness of complaints handling and the Code's administration[5].

The APMA Code: an overview

4.25 The Committee believes that the APMA Code of Conduct and its complaints review mechanisms are reasonably effective in controlling the

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4 Code of Conduct of the APMA, op cit, Preamble.

5 Trade Practices Commission, "Draft report by the Trade Practices Commission on the self regulation of Promotion and advertising of Therapeutic Goods", December 1991.

inappropriate advertising of prescription products to health professionals. However, there is room for improvement in the Code and its administration.

4.26 As Dr Ken Harvey told the Committee:

> "There is a small and decreasing problem of advertisements... To give credit to the Australian Pharmaceutical Manufacturers Association and its codes of practice, that proportion of bad advertisements is slowly decreasing". (Dr Harvey: Transcript of evidence, p 421)

4.27 A number of other interested groups have reinforced this opinion in evidence before the Committee. The Australian Secretary for the Medical Lobby for Appropriate Marketing (MaLAM), believes the APMA Code has "improved significantly but there are still some areas to be looked at". (MaLAM: Transcript of evidence, p 460) A member of the RACP Therapeutics Committee, when asked his opinion of the Code commented, "I do not think it is quite enough. I do not want to be too critical of it because I think it is basically a good code. So everything I say from now on is in that context. I think there are still problems with it". (RACP: Transcript of evidence, p 1183) Finally, the TPC in its draft report "is prepared to accept that there is evidence of an improvement in compliance [with the Code of Conduct] over the last few years"[6].

Incentives to prescribe

4.28 One method companies use to increase sales is to provide doctors with incentives to prescribe their products. The Committee has heard evidence from a number of sources that doctors have been offered free computers to take part in drug trials, invited to seminars in exotic locations and invited to enter competitions of dubious merit for substantial prizes.

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6 TPC, Draft Report, op cit, p 23.

4.29 As described by the Doctors' Reform Society (DRS):

> "they [a drug company] had the great idea to give everyone a free computer. They said, 'We are going to survey our drug and you can put all your results into the computer'. So we all got a computer and a printer and a monitor... If you got more than 20 patients enrolled you got a disc drive, and they came around with software for your kids to use the computer". (DRS: Transcript of evidence, p 1204)

4.30 However, the more blatant abuses seem to have declined. As a Senior Lecturer in General Practice at the University of Queensland noted:

> "Some years ago there were more free trips. ... Some of my colleagues have been on free trips, but not many. Some of them have received free computers as part of what I would call fairly bogus drug trials... I have not heard as much about those sorts of practices in the last two years". (Dr Copeman: Transcript of evidence, p 798)

4.31 The Committee also asked witnesses about the misuse of hospitality and entertainment in association with promotional events as an incentive to prescribe. The same Senior Lecturer told the Committee that:

> "Drug companies have become very prolific at providing free lunches and dinners... and associating those free lunches and dinners with a talk or a video presentation about a drug or an illness. While showing the course of that illness... the products of the sponsoring company will be promoted and the others be either ignored or down played. They say these occasions are contributing to continuing medical education, and I suppose to some small extent they are..." (Dr Copeman: Transcript of evidence, p 797).

4.32 However, as the Queensland University Department of Social and Preventative Medicine described:

> "on the other side of that coin, these events which ... can involve a very big expensive hotel with a slap-up dinner, are always accompanied by an educational event which has the potential, at least, of being independently run... I think it is a slightly grey area. In anything I have attended, I have not seen anything that I thought smacked of impropriety". (Dr Del Mar: Transcript of evidence, p 898)

4.33 The RACP provided the Committee with a copy of its "Guide to Ethical Principles in the Relationship between Physicians and the Pharmaceutical Industry" which covers in detail guidelines for the participation of its members in clinical trials and attempts to strike an appropriate balance between the promotional and educational aspects of joint professional - industry functions. The TPC notes that the Association of the British Pharmaceutical Industry's Code of Practice contains similar guidelines. It should also be noted that the Code of Conduct does provide guidelines for conducting competitions (subsection 3.7), symposia & trade displays (section 6) and marketing research & post marketing Surveillance studies (section 7).

4.34 **The Committee supports the recommendation by the Trade Practices Commission and similarly recommends that guidelines based on the Association of the British Pharmaceutical Industry code and Royal Australasian College of Physicians guidelines be included in the Australian Pharmaceutical Manufacturers of Australia Code of Conduct for industry sponsored trials and functions. Adoption of such guidelines would reduce the potential for pharmaceutical companies being accused of unethical behaviour in the promotion of their products.**

4.35 In addition, the Committee believes that a further ethical principle should be embodied in the Code to reinforce principles of rational prescribing. This is the principle that promotional activities be in accordance with national health policy and a national approach to drug use. This will be developed in greater detail in Chapter 6.

Code of Conduct Subcommittee: Membership

4.36 The primary purpose of the APMA's Code of Conduct Subcommittee (the "Complaints Subcommittee") is to review complaints received by the APMA alleging breaches of the Code.

4.37 The Complaints Subcommittee is chaired by a lawyer experienced in Trade Practices legislation. Other members include representatives of various professional societies and, on a rotating basis, representatives from member companies.

4.38 Included on the Complaints Subcommittee is a position for a medically qualified representative of a significant patient interest group, currently the Arthritis Foundation. The APMA believes "such a representative is suitably qualified to act in the interests of patients generally". (APMA: Submission, p 2353)

4.39 However, the Committee has received comment from Dr Ken Harvey (Harvey: Submission, p 659), the ACA and the CHF (ACA & CHF: Submission pp 1582-3) that the Complaints Subcommittee should include a specific representative of the consumer movement. Dr Harvey believes that by appointing a representative of the Arthritis Foundation to the Complaints Subcommittee, the APMA was:

> "in practice bypassing the organised consumer movement and the accountability to members that formal representation provides". (Dr Harvey: Submission, p 659)

4.40 The Chief Executive Officer of APMA has responded to such criticisms:

> "Our view is that consumer representation is appropriate in bodies where consumers are actively involved. In the case of medical advertising which is directed at the medical profession, we believe that the consumers are the medical profession, and therefore I think bodies such as the Arthritis Foundation, which represents patient groups, are providing that facility". (APMA: Transcript of evidence, p 144 - 145)

4.41 The Committee believes that the public are in fact the ultimate consumers of pharmaceutical products, and that as such should be formally represented on the Complaints Subcommittee. As to the arguments that a consumer representative would not have the expertise to sit on the Subcommittee, the Committee notes the observation by the Federal Bureau of Consumer Affairs

(FBCA) that "the notion that consumers no longer can understand is one that is rapidly disappearing". (FBCA: Transcript of evidence, p 1015)

4.42 **The Committee therefore supports the Trade Practices Commission recommendation and similarly recommends that a representative from a peak consumer health group with the appropriate background be included on the Australian Pharmaceutical Manufacturers Association Complaints Subcommittee**[7].

4.43 **Furthermore, the Committee supports the Trade Practices Commission recommendation and similarly recommends that a representative of the Department of Health, Housing and Community Services be given observer status on the Complaints Subcommittee, given the shared interest in this matter by the Department, which administers the Therapeutic Goods Act, and the Australian Pharmaceutical Manufacturers Association**[8].

Code of Conduct Subcommittee: Independence

4.44 The Committee accepts the APMA's contention that the independent members of the Complaints Subcommittee "vigorously maintain their independence". (APMA: Transcript of evidence, p 143) However, the Committee believes that public confidence in the Code of Conduct would be enhanced if the Complaints Subcommittee was allowed to make decisions in its own right. Currently, the Complaints Subcommittee can only make recommendations to the APMA Committee which makes the final decision on complaints heard.

4.45 **Accordingly, the Committee supports the recommendation of the Trade Practices Commission and similarly recommends that Sections 10.2 & 10.3 of the Australian Pharmaceutical Manufacturers Association's Code of Conduct be**

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7 TPC, Draft Report op cit, p 36.

8 ibid, p 36.

replaced with the following:

> "10.2 If the subcommittee, after making such further inquiry as is necessary or desirable, forms the opinion that a breach of the code has occurred, it shall inform the Chief Executive Officer of the breach and the reasons and of the form of Sanction to be applied to the Member, as provided for under Section 11 of the code.
>
> 10.3 If the subcommittee considers that no breach has occurred, it will so advise the Chief Executive Officer and the parties to the complaint shall be so advised"[9].

Effectiveness of sanctions

4.46 One of the most common sanctions applied against companies publishing advertisements in breach of the Code is the requirement that the offending articles be withdrawn or modified. The APMA's ultimate sanction is to suspend or expel a member from the APMA (see Section 11, APMA Code of Conduct, 9th Edition). Given the timing of the complaints review mechanism, an advertisement, later found to be in breach of the Code, will likely have run its course and achieved its promotional affect before it could be modified, withdrawn or a corrective letter sent out.

4.47 Dr Harvey wrote that:

> "Little effort is made by the APMA to publicise Code breaches. In the few instances where a 'Dear Doctor' letter of clarification was asked for, the letter produced often contained little to indicate that it had been produced as a result of a specific Code breach and it was not obvious that the intent was correcting misinformation". (Dr Harvey: Submission, p 659)

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9 TPC, Draft Report, op cit, p 39.

4.48 The ACA and CHF told the Committee:

> "the APMA has no powers to penalise offending companies other than forcing a reprimand or expelling them from the APMA, which would rather be like cutting off their nose to spite their face. In terms of real sanctions with teeth to impose an ethical code of conduct for advertising and promotion, that simply does not exist under the current self regulation system". (ACA & CHF: Transcript of evidence, p 256)

4.49 Professor Moulds of the RACP reinforced this point, stating:

> "The penalties range from a slap on the wrist to two slaps on the wrist, basically. So it is a little toothless." (RACP: Transcript of evidence, p 1183)

4.50 The APMA has argued that the ultimate threat of expulsion from the APMA is sufficient sanction:

> "Such a sanction may seem trivial to those outside the industry. However, in an environment where major Australian companies are subsidiaries of international companies who pride themselves on ethical conduct ... either suspension or expulsion would be severely detrimental to the reputation of the parent and the local management. It is therefore an effective sanction of last resort". (APMA: submission, p 2349)

4.51 The Committee supports the Trade Practices Commission's recommendation and similarly recommends that the Code be amended to empower the Complaints Subcommittee to require corrective advertising and/or to impose a fine on a member company found to be in breach of the Code. No upper or lower limit should be placed on the fine but the amount of the fine should reflect the gravity of the offence[10]. Furthermore, the Committee recommends that fines should be significantly increased for repeated offences by the same manufacturer.

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[10] TPC, Draft Report, op cit, p 43.

4.52 The Committee is concerned that any corrective advertising or letters be given due prominence by the offending company. As the Secretary of MaLAM pointed out:

> "My own feeling is that, once misleading information has been put out, doctors are going to remain misled until they are provided with corrective information. So the corrective letters are very important... I suspect that a lot of them are not read; they go straight into the waste bin. We do receive a lot of material from industry all the time. (MaLAM: Transcript of evidence, p 457)

4.53 Dr Harvey suggested that an appropriate response would be for:

> "the offending company to run a clearly headed retraction statement of the same size, in the same media, and with an identical number of insertions, to that of the original advertisement". (Dr Harvey: Submission, p 659)

4.54 **The Committee supports the Trade Practice Commission's recommendation and similarly recommends that Section 11.2 of the Australian Pharmaceutical Manufacturers Association's Code be amended to provide that member companies found to have breached the Code be required to submit a draft of any retraction statement or corrective advertisement to the Subcommittee for approval. If the Subcommittee is not satisfied with the format, size or wording of the statement it may redraft the statement. The Subcommittee should be able to determine the mode and method of publication[11].**

4.55 **Furthermore, the Committee supports the Trade Practices Commission recommendation and similarly recommends that corrective letters should be sent on Australian Pharmaceutical Manufacturers Association stationery, at the offending company's expense, to encourage doctors to read retraction statements[12].**

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11 TPC, Draft Report, op cit, p 43.

