ess an adequate reason for not complying with these guidelines is given to the satisfaction of the Secretariat or Chairman of the Code of Conduct Committee, the APMA Secretariat may not accept a complaint for evaluation.

A processing fee of $5,000 will be charged for the consideration of a complaint from a non-APMA member company.

Procedures

Dialogue between both the subject company and the complainant is required and should be meaningful with a willingness from both companies to consider each others position and concerns.

- All inter-company correspondence must have the written endorsement of the Association Representative, Chief Executive or an alternate Association Representative.

- On receipt of a letter from the complainant the subject of the complaint (subject company) shall be invited to respond to any issues raised by the complainant within 10 ten working days.

- Following a response to the issues raised by the complainant, the subject company and complainant should be provided 10 working days from the receipt of the response to organise a meeting in order to discuss any unresolved issues or forward a complaint to the APMA.

- A teleconference or video conference may be an acceptable form of a meeting. An exchange of letters regarding the complaint will not usually be sufficient.

- At this meeting senior representatives from all relevant departments of both companies should be present

- If the Association Representatives are not present at this meeting, a record of the meeting should be provided to them for their signature. This signed record of the meeting must be submitted with the complaint.

- APMA is willing to act as a mediator should the companies desire.

Inter-company complaints should not be used simply as a competi tool.

Complaints from one pharmaceutical company (whether or not an APMA Member) against an APMA Member company should include the following information to ensure a complete review.

1. A summary page containing:

   a. Subject product/company

   b. Brief description of complaint itemising the specific claims at issue with complete rationale for alleged breach to be included as an attachment.

   c. Section of Code alleged to be breached.

   d. Details of attempts to resolve matter with the subject company.

2. Medically based complaints - supporting data cross referenced to specific claims at issue and rationale for challenge.

3. Marketing based complaints - alleged consequences (damage to complainant) with supporting data if available.

4. Approved or full Product information for complainant's product if mentioned in a comparative context.

5. Written endorsement of the Association Representative or chief executive of the complainant company.

6. If a complaint and supporting data exceeds 10 pages, 16 copies of all documentation must be provided. (one copy may be sent to APMA in the first instance provided the remaining 15 copies are forwarded within 7 days).

' ddition, complainants should note that:

i. When challenging a claim on medical/scientific grounds, it is not sufficient to simply state that the claim is not supported. Evidence must be provided to support the complainants case.

ii. If these criteria are not met, then the APMA may return the complaint to the complainant for further information.

Response by Subject Company

When a complaint has been accepted for evaluation, the subject company is asked to state whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

When providing this information, the subject company should include:

a. Details of attempts to resolve the matter with the complainant

b. A brief summary of the response to each alleged breach

c. Substantiation of the specific claims at issue with full supporting data.

d. Where the response is greater than 10 pages, 16 copies of all documentation is required.

e. 16 original pieces of the promotional material at issue

f. The signature of the Association Representative or chief executive of the company.

g. 16 copies of the Product Information for the product

Appendix 2

Rules Of APMA

The following is an extract of the Rules of the APMA which refer to the disciplining of Members and rights of appeal.

13. DISCIPLINING OF MEMBERS

13.1. *Where the Board is of the opinion that a Member:*

a. has infringed or neglected to comply with any provision or provisions of the Objects, the Rules or Sections 12