12 ibid, p 43

4.56 **The Committee also agrees with the Trade Practices Commission's recommendation and similarly recommends that the Australian Pharmaceutical Manufacturers Association (APMA) Code be amended by the inclusion of a statement that should a company refuse to comply with a sanction imposed by the Complaints Subcommittee or refuse to have a complaint heard by the Complaints Subcommittee then the Chief Executive Officer may either refer the matter to the Department of Health, Housing and Community Services or institute legal proceedings on behalf of the APMA[13].**

Promotion of the Code

4.57 The APMA has pointed out that:

> "When we look at the origin of complaints, a relatively large percentage are from competing companies complaining about promotion by another APMA company... it is available for any person to complain. We do receive complaints from doctors and from other people... ". (APMA: Transcript of evidence, pp 140 - 141)

4.58 The Committee appreciates that the APMA goes to lengths to promote the requirements of its Code to the industry and believes that companies are well aware of the Code requirements (APMA: Submission p 2351).

4.59 However, the Committee is concerned that doctors, who are the principal targets of advertising are not sufficiently aware of the APMA's complaint handling mechanism.

4.60 A member of the RACP's Therapeutic Committee, when asked how aware he though medical practitioners were of the APMA Code, stated that doctors were:

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[13] TPC, Draft Report, op cit, p 9.

"Not very well aware. If you specifically asked them, 'Is there a code of conduct?', I suspect most practitioners would scratch their heads and say, 'I think there is probably something', but it is not something of which practitioners are well aware". (RACP: Transcript of evidence, p 1184)

4.61 A past president of ASCEPT reinforced this view:

"I do not think they [doctors] need to know the code in any detail. What they need to know, and they do not know at the moment, is that the code exists and that the Code of Conduct Subcommittee exists, and that they can make complaints if they wish. I think this is another area where some sort of advertising campaign is needed to inform practitioners of their rights". (ASCEPT: Transcript of evidence, pp 1157 - 1158)

4.62 **Accordingly, the Committee supports the Trade Practice Commission's recommendation and similarly recommends that the Australian Pharmaceutical Manufacturers Association develop a comprehensive publicity program including, but not restricted to, immediate steps to publish in various widely read medical journals, articles on the Code and its requirements[14].**

4.63 **The Committee also supports the Trade Practices Commission recommendation and similarly recommends that the Australian Pharmaceutical Manufacturers Association consider funding a 008 telephone information line and publish its availability to medical practitioners via the various professional associations. The 008 information line would provide callers with general information on the APMA Code of Practice and complaint submission procedures. It is not envisaged that complaints could be lodged directly over the telephone[15].**

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14 TPC, Draft Report, op cit, p 49.

15 ibid, p 49.

ADVERTISING OF NON PRESCRIPTION DRUGS

Advertising of non prescription drugs to the public

4.64 The only pharmaceuticals that can be advertised directly to the public are unscheduled and Schedule 2 drugs and there are strict controls placed on such advertisements. (Part 2, Therapeutic Goods Regulations, and SUSDP No 5, para 14)

4.65 The basis of these controls is the MCA's Therapeutic Goods Advertising Code (TGAC). This code was developed by the MCA's Therapeutic Goods Advertising Code Council, authorised by the TPC and introduced in June 1989. Regulation 8 and Schedule 2 of the Therapeutic Goods Regulations adopts relevant clauses of the TGAC, making the Code now legally binding on both MCA and non MCA members.

4.66 The TGAC places restrictions on the claims that can be made for unscheduled and Schedule 2 drugs to the public and lists special restrictions governing the advertisers of analgesics and vitamins. Advertisements are also prohibited from making claims that products prevent, alleviate, or cure a defined range of conditions that should be under the care of a medical or dental practitioner (prohibited claims - see para 2.67). The TGA has widely distributed a booklet listing acceptable and unacceptable therapeutic claims that can be made to the public[16].

4.67 As DHHCS explained:

> "The philosophy behind the Therapeutic Goods Advertising Code is that advertising to the public, first of all, should not encourage people to try to treat themselves for conditions that really require the advice or the diagnosis of a health care practitioner. So the advertising to the public is for the simple self-limiting condition primarily". (DHHCS: Transcript of evidence, p 34)

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16 TGA, "Acceptable and Unacceptable Therapeutic Claims to the Public for Therapeutic Goods", November 1990.

4.68 The Code requires that all print media advertisements gain preclearance from the Australian Publishers' Bureau (APB) before publishing and that all television and radio advertisements gain preclearance from the PMAA in its capacity as a delegate of the TGA. The PMAA has been preclearing these advertisements since December 1990 in a two year trial with authority delegated under s 100 of the Broadcasting Act.

4.69 The Committee has received no specific complaints concerning the TGAC or the PMAA or APB's preclearance of advertisements for therapeutic goods to the public. Nonetheless, advice has been received from consumer representatives that the TGAC complaints notification procedure is not adequately publicised.

4.70 **Given this, the Committee recommends that the Media Council of Australia further publicise the complaints procedures for the Therapeutic Goods Advertising Code to members of the public.**

PMAA Code of Practice

4.71 The PMAA has developed a Code of Practice for its members governing the promotion of non prescription drugs to both the public (unscheduled and Schedule 2) and health professionals (Schedule 3). The Code of Practice states, inter alia, that members shall at all times comply with provisions of the relevant Advertising Codes of the MCA, including the TGAC, and the Code of GMP[17]. The Code requires PMAA members "to submit to its provisions as an act of self-discipline"[18].

4.72 Point of Sale advertising, mail order catalogues, advertisements in private circulation magazines and promotional pamphlets ("below the line"

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17 PMAA Code of Practice, July 1991, para 4.3.

18 ibid, para 2.4.

advertisements) are currently not precleared for compliance with the TGAC even though they are required to conform with it. While the PMAA Code of Practice covers the standards required for this form of advertising by PMAA members, such advertising by non PMAA members is not covered by any code.

4.73 The Committee therefore agrees with the Trade Practices Commission (TPC) recommendation and similarly recommends that the Proprietary Medicines Association of Australia (PMAA) amend its Code of Practice to allow the complaints handling mechanism to be applied to nonmember companies with their consent. Provision should also be made in the Code for the referral of complaints against non PMAA members to the Department of Health, Housing and Community Services or the TPC[19].

PMAA Code: complaints handling procedure

4.74 Under the PMAA Code complaints handling procedure, the PMAA Executive Director is responsible for adjudicating and advertising complaints. If the Executive Director cannot resolve a complaint then a Code of Practice Complaints Panel is convened. The panel includes a number of outside representatives, (PMAA Code of Practice, Sections 7 & 8) which recommends to the PMAA Executive Subcommittee whether, and what, sanctions should be applied.

4.75 In its review of the self regulation of the advertising of the therapeutic goods, the Trade Practices Commission (TPC) expressed concern that the Proprietary Medicines Association of Australia (PMAA) Complaints Panel is not given autonomy to impose sanctions. In accordance with the TPC recommendations, the Committee similarly recommends that the PMAA amend its complaints handling mechanism to allow for an appeals process independent of the industry and that sanctions, other than those involving membership, be imposed directly by the

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19 TPC, Draft Report, op cit, p 64.

complaints panel[20]. It is further recommended that a representative from the consumer movement and the Department of Health, Housing and Community Services, at least, be included in a separate code administration committee[21].

4.76 It has been pointed out to the Committee that the PMAA does not have any mechanism for monitoring advertisements for Code breaches.

4.77 The Committee therefore recommends that the Proprietary Medicines Association of Australia establish a monitoring committee, along the lines of the Australian Pharmaceutical Manufacturers Association Monitoring Subcommittee, to review advertisements by its members, and if necessary place the advertisements before the Complaints Panel[22].

PMAA Code: publicity

4.78 The Committee has also heard evidence that the PMAA Code of Practice and complaints procedures have not been adequately publicised to health professionals and particularly to pharmacists who supply most non prescription products.

4.79 The Committee therefore recommends that the Proprietary Medicines Association of Australia publicise the existence of its Code and complaint handling mechanism both in trade journals and directly to pharmacists. It is recommended that this occur on a regular basis.

4.80 The Committee further recommends that the Proprietary Medicines Association of Australia establish a 008 telephone information line and publicise it

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20 TPC, Draft Report, op cit, p 64.

21 ibid, p 66.

22 ibid, p 66.

in trade journals and directly to pharmacists.

ADVERTISING CODE FOR THE ALTERNATIVE MEDICINE INDUSTRY

Advertising of alternative medicines to the public

4.81 Until passage of the Therapeutic Goods Act there was no national regulatory system controlling the advertising of health foods, vitamins, minerals supplements, herbal, homoeopathic or dietary supplements products ("alternative medicines").

4.82 In 1985, however, the NFA, which represents the manufacturers, importers, wholesalers and retailers of alternative medicines, adopted a code of advertising for its members covering advertisements to the public. The Code was based on the TGAC and applied on a voluntary basis to NFA members.

4.83 Compliance with the NFA Code was voluntary for NFA members and there was no formal complaints review mechanism. These factors, coupled with the NFA's limited resources to administer the Code, appear to have contributed to the Code falling into disuse. Furthermore the Code's effectiveness was hampered by the NFA's limited industry coverage. Even now, the NFA represents approximately 85% of the industry's importers, manufacturers and distributors and only approximately 60% of the industry's retailers.

4.84 With passage of the Therapeutic Goods Act, advertisements to the public for alternative medicines, as with other unscheduled and Schedule 2 products, are now required to meet the provisions of the TGAC.

4.85 However, as already mentioned, "below the line" advertisements and,

in practice, advertisements in some smaller suburban newspapers, are not precleared by the PMAA or APB. This lack of preclearance has led to a number of advertisements being published that breach the TGAC. As DHHCS explained:

> "To date, advertisements for alternative therapy products are the source of nearly all advertising complaints. There appear to be two reasons for this: a disregard for the Regulations and the Therapeutic Goods Advertising Code, or a misguided belief that the association of a product with a proscribed claim is acceptable, provided a direct therapeutic claim is not made"[23].

4.86 Furthermore, advertisers of alternative medicines:

> "tend to manoeuvre between the grey area created by the therapeutic goods legislation and the food legislation. They try to escape scrutiny - in some cases, anyway - by going down that grey area". (DHHCS: Transcript of evidence, p 22)

4.87 The NFA has admitted:

> "In the past there have always been manufacturers who have pushed the limits of advertising claims and this has sometimes created a problem for our Association". (NFA: Transcript of evidence, p 232)

4.88 Both DHHCS and the NFA have been trying to educate manufacturers about their responsibilities under the Therapeutic Goods Act and the TGAC. The NFA has:

> "endeavoured, firstly, to educate our members in this area to make sure that they are aware of their responsibilities and to put them on the straight and narrow where we regard their claims as being unacceptable in some way. (NFA: Transcript of evidence, p 232)

4.89 Likewise, DHHCS has commented that:

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[23] TGA, News No 8, December 1991, p 12.

"with the legislation [Therapeutic Goods Act] quite new we are basically in an education mode. We are bringing it to the attention of sponsors and advertisers when they have breached existing law, and we are requiring in some cases that they immediately retrieve and destroy promotional material". (DHHCS: Transcript of evidence, p 993)

4.90 DHHCS is confident that the number of complaints will drop as advertisers gain experience with the TGAC. However, the Department:

"will be moving into an enforcement mode once this transitional phase is over within the coming few months. It will definitely be necessary to prosecute persistent offenders in relation to herbal products". (DHHCS: Transcript of evidence, pp 993- 994)

Advertising alternative medicines to health professionals

4.91 The Therapeutic Goods Act as it now stands, effectively grants alternative medicine practitioners the same status as general practitioners, veterinary surgeons and dentists for the purposes of advertising access. (see Therapeutic Goods Regulations R4(1) & 4(2)). They are therefore exempted from the controls on advertising to the public. Alternative medicine practitioners were granted this exemption by DHHCS, conditional on the NFA developing a code of conduct controlling the advertising of alternative medicines to appropriately trained health professionals. (DHHCS: Transcript of evidence, p 992)

4.92 It has been "a matter of concern and disappointment" to DHHCS that NFA has not yet finalised such a code. (DHHCS: Transcript of evidence, p 992) Through 1991, the NFA had a series of meetings with the TGA and the Trade Practices Commission in an effort to develop a Code and the Committee believes that discussion will continue into 1992.

Self regulation of the alternative medicines industry

4.93 The question has been raised as to whether the alternative medicine industry is too fragmented to be able to effectively self regulate its own advertising.

4.94 The TPC has commented that:

> "to date the natural therapies industry has not produced a viable or credible self-regulation scheme and the approach of the NFA to the task does not engender sufficient confidence that it has either the commitment or the resources to introduce such a scheme"[24].

4.95 As the NFA itself admitted:

> "one of the biggest problems that we have is that there are a lot of manufacturers and marketers that do not belong to the Association". (NFA: Transcript of evidence, p 232)

4.96 Furthermore, the NFA is a small association with limited funding that can offer few sanctions against abusers of any advertising Code. Whilst the expulsion of the Australian branch of an international pharmaceutical company from the APMA for breaching the APMA Code of Conduct would lead to considerable adverse publicity for the company concerned and may be an effective sanction, it is unlikely that the threat of expulsion from the NFA offers an equivalent deterrent.

4.97 On a positive note, the NFA believes that there is "a much greater awareness now amongst sponsor manufacturers of their responsibilities". (NFA: Transcript of evidence, p 232) Furthermore, as DHHCS points out, the NFA "realise that their credibility is at stake if they cannot control advertising. They are taking a fairly responsible attitude". (DHHCS: Transcript of evidence, p 993)

4.98 The Committee views with concern the number of complaints about

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[24] TPC, Draft Report, op cit, p 70.

advertising by the alternative medicines industry and the fact that the NFA has not developed a self regulatory code governing the advertising of alternative medicines to health professionals.

4.99 Furthermore, the Committee is concerned that the NFA does not have the resources or the support of enough of the industry to administer a successful self regulatory code.

4.100 **The Committee therefore recommends that the Nutritional Foods Association (NFA) be required to report its progress towards developing a viable code for self regulation to the Trade Practices Commission (TPC) on a six monthly basis.**

4.101 **The Committee also recommends that the classification of alternative medicine practitioners as "health professionals" for the purposes of Regulation 4 of the Therapeutic Goods Regulations be removed unless the NFA can demonstrate to the TPC by 1 January 1994 that it has the resources, industry coverage and expertise to administer such a code effectively.**

4.102 The Committee also endorses the TGA's decision to prosecute manufacturers, wholesales or retailers who persistently breach the various advertising standards.

RESEARCH AND DEVELOPMENT

4.103 As described earlier, the Australian Government tries to balance the competing objectives of keeping drug prices low, while at the same time trying to foster and promote a viable pharmaceutical industry with incentives for greater industry involvement in research and development activities in Australia. The development and operation of the pharmaceutical industry in Australia is detailed in the Bureau of Industry Economics Program Evaluation Report already referred

to in this Chapter.

4.104 The Australian pharmaceutical industry is dominated by the subsidiaries of multinational enterprises which supply 94% of the Australian market. While there are Australian-based companies, including the Commonwealth Serum Laboratories and Faulding, involved in the export of products, during the 1980's an increasing deficit has developed in the pharmaceutical balance of trade, rising from 1.1% to 2.2% of the current account deficit[25].

4.105 Most of the pharmaceutical activity in Australia is involved in the formulation and packaging of final products from largely imported active ingredients. In the 1960's and 1970's, local companies tended to locate formulation and packaging plants near a major market and most companies now look to supplying a region rather than a single country from each plant. Hence, plants tend to be located in countries with a reservoir of skilled labour and a quick return on investment. Australia has been seen as a relatively unattractive place in which to locate activities.

4.106 Clinical trials are the final stage in the commercial process prior to marketing and a major component of R&D expenditure. Quality and timeliness are the key factors determining location, with cost being of lesser significance. In some therapeutic areas, Australia is already able to participate in key trials for new global products. With the recent introduction of clinical trial notification procedures and planned improvements to clinical trial exemption procedures, the timeliness of clinical trial approvals should improve and Australia may be able to attract more clinical trial work.

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25 Bureau of Industry Economics, op cit.

Conduct of clinical trials

4.107 As outlined in Professor Baume's report on the future of drug evaluation in Australia, there are currently two streams of clinical trials being carried out. The first of these is the Clinical Trial Exemption (CTX) Scheme which commenced in 1987. The second is the Clinical Trial Notification (CTN) Scheme which commenced in May 1991 in line with the changes to the Therapeutic Goods Regulations. The reason for the introduction of the CTN Scheme was to counter criticisms of the conduct of trials being too restrictive under CTX. Professor Baume has made several detailed observations concerning the CTX and CTN Schemes and the Committee, in examining witnesses at public hearings, sought views about the effectiveness of the new CTN Scheme from industry, the medical profession and consumers. According to the APMA:

> "When the clinical trial exemption scheme was introduced in 1987, it was in part to address departmental concerns regarding the workload involved in reviewing the very detailed information and very comprehensive information that was being provided to it prior to that time, and the delays relating to it, and also partly to address industry's concerns that a very detailed dossier was being requested in Australia to be reviewed by the Department, and that was not the case in all countries overseas and therefore Australia was missing out on research opportunities. ... The CTX scheme did lead to some improvements, but not as many as had been hoped...
>
> When the CTN scheme came into place in Australia, ... it was decided to keep our CTX scheme but offer an option of a notification scheme, a CTN scheme where the Department had no involvement in reviewing data, and in so doing it was perhaps remiss in not recognising the fact in this scheme that indeed many of those trials had been reviewed by agencies overseas. Therefore, companies have been very careful to only put forward CTN proposals which it felt that the [Institutional Ethics Committees] would be comfortable to approve, based on the stage of drugs development or whether perhaps that trial had been approved overseas. I think it is going through a transitional phase at the moment." (APMA: Transcript of evidence, pp 1038 - 1040)

4.108 In relation to the impact of the CTN Scheme on the conduct of clinical trials in Australia, the APMA told the Committee that while comprehensive

data is still not available at this stage the feeling was that it had not lead to an upsurge in trials. However, as it was considered that the CTN Scheme was still going through a settling in period and as the CTN Scheme will be reviewed in May 1992, some companies may still be holding off in their research initiatives in this area.

4.109 The Committee supports the recommendations made in the Baume Review and hopes that the streamlining of clinical trial procedures may remove some of the disincentives for companies to conduct trials in Australia. However, the Committee has been advised of problems relating to the added responsibilities which have been placed on Institutional Ethics Committees (IECs) to take full legal responsibility for the evaluation of chemistry and toxicology data, previously undertaken by the TGA and considers that this area should be more fully investigated.

4.110 A further development in the clinical trials area has been the establishment of the Community HIV/AIDS Trial Network (CHATN). This initiative, which is based on US community trials, is still at a formative stage. It enables community doctors and patients away from major medical centres to participate in drug trials under specific approved protocols coordinated through hospitals and backed by a hospital ethics committee.

4.111 The advantage of this for industry is that it has the potential to provide a broader base for clinical trials of new products with quality controls on data collection and trial design. It also provides a pool of clinicians and institutions with greater experience in the conduct of such trials which can be used reliably in building up a profile on a new drug entity. Australia can provide high levels of clinical trial compliance and quality control and the Committee considers that this is a worthwhile extension of the clinical trial system.

Institutional Ethics Committees

4.112 Since 1976, the NHMRC has required that applicants for research grants should have the applications submitted to a committee in their institution for ethical approval. The original intention was to ensure peer review and the stipulation was made that they should include one person not connected with the institution.

4.113 The Australian Health Ethics Committee (AHEC), established under the NHMRC, was formed in 1991. AHEC subsumes the former Medical Research Ethics Committee of the NHMRC and also replaces functions of the National Bioethics Consultative Committee. It brings forward advice on matters of health ethics and also has a specific role in maintaining the system of medical research ethics, including IECs. Guidelines are presently being drawn up for IECs to evaluate clinical trial proposals. Under existing arrangements, the NHMRC provides advice to ethics committees on clinical trials. The AHEC is reviewing this process, including a response to Professor Baume's recommendation that it should also review the need to take into account multi-centre international trials.

4.114 In response to questioning concerning reservations that IECs do not necessarily have the expertise to properly commission or evaluate some of the clinical and toxicological data for proposed clinical trials, the NHMRC commented:

> "At its 111th session in Brisbane in June, the Council expressed some concern that, under the CTN scheme, institutional ethics committees may be required to make technical assessments for which they were not constituted ... The issue is still under some debate and the scheme itself will be reviewed after 12 months of operation." (NHMRC: Transcript of evidence, pp 1003-1004)

4.115 When questioned about the possibility of individual drug companies selectively targeting sympathetic IECs and not disclosing previous rejections of clinical trial proposals, the NHMRC responded:

"In setting up the whole system of institutional ethics committees, which was set up with medical research in mind, the NHMRC consciously took a decision not to set up a large national uniform system where everybody ran the same rules, but rather to set up a structure whereby people would be drawn from the community, but they would obviously be offered some guidance in the form of the various notes that it produced from time to time, but that otherwise the decisions were their own, formed in the light of the information presented to them and the judgements they made as to what was acceptable, ethical behaviour." (NHMRC: Transcript of evidence, p 1006)

4.116 **In order to prevent individual companies from not disclosing previous rejections of proposed trials, the Committee supports the recommendation made by Professor Baume that Institutional Ethics Committees should request that the sponsor indicate if objections have been raised previously by the Therapeutic Goods Administration under a Clinical Trials Exemption Scheme application and provide details of any objections[26] and further recommends that the National Health and Medical Research Council include in its note on clinical trials that companies provide *information about an approach to another institutional ethics committee concerning* the same clinical trial proposal and a requirement to submit a full record of that decision.**

4.117 Considerable debate has arisen about the representativeness of members of IECs. The composition and membership of IECs was described as follows:

"Institutional ethics committees shall be composed of men and women reflecting different age groups and include at least five people as follows:

- a laywoman, not associated with the institution;
- a layman, not associated with the institution;
- a minister of religion;
- a lawyer; and
- a medical graduate with research experience.

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[26] Baume, P, op cit, p 117.

It is also specified that:

> "a layperson in this context is one who is not closely involved in medical, scientific or legal work." (NHMRC: Transcript of evidence, pp 1006-1007)

4.118 According to NHMRC:

> "There has been a suggestion that those people should somehow be consumer representatives, or report back to some constituency. There has been a long debate about that but I think that the Council's view that it is better that they are people who are not in any way representative or required to report, that they are there as people from the community, who bring to it community norms and ethical judgement". (NHMRC: Transcript of evidence, p 1007)

4.119 The Committee is not in a position to make recommendations concerning membership of IECs but considers that, due to the degree of influence wielded by these bodies within the hospital setting, that the NHMRC specifically report on the experience of IECs with the CTN Scheme.

The Factor F Scheme

4.120 It is undeniable that the Government's pricing policies have influenced the level of local activity of the pharmaceutical industry in Australia. Industry claims that the Australian prices are only about half of world average prices has been contested by the Bureau of Industry Economics which in its report, while acknowledging that Australian prices are considerably lower than the world average, also points out that pharmaceutical prices in a world context vary considerably between markets. The world "average price" is greatly influenced by very high prices in the USA, Canada, Japan and a small number of European countries. The average price in the European Community (EC) is significantly lower than the world average and within the EC the price index varies considerably between low priced countries such as Spain, Italy and France and high priced

countries such as the UK, Ireland and Germany. The EC average reflects a mix of outcomes in individual markets reflecting varying priorities between health or social policy objectives and industry development goals. The Bureau's analysis suggest that the Australian prices are, on average, about 30% below EC prices.

4.121 As the EC average price seems a more relevant benchmark against which to compare Australian prices than the world average price, the Bureau has recommended that, if the Factor F Scheme is continued, the ceiling for price increases be reduced to the EC average. This leads into a discussion of the Factor F Scheme which is one of the eight factors considered by the PBPA in determining PBS prices. Only firms which sell products on the PBS can benefit from the Factor F Scheme which is a measure of the amount of local activity being undertaken in Australia by the sponsoring company including new investing, production, research and development, as already referred to in para 3.37 of this report.

4.122 Benefits payable under Factor F are translated into notional price increases on PBS products, though they take the form of quarterly payments directly by the Government. Notional price increases are granted by the PBPA to companies which increase the value added on exports or domestic sales and increase R&D expenditure. There are strict quantitative performance requirements, though in principle, firms can become eligible on the basis of a qualitative assessment of proposed additional activity where there is likelihood of significant benefits to Australia.

4.123 To date, nine firms have become eligible for Factor F, of which six are subsidiaries of global companies. Seven firms, including two current participants, are awaiting advice on whether their Factor F proposals will be accepted. Over the life of the program (to conclude in 1993) activity levels in Factor F firms are expected to increase by about $860 million as a result of investment of around $260 million. The forecast increase in activity consists of $533 million in value added on exports, $211 million in value added on domestic sales, and $117 million in R&D.

The cost to Government, through direct payments to the participating companies, will be a maximum of $173 million.

4.124 A full assessment of the current operation of the Factor F Scheme has been conducted by the Bureau of Industry Economics and will not be discussed in detail in this report. In the final chapter of its report, the Bureau discusses strategic options which may better meet the Government's objective of providing a competitive environment for the pharmaceutical industry while obtaining pharmaceutical products at the lowest price. The point is made that local activity has been suppressed by PBS pricing policy, though the amount of activity lost is low compared to the welfare gains to consumers from low prices. The point is also made that Factor F has been effective in restoring certain types of activity.

4.125 From evidence gathered by the Committee, there seems to be general support from industry for the continuation of the Factor F Scheme. According to the APMA:

> "those low prices have had a very definite effect of depressing additional investment in this country, a problem which the Government has endeavoured to rectify, quite successfully, I would suggest, by the factor F program. This has attracted about $140m of additional research and development into Australia, mainly going to Australian third party institutions, and it is generating a substantial amount of export rolling from Australia. But, generally speaking, it is true to say that the low prices have not made Australia an attractive investment opportunity for pharmaceutical companies. It has taken factor F to at least partially rectify that situation." (APMA: Transcript of evidence, p 1032)

4.126 The Bureau of Industry Economics does not, in the final analysis, make a strong recommendation either for continuing or discontinuing the Factor F Scheme, however, it stipulates certain modifications to improve the effectiveness and efficiency of the Factor F Scheme, should it be continued.

4.127 The Committee considers that there is some potential for Australia to become a regional centre for pharmaceutical distribution and potentially for providing an environment for increased research and development activities. The Factor F Scheme would appear to increase this potential and should be supported.

4.128 **The Committee therefore recommends that the Factor F Scheme be continued, subject to a further analysis of the conclusions and recommendations made by the Bureau of Industry Economics in its report.**

Chapter 5

CONSUMER ISSUES

CONSUMER INFORMATION

The need for consumer information

5.1 The real consumers of pharmaceuticals are the individuals who take them. The Committee believes they have a right to information on drug and non drug therapies, the effects of drugs and any possible adverse reactions that can be expected from taking medication. As noted by Product Information on Pharmaceuticals in Australia (PIPA):

> "In an increasingly sophisticated society, consumers are expecting the right of access to information about drugs they are prescribed and to participate more fully in decisions affecting their health care". (PIPA: Submission, p 596)

5.2 The FBCA also described the consumer demand for more information:

> "We spend billions of dollars in education to enable the citizenry of our country to, amongst other things, make better informed choices. It should be no surprise to us that they start doing that, and as they do they require a better quality of information". (FBCA: Transcript of evidence, p 1015)

5.3 Furthermore, a number of witnesses before the Committee argued that there is a relationship between a lack of consumer information and patient non compliance. The ACA and the CHF told the Committee that:

"There are sufficient studies to show that where people have the information, have expectations and knowledge about how to use a drug and where it might fit into their own regime, where it might fit into their other medications, it affects what the medical profession call its compliance... That sort of information use actually affects positively health outcomes in consumers". (ACA & CHF: Transcript of evidence, p 275 - 276)

5.4 PIPA reinforced this argument:

"Lack of appropriate drug use by consumers is exacerbated by lack of information. It is recognised that education of consumers is a necessary component in the safe use of pharmaceuticals, that better informed consumers are better users of medicinal drugs". (PIPA: Submission, p 596)

5.5 From an international perspective, the Association of the British Pharmaceutical Industry (ABPI) recognises that "successful treatment with medicines is more likely to be achieved with the cooperation of patients, who must therefore be reasonably informed about the medicines prescribed for them"[1].

5.6 The need to educate consumers about pharmaceuticals is also taking on growing importance as patients increasingly self diagnose and use non prescription medicines. This was also highlighted by the FBCA:

"With the increasing level of self-medication in our society, it is important to consider the role played by OTCs [non prescription drugs] and the information available to assist consumers in administering them... The prevalence of self-medication requires more and better education of the public and of health professionals to avoid irrational drug use". (FBCA: Transcript of evidence, p 928)

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1 ABPI, "Information to Patients on Medicines", 1987, p 5.

Sources of consumer information

5.7 Consumer education requires a multi disciplinary approach with involvement from manufacturers, health professionals, consumer groups and government agencies.

5.8 Medical practitioners have traditionally been the principal providers of product information to consumers, usually by talking to patients. The role of pharmacists has also been highlighted in reinforcing doctors' directions and providing advice on non prescription products to the public. However, the Committee has heard evidence that oral advice provided to patients by both doctors and pharmacists is often not understood, is easily forgotten or fails to meet patients' information needs. The problem is compounded for consumers because they can gain very little additional product information from manufacturers' and pharmacists' labels (refer paras 2.42 - 2.64).

5.9 This Chapter focuses on the important role that the pharmaceutical industry can play in providing product information (as distinct from advertising) specifically for consumers. The Committee will focus on patient/doctor and patient/pharmacist relations and the wider issues of consumer education in the second and third reports of the inquiry.

The industry view on consumer information

5.10 The need for greater product information for consumers has the support of the two major peak pharmaceutical manufacturing bodies in Australia. The APMA "certainly support the concept of information being made available to the consumer" (APMA: Transcript of evidence, p 149) and "considers that companies in Australia should be encouraged to further their patient information and initiatives...". (APMA: Submission, p 1041) The PMAA believes that "Industry has a vital part to play in this [education] process, for it is best placed and best qualified

to provide the information base". (PMAA: Submission, p 273)

5.11 However, as the APMA pointed out, the content and format of the information is of critical importance:

> "The key aspect of all of this is that the consumer does not simply need more information. The consumer/patient needs appropriate information in a form that can be absorbed in order to positively affect compliance with and utilisation of the available medicines". (APMA: Submission, p 1041)

5.12 This view was backed up by the PMAA:

> "The real need is to provide information that is appropriate - appropriate to the psychological condition of the patient, to the patient's level of literacy and ability to fully comprehend the risk/benefit ratio of the treatment and the significance of cautionary statements". (PMAA: Submission, p 270)

5.13 The Committee acknowledges that industry's response to the consumer information issue will be influenced by the details of product liability legislation still to be introduced in Parliament.

PRODUCT INFORMATION

5.14 As part of the drug evaluation process, manufacturers are required to produce a Product Information (PI) document for all prescription drugs and New Chemical Entities (NCE). PI requires endorsement by ADEC as a precondition for drug marketing approval. PI lists in detail a drug's approved indications, method of action, dosage rates, any appropriate warnings and precautions, possible adverse reactions and potential contra indications. PI, in an abridged form, is required to accompany all drug advertising in trade journals and forms the basis of the Monthly

Index of Medical Specialties (MIMS) which is used by many medical practitioners as a prescribing guide (refer para 6.12).

5.15 PI, however, is intended for health professionals, is written in highly technical language and is not directly appropriate as consumer information.

Patient package inserts

5.16 A number of groups have given evidence to the Committee that the most effective way of providing patients with product information is through pamphlets inserted in each individual drug package. These pamphlets are called Patient Package Inserts (PPI) and are currently placed in drug packages on a voluntary basis by a number of companies. It has been suggested that PPIs should be mandatory for all drugs in Australia. Currently, oral contraceptives are the only prescribed products in Australia that have a legal requirement for PPIs.

5.17 The ACA & CHF believe that PPIs are the most effective format for ensuring that patients receive consumer information:

> "We believe that patient package inserts do provide certain advantages over reference manuals in that they are accessible and that they come with the final product for people who are house bound, who cannot go to pharmacies ... We think the whole question of accessibility ought to be taken into account when we talk about who sort of information ought to be made available to consumers". (ACA & CHF: Transcript of evidence, p 275)

and that:

> "In conclusion, our position is that we would prefer [patient information] to be package inserts... The most important criterion is that it can be guaranteed to get to everyone. It seems to me that the only way of guaranteeing that is by having it as an insert...". (CHF: Uncirculated workshop transcript, p 99)

5.18 There are a number of problems with PPIs as a source of consumer information. The principal one being that manufacturers tend to provide excessive information to ensure that they cannot be held liable for leaving out cautionary advice on possible adverse reactions. As SACOA explained:

> "It is not appropriate to give [consumers] all the information that manufacturers give, because it does stop them from taking [medication] and causes a great deal of alarm. Since the thalidomide scare companies now give two or three pages of possible side effects. You might get one person in a million, but manufacturers are putting all those possible side effects down simply so that they will not get sued afterwards if something does happen. So it is a real problem". (SACOA: Transcript of evidence, pp 502 - 503)

5.19 The FBCA Director noted:

> "I guess if you have got time to sit down and read (PPI's) then you would probably end up being informed, but the caveats that are provided in those are such that I suspect it is more to avoid negligence claims than it is to inform the consumers". (FBCA: Transcript of evidence, p 1017)

5.20 This concern was reinforced by the APMA:

> "the US experience with package inserts is that they are basically written by lawyers to be read by lawyers. We do not believe that that is an appropriate means of producing patient information". (APMA: Transcript of evidence, p 149)

5.21 The Committee was told at its workshop that there is no compelling research to show that consumers read PPIs in any event and that, even if they are read once, they are often not retained.

5.22 The APMA has also pointed out the cost to industry of retooling and purchasing new equipment to allow the insertion of PPIs in product packages; costs which the APMA believes could not be borne without price increases.

5.23 On the basis of evidence provided, the Committee does not believe that PPIs should be mandatory.

Pharmacy computer printouts

5.24 Currently, pharmacies equipped with computers (approximately 95%) have potential access to privately produced software that provides several paragraphs of consumer information on individual drugs. Pharmacists can print out the information extracts to give to consumers when purchasing drugs to underscore verbal counselling. However, as the APMA explained, liability problems arise when third parties, other than drug manufacturers, try to provide consumer information in an understandable form:

> "At the moment there are pharmacy software programs and also printed publications that do try to do this. The people preparing that material usually go back to the manufacturer to check that the material they have put together is accurate. Often that leads to revision because sometimes their emphasis in preparing that material has been regarded as inadequate in some areas and excessive in others. It is quite difficult to prepare material that covers the liability issues and also informs the patient". (APMA: Transcript of evidence, pp 152 - 153)

5.25 Currently, the APMA, the Pharmaceutical Society of Australia (PSA) and a private company are conducting preliminary negotiations to run a pilot study where a number of pharmacies have access to a computer database on consumer drug information. The information contained is endorsed by manufacturers and consistent with PI. It is proposed to make the information contained in the database available in a written compendium as a reference document, along the lines of the Swedish "Patient FASS".

5.26 "Patient FASS" is a book published on a non profit basis by the drug manufacturers of Sweden that provides consumer information on medications

available in Sweden. The Committee notes the work already done by PIPA to create an Australian version of Patient FASS. (PIPA: Submission, pp 582 - 643 & Transcript of evidence, pp 281 - 298)

5.27 The Committee supports any initiative to develop both consumer information software and a reference book. However, the APMA & PSA proposal does not include information on non prescription products at this stage.

Approved consumer information

5.28 In the Baume Report comment was made that consumers should be as well informed as is possible about the drugs they are taking. Accordingly, it was recommended that:

> "By 1 January 1993, a mandatory requirement should be introduced for the provision of Patient Information for all new drugs and variations to existing drugs approved after that date. All existing drugs should have patient information provided by 1 January 2002.
>
> Patient Information, which is consistent with the Product Information should be prepared by the company and lodged for evaluation by the TGA at the time of application. All applications for NCEs should contain draft Patient Information by 1 January 1992"[2].

5.29 These recommendations have been adopted by Government and mirror similar recommendations made by the Public Service Board in 1987[3].

5.30 The TGA is only required to evaluate patient information and does not have to approve it formally. The Committee believes that this information should have the imprimatur of the TGA so that consumers can have confidence that it has been independently evaluated.

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2 Baume, P, op cit, pp 63-64.

3 PSB Review, op cit, para 4.209.

5.31 This would be in line with European Community guidelines for standardised patient information for medicinal products for human use. A proposed EC directive, nearing completion, recognises the right of the consumer to better information in order that medicinal products may be used correctly on the basis of complete and comprehensive information[4].

5.32 Accordingly, the Committee recommends that the Therapeutic Goods Administration (TGA) be required to formally approve consumer information, to be termed Approved Consumer Information (ACI). ACI should be evaluated and approved in the same way that Product Information is. To this end, the Committee recommends that the TGA, in consultation with industry and peak consumer bodies, draws up an appropriate format for ACI, based on European Community guidelines.

5.33 The Committee recommends that once the Therapeutic Goods Administration has evaluated the clinical details of Approved Consumer Information (ACI), they be forwarded to appropriate health education specialists to ensure that the ACI have been written in Plain English and are likely to be understood by non specialists.

5.34 ACI should explain in simple language what the drug is, what it does, how it should, and should not, be taken, when it should, and should not, be taken, what other drugs it might interact with, and how, and any significant adverse reactions that might occur (see Public Service Board, "Review of Drug Evaluation Procedures", June 1987, para 4.209).

5.35 The format of consumer and information leaflets as recommended by the ABPI provides an appropriate guide[5] and the Committee considers that ACI should be distributed to consumers via pharmacy computers and used as a

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4 Draft Council Directive on the Labelling of Medical Products for Human Use and on Package Leaflets, The Council of the European Communities 10901/90 (Annex A).

5 ABPI, "Patient Information: Advice on the Drafting of Leaflets" 1988.

supplement to pharmacists' verbal counselling. The Committee is reluctant to make detailed recommendations about the mechanics of distributing ACI from the TGA to pharmacies. However, the Committee notes the existence of "GuildNET", a computer network established by the Pharmacy Guild of Australia and believes this could be an appropriate medium. The pilot study being planned by the APMA & PSA, offers a possible alternative.

5.36 Distribution of computer printed ACI by pharmacists should not be mandatory. However, the Committee would rely on pharmacists' sense of professionalism and encourage them to provide the printouts as a reinforcement to verbal counselling.

5.37 **In order to increase availability of consumer information, the Committee recommends that Approved Consumer Information should be printed in a compendium available for purchase by the public.**

5.38 The Committee is reluctant to make detailed recommendations about possible funding sources, but believes that it would be in the interests of the industry to provide financial assistance to distribute ACI.

5.39 More detailed observations about the role of pharmacy will be made in the third report of this inquiry.

Non prescription drugs

5.40 Baume's recommendations concerning consumer information do not extend to Schedule 3 products, which the Committee believes should also require ACI.

5.41 **Accordingly, the Committee recommends that by 1 January 1994,**

Approved Consumer Information (ACI) should be required for all new Schedule 3 drugs and variations to them approved after that date. All existing schedule 3 drugs should have ACI provided by 1 January 2004.

OTHER SOURCES OF CONSUMER INFORMATION

5.42 The Committee is aware of the limitations of computer generated information, including the difficulty some have in reading printouts from the current dot matrix printers available in pharmacists, the varying information requirements of consumers and the comprehension problems for non English speaking members of the community. Computer printouts of ACI should be seen as a supplement to verbal counselling by health professionals and not a replacement. Given this, despite their limitations, computer generated ACIs, could usefully augment patient counselling and education.

5.43 A number of other sources of consumer information exist, including a range of consumer orientated guides on pharmaceuticals that are of variable quality and ease of use. The Committee supports the publication of any helpful consumer information, providing it is accurate and balanced. The availability of ACI, referred to earlier, is likely to improve such consumer manuals and increase the acceptability of the information provided, as long as this is subject to appropriate authorisation. A number of manufacturers also produce explanatory pamphlets on particular drugs for distribution to patients through medical practitioners and the Committee wishes to encourage this practice.

COORDINATING THE INITIATIVES

5.44 The Committee welcomes the initiatives being undertaken to improve the range and quality of consumer information. However, the production of consumer information requires greater coordination between industry, DHHCS and

peak bodies representing the medical profession and consumers than is occurring at present. As noted by the Director of PIPA, the "long term viability of the industry relies on consumer education occurring":

> "I also found that it was like re-inventing the wheel. The information exists; everything exists, except a working relationship between all the parties involved". (PIPA: Transcript of evidence, p 283)

and that:

> "The very strategies that people have developed do not work because it is always a little bit for a few people for a little while. There is nothing all together; on-one is working all together". (PIPA: Transcript of evidence, p 284)

Chapter 6

A NATIONAL DRUG STRATEGY

6.1 In July 1991, the Committee convened a two day round table discussion with invited participants representing the pharmaceutical industry, the medical profession, pharmacists, consumers and Government to provide the Committee with an overview from each of these perspectives on the inquiry. It was also intended to come up with a consensus of the major issues confronting rational drug use and the development of a coordinated approach to drug policy. The overall title of these discussions was "A Strategic Approach to Medicines" and it assisted the Committee greatly in providing a practical perspective on the interdependency of the various factors influencing rational drug use and identifying many of the shortcomings and problems still confronting policy makers and Government.

6.2 At the conclusion of the deliberations, it was commonly agreed that any national drug strategy must take account of the various interest groups who play a role in the production, distribution and consumption of drugs and that there has to be a high degree of partnership between the pharmaceutical industry, health professionals and consumers. It was decided that the notion of a national medicinal drug policy should be addressed by looking at four major components, namely:

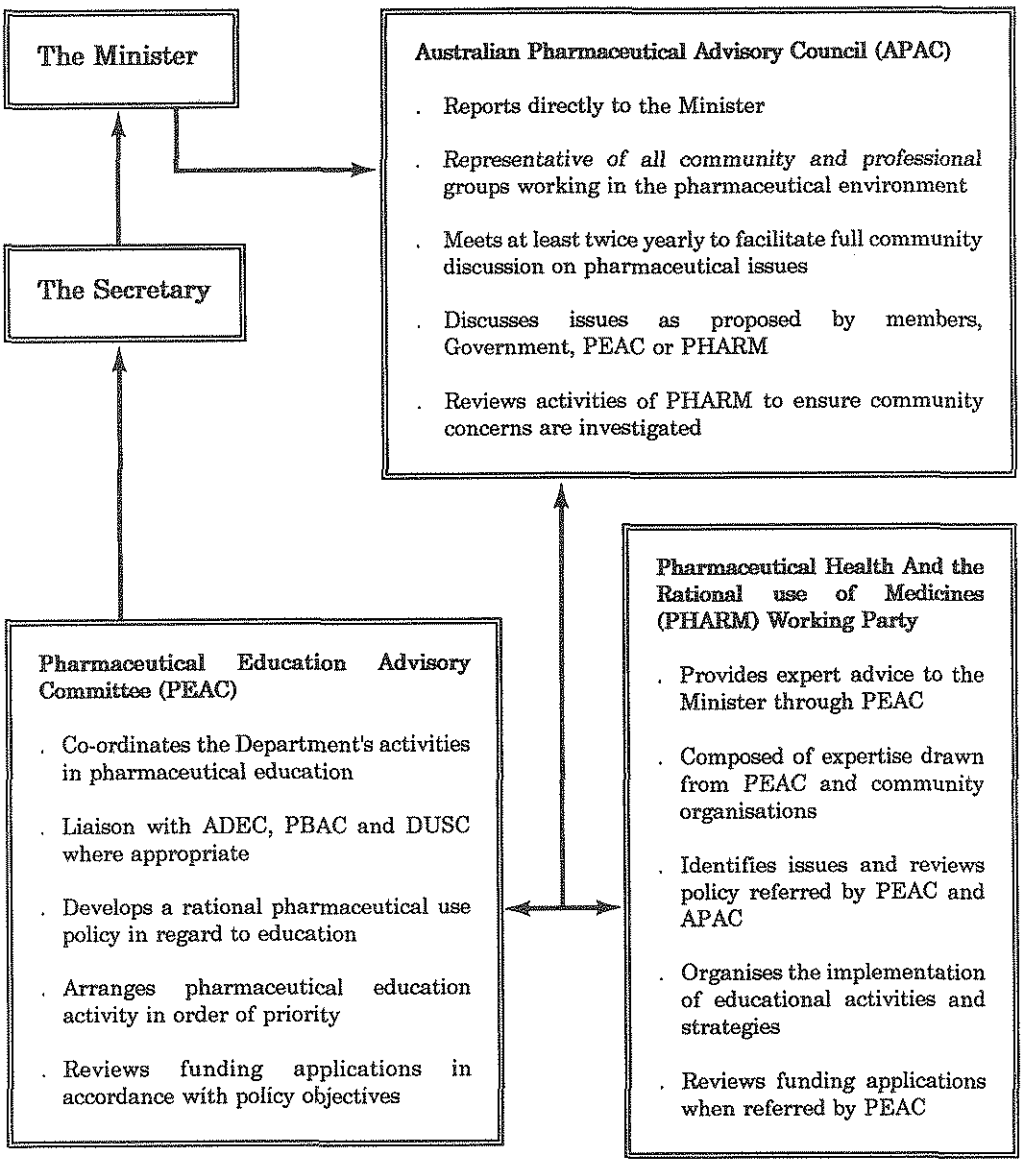
- a viable pharmaceutical industry;
- high quality products;
- equity of access; and
- quality of use.

6.3 This report has already dealt with the pharmaceutical industry and the PBS. Professor Baume has dealt with drug evaluation and the quality of products marketed in Australia. The question of quality of medicinal drug use relies on a commitment from all participants to better information, more education and greater

degrees of cooperation overall.

6.4 DHHCS, as part of its attempt to better coordinate an education strategy, has set up a series of bodies with links between them reporting to the Minister which aims to provide this level of national coordination. This structure is summarised in the following table:

THE PHARMACEUTICAL EDUCATION STRATEGY



6.5 One of the components of this pharmaceutical education strategy is the PHARM working party which has as its aim the optimisation of the quality of drug use in Australia. The basic philosophy that PHARM operates under is the endorsement of the World Health Organisation's definition of rational drug use which is as follows:

> "Drugs are often required for prevention, control and treatment of illness. When a drug is required, the 'rational use of drugs' demands that the appropriate drug be prescribed, that it be available at the right time at a price people can afford, that it be dispensed correctly, and that it be taken in the right dose at the right intervals and for the right time. The appropriate drug must be effective, and of acceptable quality and safety ..... The formulation and implementation by governments of a national drug policy are fundamental to ensure rational drug use." (World Health Organisation 1987)

6.6 In their joint submission to the Committee's inquiry, ACA and the CHF also endorsed the World Health Organisation's definition of rational drug use and stressed the promulgation of a national drug policy to underpin and provide an overall framework for future policy direction. (ACA & CHF: Submission, p 1569)

6.7 As some of the issues related to education also includes education of health professionals, discussion of the role and responsibilities of doctors and pharmacists will be discussed in greater detail in parts 2 and 3 of the Committee's report on this inquiry. For this reason, this Chapter will concentrate mainly on the need and development of a national drug formulary and guidelines and the role of Government in providing leadership, giving direction and setting a framework for a national drug policy to be effective.

DRUG FORMULARIES AND GUIDELINES

6.8 The previous Chapter of the report discussed available sources of consumer information and ways of making information about drugs provided through the evaluation process available to consumers. The provision of information

to health professionals on which to make judgements about the treatment of various conditions by use of drugs or non-drug therapy is an area which fits in with overall health objectives and a national drug strategy.

6.9 Prescriber information will be covered in later reports relating specifically to the role of prescribers and pharmacists. However, in terms of current information available to prescribers to enable clinical judgements to be made about appropriate drug therapy, some concerns have been expressed to the Committee both during public hearings and at the round table discussion referred to earlier about the lack of a national drug formulary.

6.10 In the general area of therapeutics and therapeutic guidelines there are a number of written standards including the excellent series of guidelines covering specific areas of therapeutics put out by the VDUAC. A proposal which has been raised through PBAC as well as in other forums has been the creation of an Australian National Formulary (ANF) which could also include Australian Therapeutic Guidelines.

6.11 DHHCS conducted a survey in 1991 which sampled over 2 000 doctors comprising over 1000 general medical practitioners and 994 specialists. The purpose of this survey was to provide an indication of the kinds of drug references practitioners are currently using when making decisions about drug therapy, what they consider the most important function of such a reference to be and what content and format a proposed ANF should have to be most acceptable to doctors.

6.12 The results of this survey indicated that the majority of practitioners used the MIMS Monthly and MIMS Annual/Prescription Proprietary Guide (78% and 69.5% respectively) as the major reference in obtaining information about therapeutic categories of drugs. It should be noted in this context that MIMS is an information manual on drugs by drug type produced by Intercontinental Medical Statistics Proprietary Limited and funded by product advertising. As such, it lists drugs under trade names with a summary of approved product information and is

industry generated.

6.13 In the Departmental survey, other sources of information included antibiotic guidelines, the Pharmaceutical Benefits Book and the British National Formulary. The British National Formulary (BNF) is a pocket book for those concerned with the prescribing, dispensing and administration of medicines. The basis of selection of drugs is designed to include most products available to prescribers in the United Kingdom and the entries, coupled with the relevant notes for prescribers, are intended to help in the choice of appropriate treatment for each patient. Most of the preparations follow immediately after the notes for prescribers with which they are associated. It is considered that this arrangement helps in the selection process.

6.14 The BNF also includes details of prices, with basic net prices providing a better indication of relative cost and enabling prescribers to take into account the need to make the best use of available resources. The BNF is revised twice yearly and numerous changes are made between issues. It is thus intended to be a pocket book for rapid reference and because it cannot contain all the information necessary for prescribing and dispensing it is supplemented, as necessary, by specialist publications.

6.15 A shortcoming of the survey conducted by the Department may have been that no examples were given of publications referred to such as the BNF and this may reflect the very low response rate to the current use of the BNF to select the best drug for a given indication (3.7%).[1]

6.16 In the concluding remarks to the survey, it was evident from responses that a proposed ANF should provide two major functions; that is, drug information and the selection of the best drug for a given indication. The drug information function could be provided through a desk reference and updated on a yearly basis,

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[1] Australian National Formulary Survey, Benrimoj and Bowden, Department of Pharmacy, University of Sydney, October 1991.

however, consideration should be given to the provision of more regular updates considering the high use of the MIMS bi-monthly publication as a source of drug information. The selection of the best drug for a given indication function could be provided either as a desk reference or pocket sized format.

6.17 Another initiative to develop an ANF is the conversion of the current Australian Pharmaceutical Formulary and Handbook, issued by the PSA to all pharmacists, into an Australian National Formulary. The PSA Formulary and Handbook will be published this year in a new format and the PSA is working with ASCEPT to develop this. A decision has been made not to use Government funds in an attempt to make it self funding.

6.18 It is obvious to most professional groups that there is a need for an ANF which would be an up-to-date reference source of approved product information without extraneous material such as drug advertising. There must be a coordinated approach to devising a suitable format for such an independent reference source. It is the Committee's view that this should be a joint undertaking by the DHHCS, pharmacy groups, representative medical organisations with input from industry and funded jointly.

6.19 **The Committee therefore recommends that the Department of Health, *Housing and Community Services coordinates the preparation of an Australian* National Formulary to provide drug information to prescribers and dispensers and furthermore that this be made available in computerised format for use by prescribers and dispensers as an independent database on drugs in Australia.**

6.20 In addition, there is a need for national Therapeutic Guidelines, along the lines of those produced by the VDUAC which would assist in the selection of the best drug for a given indication. The Committee will consider the question of therapeutic guidelines in greater detail in the next report on this inquiry.

OVERVIEW

6.21 Government does have a major role to play in drawing together the various threads of a national drug strategy and reinforcing the partnership between industry, health professionals and consumers.

6.22 As pharmaceutical products form part of the strategy for better health, it is important that all participants work in concert with the Government's broad health objectives. This should assist in optimising the quality of drug use in Australia within the context of a rational drug policy. Quality of use is one of the four key elements referred to in the national drug strategy.

6.23 The Committee supports the work of the PHARM Working Party in developing an appropriate educational strategy to achieve this. This initiative will assist in providing a framework and mechanisms for continuing the promotion of quality use of pharmaceuticals.

6.24 For Government initiatives to be successful, it is important that outcomes be identified against which to measure the effectiveness of strategies undertaken. Indicators must be determined in order to measure change against stated objectives such as improvements in health status, quality of life, reduction in iatrogenic morbidity and mortality.

6.25 It is also important to establish reliable data sources and baselines for measurement. In the area of drugs and drug therapy this is beginning with the work of the HIC, Australian Institute of Health and DUSC.

6.26 The role of Government in coordinating all of these activities cannot be overstated, as it is the main participant with responsibility in all areas of drug administration and with a commitment to the better health of all Australians.

Epilogue

DEVELOPING ISSUES

Reference was made in Chapter 1 of this report to the fact that due to the very broad terms of reference for the inquiry, it would be reported on in three separate stages. This report, Part 1 of the inquiry, has dealt with regulation and the pharmaceutical industry.

The Committee has received a wealth of information on other aspects of the inquiry and will be pursuing the question of prescribing and dispensing drugs in further public hearings, inspections and discussions prior to the drafting of its second and third report.

In order that areas to be covered subsequently may be brought to attention and canvassed at this stage, the following is a summary of some key issues which have been identified and which will be addressed as the inquiry progresses.

Information needs of prescribers

- The Committee will be examining ways of improving quality of health care by looking at current professional and continuing education of medical professionals, including the adequacy of pharmacology components in current medical curricula.

- In order to provide better feed back to practitioners about their prescribing habits and as part of an overall quality assurance program, the Committee will examine the potential for auditing individual practitioner's prescribing patterns and the potential for providing feedback on this to

the individual practitioner.

- A need has also been expressed for comprehensive therapeutic guidelines for doctors from which to make optimal choices of the best drug therapy for given indications.

- Some concern has been expressed at the lack of alternatives to drug treatment and non-drug therapies as a component, both in undergraduate medical education and in continuing medical education.

- Discussion will also cover the role of academic detailing as an alternative channel of information to practitioners about new drugs other than from drug representatives.

Other health professionals

- The role of nurses both in a hospital and community setting as critical partners in drug treatment options and as patient educators will be addressed.

- The use of health care teams and the role of community health centres may be a model for a better coordinated approach to monitoring the appropriateness and effectiveness of drug therapy.

- Increased adverse drug reaction surveillance by use of a greater range of health professionals will be addressed.

The role of pharmacy

- An examination of pharmacists as community educators and the counselling role of pharmacists in reinforcing better quality use of pharmaceutical products will be covered extensively in Part 3 of the

inquiry, including;

- The role pharmacists can play in encouraging greater patient compliance in the taking of medicines.

Consumer issues

- Consumer education including compliance, polypharmacy and medication record management.

- Community and other support for medicinal drug dependence (eg benzodiazapines)

The above is not meant to be a comprehensive list of areas to be discussed but gives an indication of issues which have been highlighted and which will receive attention in the second and third parts of the Committee's inquiry.

Harry Jenkins
(Chairman)

4 March 1992

APPENDIX 1

LIST OF SUBMISSIONS

Individuals

Bowen, Ms L (Hampton, VIC)
Cossar, Mr B and
Kemp, Mr R (VIC)
Dodd, Mrs H (Karana Downs, QLD)
Dowling, Mr D (Glenelg, SA)
Faust, Ms B (Morwell, VIC)
Grimsley, Mr S W (Holt, ACT)
Hempton, Dr D (Vaucluse, NSW)
Horsburgh, Ms I (Forster, NSW)
Howard, Mr J (Gladstone, QLD)
Kramer, Dr J (Emerald Beach, NSW)
Miller, Mr G C (Nedlands, WA)
Murdoch, Dr I (Aberfoyle Park, SA)
Norman, Mrs D (Frankston Hospital, VIC)
Ortiz, Dr M (Marsfield, NSW)
Palmer, Mr R V (Kempsey, NSW)
Patrick, Mr T G (Pennant Hills, NSW)
Sharwood, Mr J & Mrs P (Mitcham, VIC)
Sheahan, Dr N A (Grovedale, VIC)
Teed, Mr A L (Harcourt, VIC)
van Hazel, Dr G A (Perth, WA)
Wickham, Dr W (Port Macquarie, NSW)

Organisations

ACT Community & Health Service
ACT Department of Community Services & Health
ADIS Press Australasia Pty Ltd
AIDS Council of NSW Inc
Alcohol and Drug Foundation

Alcohol and Drug Services Unit, Royal Newcastle Hospital

Alcoholism and Drug Dependence Recovery Centre Inc

Alphapharm Pty Ltd

Arthritis Foundation of Australia

Australasian Society of Clinical & Experimental Pharmacologists & Toxicologists

Australian College of Pharmacy Practice Ltd

Australian Consumers' Association

Australian Council on the Ageing

Australian Drug Evaluation Committee

Australian Federation of AIDS Organisations Inc

Australian Medical Association Ltd

Australian National Therapists Association Ltd

Australian Nursing Federation

Australian Pensioners' & Superannuants' Federation

Australian Pharmaceutical Manufacturers Association

Australian Prescriber

Communication Research Institute Australia

Council for Safe Medicine

Country Shire Council's Association

Country Women's Association of WA Inc

Curtin University of Technology

Department of Health & Community Services (NT)

Department of Health, Housing & Community Services

Department of Health, NSW

Department of Medicine, Princess Alexandra Hospital

Department of Pharmacology, University of Melbourne

Department of Pharmacy, University of Queensland

Department of Social & Preventative Medicine, University of Queensland

Department of Veterans' Affairs

Diabetes Australia

Doctors' Reform Society (NSW) Inc

Drug Adverse Reaction Council

Endometriosis Association (Vic)

Extended Hours Pharmacies Association

Federal Bureau of Consumer Affairs

Feros Riley & Associates

Fremantle Education Centre Inc

Friendly Societies Pharmacies

Heathcote Community Health Service

Hunter Area Health Service

Illawarra Pharmacists' Association

Kenmore Hospital

Manrex Australia Pty Ltd

Medical Lobby for Appropriate Marketing

Medreach Pty Ltd

Merck Sharp & Dohme (Australia) Pty Ltd

Minister for Business and Consumer Affairs (NSW)

Minister for Education and Youth Affairs (NSW)

Minister for Education, Recreation and the Arts (TAS)

Minister for Education, Youth, Sport & Recreation (Qld)

Minister for Education (WA)

Minister for Health (Qld)

Minister for Health (WA)

Ministry of the Premier and Cabinet (WA)

Narcolepsy and Overwhelming Daytime Sleep Society

National Association of Pharmacy Students of Australia

National Centre for Research into the Prevention of Drug Abuse

National Health & Medical Research Council

National Medical Media Council

National Pharmaceutical Distributors Association

North & North-West Pharmacists' Association

NSW Nurses' Association

NSW Therapeutic Assessment Group

Nutritional Foods Association

P & I Printing (Sales) Pty Ltd

Pharmaceutical Benefits Advisory Committee

Pharmaceutical Society of Australia

Pharmaceutical Society of WA

Pharmacy Board of New South Wales

Pharmacy Board of Tasmania

Pharmacy Board of the ACT

Pharmacy Board of Victoria

Pharmacy Guild of Australia

Premier of Tasmania

Premier's Department (QLD)
Prince of Wales Hospital
Princess Margaret Hospital
Product Information on Pharmaceuticals in Australia
Proprietary Medicines Association of Australia
Returned Services League
Royal Australasian College of Physicians
Royal Australian & New Zealand College of Psychiatrists
Royal Australian College of General Practitioners
Royal District Nursing Service
Royal District Nursing Society of SA
Royal Perth Hospital
SA Council on the Ageing
School of Pharmacy, Curtin University of Technology and
Department of Pharmacy, Fremantle Hospital
Society of Hospital Pharmacists of Australia
Spastic Welfare Association of WA Inc
St Vincent's Hospital Drug Committee
Tasmanian Pensioners Union
Therapeutic Goods Advertising Code Council
Tranquilliser Recovery and New Existence Inc
University of Queensland
University of Sydney
University of Tasmania
Victorian College of Pharmacy Ltd
Victorian Drug Usage Advisory Committee
Victorian Medical Postgraduate Foundation
Voice of the Elderly (SA) Inc
Youth Programmes Incorporated

APPENDIX 2

DETAILS OF PUBLIC HEARINGS AND WITNESSES

CANBERRA - 15 MARCH 1991

Department of Community Services and Health

- Mr Thomas Carroll, Deputy Campaign Manager, Health Advancement Campaign Unit
- Ms Margaret Ford, Principal Adviser, Pharmaceutical Benefits
- Dr David Graham, Director, Compliance Branch, TGA
- Mr John Gregan, Secretary, Drugs & Poisons Schedule Committee
- Mr Stuart Hamilton, Secretary
- Dr John Primrose, Medical Adviser, Health Care Access Division

Pharmaceutical Society of Australia

- Ms Leone Coper, Assistant Director, Public Health Programs
- Mr Peter Crothers, Deputy National Director
- Mr Neil Naismith, National President

Pharmacy Guild of Australia

- Mr Robert Davies, Executive Director
- Mr Colin Johns, National President
- Dr Philip Tatchell, Director, Health Economics Division
- Mr Walter Williams, Director, Communications

SYDNEY - 25 MARCH 1991

Alphapharm

- Mr David Duchen, Managing Director

Australian Consumers' Association

- Ms Yong Sook Kwok, Policy Officer

Australian Pharmaceutical Manufacturers Association

- Mr Kerry Bell, Chief Executive Officer
- Dr Janice Hirshorn, Technical Affairs Manager

Consumers' Health Forum of Australia

- Ms Janne Graham, Chairperson
- Mr Bruce Shaw, Coordinator

Media Council of Australia

- Dr David Graham, Member, Therapeutic Goods Advertising Code Council
- Mr Jeffrey Rushton, Chairman, Therapeutic Products Advertising Code Council
- Mr Garvin Rutherford, Executive Director,

Merck Sharp and Dohme

- Ms Lee Ausburn, Director, Economic and Public Affairs
- Mr Paul Bell, Managing Director
- Dr Rodney Hall, Medical Director
- Mr Warwick Wilkinson, Director, External Affairs

National Pharmaceutical Distributors Association

- Mr Alexander Ferguson, Executive Director
- Mr Ian Stephens, President

Nutritional Foods Association

- Mr Philip Daffy, Technical & Standards Committee
- Mr Anthony Morgan, Executive Director

Proprietary Medicines Association of Australia

- Mr Derek Tye, President
- Mrs Juliet Wolfgang, Executive Director

MELBOURNE - 22 APRIL 1991

Australian Nursing Federation

- Ms Marilyn Beaumont, Federal Secretary

Endometriosis Association (Victoria)

- Mrs Lorraine Henderson,, Member, Management Collective
- Ms Rosalind Wood, Member, Management Collective

Medreach Pty Ltd

- Dr Ken Harvey, Director

Product Information on Pharmaceuticals in Australia

- Ms Deborah Homburg, Director

Royal Australian and New Zealand College of Psychiatrists

- Dr Isaac Schweitzer, Victorian Branch Member
- Professor John Tiller, Victorian Branch Representative

Royal District Nursing Service

- Miss Beverly Armstrong, Director of Nursing
- Miss Patricia McPherson, Nurse Administrator and Policy & Planning Officer

Society of Hospital Pharmacists of Australia

- Miss Pamela Nieman, Federal Vice-President
- Mr Michael Ryan, Federal Councillor

Tranquilliser Recovery and New Existence

- Ms Gwenda Higgins, Co-Director

Victorian Drug Usage Advisory Committee

. Mrs Mary Hemming, Executive Pharmacist
. Mr Neil Naismith, Chairman

Victorian Medical Postgraduate Foundation

. Dr Maurice Mashford, Chairman, Therapeutics Committee

ADELAIDE - 17 JUNE 1991

Ethnic Communities Council

. Mrs Liama Bogens, Vice President

Medical Lobby for Appropriate Marketing

. Dr Peter Mansfield, Secretary

Older Persons Advisory Council

. Mrs Heather Southcott, Member

Royal District Nursing Society of South Australia

. Ms Aine Greene, Assistant Director of Nursing - Clinical

South Australian Council on the Ageing

. Mrs Joan Watkinson, Community Services Manager

South Australian Council of Pensioners and Retired Persons Associations

. Mrs Mary Miller, President

Mr Dean Dowling - private individual

PERTH - 18 JUNE 1991

Pharmaceutical Society of Western Australia

. Mr John Gibson, Member
. Ms Sheryl Grimwood, Member
. Mr Kevin McAnuff, President

Princess Margaret Hospital for Children

. Mr Malcolm Roberts, Chief Pharmacist

Royal Perth Hospital

. Mr Stuart Gibb, Chief Pharmacist
. Dr Arthur Harris, Chairman, Drug Committee

School of Pharmacy, Curtin University of Technology

. Mr Constantine Berbatis, Researcher

- Mr Maxwell Page, Senior Lecturer
- Dr Vivian Sunderland, Head

Western Australian Department of Health

- Mr Brian Wall, Director of Environmental Health

Dr Guy van Hazel, private individual

HOBART - 18 SEPTEMBER 1991

Pharmacy Board of Tasmania

- Mr Keith Graver, Member
- Mrs Cecelia Wedd, Member

School of Pharmacy, University of Tasmania

- Dr Stuart McLean, Senior Lecturer
- Dr Gregory Peterson, Lecturer
- Dr Alan Polack, Head

Tasmanian Department of Health

- Mr John Galloway, Chief Pharmacist

Youth Programmes

- Mr John Evans, President
- Ms Kathy Kinnaird, Ex-employee

BRISBANE - 25 SEPTEMBER 1991

Inala Community Health Centre

- Dr Richard Copeman, Senior Lecturer in General Practice

Queensland Department of Education

- Mr Rodney Ballard, Acting Principal Education Officer, Special Health Issues

Queensland Health

- Mr Rodney Lowry, Chief Environmental Health Officer (Drugs & Poisons)
- Mr Andrew Petrie, Adviser in Pharmacy
- Dr Ronald Ramm, Director, Environmental Health

University of Queensland Medical School

- Dr Christopher Del Mar, Senior Lecturer in General Practice

Private Individuals

- Mrs Helen Dodd, private individual
- Dr Julia Potter, private individual
- Professor Michael Roberts, private individual

CANBERRA - 18 OCTOBER 1991

Australian Federation of AIDS Organisations

- Ms Leanne Joyce, Executive Director
- Mr Hernan Pintos-Lopez, Policy Coordinator

Australian Pharmaceutical Manufacturers Association

- Mr Kerry Bell, Chief Executive Officer
- Dr Janice Hirshorn, Technical Affairs Manager

Department of Health, Housing and Community Services

- Dr Tony Adams, Chief Medical Adviser
- Ms Margaret Atkinson, Head, Drug Listing & OTC Registration Section, TGA
- Dr Allan Black, Medical Adviser, Toxicology
- Dr John Cable, Acting National Manager, TGA
- Mr Jeffrey Dutton, Head, Advertising Section, TGA
- Ms Fiona Howarth, Principal Adviser, Pharmaceutical Benefits Branch
- Mr John Loy, Head, Health Research and Services Division
- Mr Andrew Mitchell, Director, Pharmaceutical Evaluation Section
- Mr Peter Pflaum, Head, Baume Task Force
- Dr John Primrose, Medical Adviser, Pharmaceuticals & Health Care Evaluation
- Mr Michael Roche, Deputy Secretary
- Mr Desmond Threlfall, Secretary, Pharmaceutical Benefits Advisory Committee
- Mr Robert Tribe, Chief GMP Auditor, TGA

Federal Bureau of Consumer Affairs

- Mr John Wood, Director

SYDNEY - 19 NOVEMBER 1991

Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

- Associate Professor Gillian Shenfield, Past President,
- Associate Professor Lindon Wing, President

Australian Medical Association

- Dr William Coote, Assistant Secretary-General
- Dr Paul Mara, Federal Councillor
- Associate Professor Barry McGrath, Federal Councillor

Doctors Reform Society

- Dr Con Costa, National Vice-President

Royal Australasian College of Physicians

- Associate Professor Robert Moulds, Member, Therapeutics Committee

Royal Australian College of General Practitioners

- Dr Neil Jensen, Assistant Secretary-General
- Dr Andrea Mant, Director, General Practice and Primary Care Research Unit

APPENDIX 3

WORKSHOP - A STRATEGIC APPROACH TO MEDICINES
Canberra - 30 and 31 July 1991

LIST OF PARTICIPANTS

Ms Linda Adamson	Executive Officer, Australian Pensioners' & Superannuants' Federation
Ms Sue Akeroyd	Technical and Scientific Adviser, Nutritional Foods Association
Mr Kerry Bell	Chief Executive Officer, Australian Pharmaceutical Manufacturers Association
Ms Christianna Cobbold	Manager Pharmaceuticals, Aerospace & Biological Industries Branch, Department of Industry, Technology and Commerce
Prof Richard Day	Director of Clinical Pharmacology and Toxicology, St Vincent's Hospital
Ms Jan Donovan	Policy Officer, Australian Council on the Ageing
Mr David Duchen	Managing Director, Alphapharm
Dr David Graham	Director, Compliance Branch, Therapeutic Goods Administration
Dr Ken Harvey	Consultant Microbiologist, La Trobe University
Ms Mary Hodge	Freelance Consultant in health issues
Mr Colin Johns	National President, Pharmacy Guild of Australia
Ms Elizabeth Lavender	Senior Lecturer, Department of Nursing, La Trobe University
Mr John Low	Federal President, Society of Hospital Pharmacists of Australia
Dr Andrea Mant	Director, General Practice and Primary Care Research Unit, Royal Australian College of General Practitioners
Dr Robert Marr	Consultant (part time), Better Health Program
Mr Neil Naismith	President, National Council of the Pharmaceutical Society of Australia
Dr John Nearhos	Medical Director, Health Insurance Commission
Dr John Primrose	Medical Adviser (Pharmaceuticals), Health Care Access Division, Department of Health, Housing and Community Services
Mr Bruce Shaw	Coordinator, Consumers' Health Forum of Australia
Dr Alison Turner	Assistant Secretary, Community Based Health Care Branch, Department of Veterans' Affairs
Mrs Juliet Wolfgang	Executive Director, Proprietary Medicines Association of Australia

SCHEDULES FOR POISONS AS IN THE STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS NO 5

Poisons are classified according to the schedules in which they are included, as follows:

- **Schedule 1** - Poisons of plant origin of such danger to health as to warrant their being available only from medical practitioners, pharmacists or veterinary surgeons.

- **Schedule 2** - Poisons for therapeutic use that should be available to the public only from pharmacies; or where there is no pharmacy service available, from persons licensed to sell Schedule 2 poisons.

- **Schedule 3** - Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners.

- **Schedule 4** - Poisons that should, in the public interest, be restricted to medical, dental or veterinary prescription or supply, together with substances or preparations intended for therapeutic use, the safety or efficacy of which requires further evaluation.

- **Schedule 5** - Poisons of a hazardous nature that must be readily available to the public but require caution in handling, storage and use.

- **Schedule 6** - Poisons that must be available to the public but are of a more hazardous or poisonous nature than those classified in Schedule 5.

- **Schedule 7** - Poisons which require special precautions in manufacture, handling, storage or use, or special individual regulations regarding labelling or availability.

- **Schedule 8** - Poisons to which the restrictions recommended for drugs of dependence by the 1980 Australian Royal Commission of Inquiry into Drugs should apply.

- **Schedule 9** - Poisons which are drugs of abuse, the manufacture, possession, sale or use of which should be prohibited by law except for amounts which may be necessary for medical or scientific research conducted with the approval of Commonwealth and/or State or Territory Health Departments.

APPENDIX 5

SCHEDULE 1 OF SUSDP NO 5

ACONITE (Aconitum spp).

COMFREY (Symphytum spp) for human internal use being:

(a) any preparation; or

(b) any part of the dried plant.

CROTON OIL.

SAVIN OIL.

TANSY OIL.

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A GUIDE TO ETHICAL PRINCIPLES IN THE RELATIONSHIP BETWEEN PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY

Introduction

This statement by The Royal Australasian College of Physicians has been prepared by a special subcommittee of Council and is a revised version of the statement issued in April 1984.

The Royal Australasian College of Physicians acknowledges that the pharmaceutical industry has made significant contributions to medical research and to the support of post graduate and continuing medical education in Australia. It is important however that the high reputation of Fellows of the College and the pharmaceutical industry be maintained.

There is increasing concern that some interactions between representatives of pharmaceutical companies and physicians, especially clinical investigators involved in commissioned research projects, may compromise the autonomy and independence of physicians to a variable extent and may lead to unethical conduct. The following discussion highlights areas of concern and suggests appropriate standards for these situations. The areas covered include:

(a) Ethical principles in the conduct of clinical trials including commissioned research projects
- responsibilities of the investigator
- responsibilities of the Ethics and Research Committee
- the role of the Hospital Drug Committee.

(b) Pharmaceutical industry sponsored travel
- sponsored travel for an individual
- sponsored travel for a group of physicians
- soliciting funds for travel from pharmaceutical companies.

(c) Guidelines for the conduct of supported meetings.

ETHICAL PRINCIPLES IN THE CONDUCT OF CLINICAL TRIALS INCLUDING COMMISSIONED RESEARCH PROJECTS

Representatives of pharmaceutical companies may approach physicians, and especially clinical investigators, to conduct a clinical trial of "a new drug" for a variety of reasons and with varying inducements. In these circumstances the investigator and the hospital or university Ethics and Research Committee have a number of responsibilities.

Responsibilities of the Investigator

The investigator should consider:

(a) The motives of the pharmaceutical company in proposing the study.

(b) Whether the study has scientific merit and is likely to be published in a refereed journal or whether it is a study to familiarize doctors with the drug and encourage usage.

(c) The risks and inconvenience for the involved patients or volunteers.

(d) The costs of the study to the hospital (investigations and bed usage).

(e) Who will pay for the investigational drugs.

(f) Realistically whether he/she has the patients, resources and time to complete the study within the agreed time period.

(g) His/her responsibility to fulfil the contract with the pharmaceutical company.

(h) **Payment to the investigator or department or institution.** It is recommended that the investigator derives no personal, financial or medical benefit from the conduct of the study. However, it is wrong for a clinical researcher to be financially penalised by his involvement in a study without some compensation. The amount of compensation must reasonably relate to the income or time lost and should be approved by the institutional Ethics Committee/Drug Committee.

In particular, per capital payments from pharmaceutical companies are improper unless specifically approved by the hospital and/or university Ethics and Research Committee. Any remuneration should be paid into a trust fund and used to finance the execution of the study, the programmes of the department responsible for the study, or, approved travel by departmental members. Investigators should satisfy themselves that the amount of money involved is reasonable so that the investigator's judgement concerning cost/benefit analysis of the study will not be impaired. Grants of money or equipment by firms to institutions such as hospitals, health care centres and universities donated specifically for the purposes of research, are generally quite acceptable. If the donation is linked to, or contingent upon, a clinical trial the Ethics Committee should be aware of the arrangement.

(i) **Notification of appropriate Ethics Committees.** Since payments to investigators, departments and institutions have ethical implications it is recommended that the hospital and/or university Ethics Committee be made aware of the financial arrangements for the proposed study. The Committee should be informed of all proposed payments to volunteers and should be satisfied that they are reasonable and not so large as to excessively reward subjects for the time and trouble involved. This

principle applies not only to volunteers who are healthy but also to volunteer patients who may be asked to undertake extra activities or attendances which are therapeutically unnecessary.

(j) **Publication of results.** The investigator and the Ethics and Research Committee should ensure that decisions concerning publications of the results of proposed studies are the responsibility of the investigator and not the sponsoring company. Financial and other support should be acknowledged on publications.

Responsibilities of the Ethics and Research Committee

The hospital and/or university Ethics and Research Committee may be asked to consider a variety of applications which have been developed jointly by the investigator and a pharmaceutical company as a local project or part of a multicentre trial. The Committee has a particular responsibility to establish that the benefit of the human experimentation is reasonable in terms of the patient, advances in patient care, clinical research, hospital cost and the reputation of the investigator. The following questions should be addressed:

(a) Does the proposed study have scientific merit?

(b) Is the study designed to answer specific and relevant questions?

(c) Are the design and the available patient numbers adequate to achieve the study's aim?

(d) Is the drug novel or related to existing drug classes (e.g. beta blockers) and is the toxicological and adverse effects profile satisfactory? (The investigators' brochure, investigational drug profile, approved product information and/or the Department of Health's new drug information profile should be reviewed.)

(e) Is it a "familiarization" or "open usage" study so that Australian physicians may obtain experience in using a new drug and is the trial proposed so that the pharmaceutical company can claim that the drug is being used by a reputable physician or hospital?

(f) Will the hospital have to pay for additional research investigations such as blood studies or radiological studies?

The role of the hospital drug committee

The Drug Committee of most teaching hospitals consists of representatives of medicine, surgery, pharmacy, nursing, administration and laboratory and diagnostic services. The Committee usually has a Clinical Pharmacologist and the Chief Pharmacist as members. Smaller hospitals may not have as wide a representation. The Drug Committee is experienced in the evaluation of new drugs that have been requested for the hospital pharmacopoeia. The Committee is also experienced in assessing the cost/benefit ratios of medication and has the expertise to comment on some of the ethical issues concerning the clinical trial of pharmaceuticals in hospitals. The skills of the Drug Committee might be used by the Ethics and Research Committee in reaching a decision concerning a particular project.

Pharmaceutical industry sponsored travel

Over the last 25 years the pharmaceutical industry has been exceedingly generous in its support of Australian and New Zealand physicians. Numerous fellows have been encouraged to travel to various parts of the world to teach, to research and to observe other clinicians. On their return they were able to turn this experience to advantage. However, as budgets have become tighter and margins finer, especially in the pharmaceutical industry, we should all be aware that the days of generous travel support have passed. In the present climate, sponsored overseas trips are often closely related to favours rendered or anticipated. Under these circumstances the physician should be aware of the pressures which are placed on the industry to reach sales targets, and that in some circumstances these pressures could also be placed upon the physician. Industry sponsored travel can be divided into support for an individual and support for a group of physicians.

(a) **Sponsored travel for an individual.** An individual physician may act as a consultant for the company. It is a legitimate function of an expert in a particular field to be able to provide services to a pharmaceutical company at its head office or in another place. This may be in general terms or in relationship to a particular drug or problem. The arrangements should be that of any business undertaking with appropriate travel provided and recompense for time spent in the meeting and if necessary in preparation for the meeting. if the physician acts as a consultant this should be public knowledge and recognised at hospital and governmental advisory committees.

(b) **Participation in a meeting.** Sponsorship may be offered for an individual to travel to a meeting in which he or she is already involved as a speaker or chairman. This is a form of sponsorship which recognises the standing of the individual and has the support of the College. Obviously meetings vary in their scientific and educational importance. A rank order of such meetings can be produced and should be considered. There is a grey zone at the lower end of this ranking system in which the meetings are sponsored by the company for the company. If however the individual is already contributing to the meeting it would seem that some degree of choice has already been exercised. The support for travel should however be declared to hospital and other committees, as appropriate.

(c) **Attendance at a meeting.** It is more difficult to justify this form of support. The individual should determine to his or her own satisfaction the motives behind the support. The support should be made known so that the individual is not compromised by a conflict of interst in subsequent decisions made about the company's product.

(d) **Attendance at a meeting with spouse or friend with travel and other expenses provided** for both. This form of sponsorhip is the least desirable and may be ethically unacceptable.

Sponsorship travel for a group of physicians

Concern has arisen over the rather aggressive marketing policies adopted by some pharmaceutical companies with the

release of new drugs. For example, a recent promotional exercise taking a larger number of rheumatologists from Britain and Europe on the Orient Express was reported in the popular press. The latter is ever watchful to expose these activities and consumer groups and the public at large are likely to question the role that these promotional activites have on determining doctors' prescribing habits much more closely than in the past.

Sponsorship travel for a group of physicians may take the form of:

(a) **Participation in a meeting.** There have been a number of instances where groups of physicians with a similar interest have been taken to a distant venue for a meeting to which they have actively contributed and from which they gained. Carefully designed, such meetings can be of educational value for all concerned. They may further advance the pharmaceutical companies'corporate image. Variations on this theme have on occasions been crass and ostentatious. However, on balance such meetings can be useful and may serve a legitimate purpose. Care is needed in producing both the scientific programme and controlling the non-educational features of the meeting. It would be preferable if these meetings could be arranged under the auspices of the College or a learned Society.

(b) **Attendance at a meeting.** On several occasions pharmaceutical companies have taken groups of practitioners to international meetings to which the practitioner would not otherwise have gone. This is usually a purely commercial exercise in which the company hopes to influence the prescribing habits of the individual. If undertaken by a physician, such tours should be declared by the individual to appropriate committees, or other relevant bodies, so that if the company's product is being considered, any inappropriate influence can be discounted.

(c) **An educational experience.** Several entrepreneurs have organized groups of practitioners on joint study tour/holidays. Sponsorship for these varies from negligible to large, but, in the main, participants have paid a major part of the costs. By having a sufficiently high educational content the cost becomes tax deductible and the holiday component relatively inexpensive.

Properly designed the tours can be of considerable educational value, but on the whole they are probably not cost effective. Unless such programmes are structured to the very highest standards they should not be supported.

Soliciting funds for travel from Pharmaceutical Companies

An individual physician may seek funds from the pharmaceutical industry to enable him/her to attend an international meeting or to sponsor the travel of a registrar or trainee for the same purpose. If an individual has been invited to participate in a meeting but the organizing committee is unable to meet his travel expenses, it may be appropriate for the individual to approach a pharmaceutical company indicating why support is being sought and the topic of any presentation which is going to be made. If on the other hand the individual is simply seeking travel support to attend a meeting, it is unlikely that the pharmaceutical industry will support such a request unless they feel in some way obligated to the individual. Under either circumstances, it would be important for the individual to notify the hospital or university committee of the support which they have received from the pharmaceutical industry. When an individual obtains support for a member of his laboratory staff, or registrar, or a trainee, a similar declaration of support to the employing hospital or authority should be considered.

In summary, therefore, whilst sponsorship of individuals and groups may on occasions be altruistic, on most occasions the support will have been calculated against an expected return. To protect the individual and the pharmaceutical company such support should be openly declared to appropriate hospital and/or university committees. Furthermore, the individual should carefully consider whether his or her prescribing habits are being, or likely to be, unduly influenced. These possible conflicts of interest may also arise if the physician sits on any government or other advisory committees.

GUIDELINES FOR THE CONDUCT OF SUPPORTED MEETINGS

All of the following, if carefully arranged, are legitimate extensions of a mutually advantageous liaison between physicians and the pharmaceutical company. Where the support of drug companies is sought for meetings, the College or Society should attempt to maintain an even-handed approach and be careful not to favour one company over others as a matter of policy. This will, of course, be modified by the willingness of the individual companies to assist in approved educational and other exercises.

The supporting Pharmaceutical Company offers the speaker and the meeting

Under these circumstances it is appropriate that the supporting company sends out the invitation in its own name, that it supplies the venue for the meeting, that it supports the speaker and meets other costs. The College or Society associated need not be mentioned. It is appropriate, if the topic is of interest, that the pharmaceutical company may be offered the appropriate College or Society mailing list. An offer of a mailing list merely means that the members who may be interested have an opportunity to attend such a meeting. Additional speakers may be offered if appropriate and a chairman may be suggested. The company responsible for the meeting should not be obligated to accept any of these offers or advice from the College or the Society.

At the end of the meeting the chairman should thank the company for inviting the visiting speaker and supplying the venue. It is usual for local speakers and the chairman to be thanked in writing after the meeting. Whether they receive an emolument is optional and what they do with it is their affair.

The Pharmaceutical Company offers a speaker and support for a meeting primarily to be organised by the College, Society or an Institution

In this instance the speaker is likely already to be coming to the country. The College, Society or Institution is invited to conduct a meeting and is in a position to agree with the supporting company on a venue. The College, Society or Institution will then have the opportunity to invite its own members to the meeting with the programme arranged by the College, Society or Institution around the visiting speaker. The venue is determined by and payment for the venue is made by the supporting company. The supporting company meets all the costs, but the meeting is a College, Society or Institution meeting with the mailing list limited appropriately.

Acknowledgement of the support of the pharmaceutical company is appropriate with the invitation, which should go out under the name of the College, Society or Institution. It is usual to thank the supporting company at the end of the meeting.

The College or Society approaches a supporting body

The College or Society may approach a pharmaceutical or other company to support a meeting by supplying a speaker. If an agreement is reached, The College or Society would then supply additional speakers and a chairman, plan the meeting, send out invitations and acknowledge the supporting company.

The College or Society seeks support for a normal meeting

A pharmaceutical company may be approached to support normal meetings, for example by way of supplying a dinner, programmes or satchels. The meeting is conducted in the normal way. The supporting company is thanked for its contribution at the end of the meeting.

Advertising

For any meeting where support is obtained from the pharmaceutical company or appliances manufacturer, limited advertising facilities should be made available in the form of stationery, programme, satchels, etc. With advertising content or a small trade exhibit at the option of the supporting body. Good sense should prevent this from being excessive or too obtrusive.

The College or Society should avoid:

(a) Inviting its own members to attend a meeting conducted by a pharmaceutical company.

(b) Inviting its own members to attend a meeting also attended by non-members or persons not invited by the College or Society.

(c) Appearing to support a product or the views of the speaker.

(d) Appearing to consider that any one meeting is more important than another.

(e) An unusually large or ostentatious trade exhibit.

(f) Failure to thank the supporting body for its contribution.

Finally physicians and pharmaceutical companies have much to gain in a close cooperative liaison. Both must work together in a spirit of mutual respect. In the words of Albert Schweitzer "The first step in ethics is a sense of solidarity with other human beings".

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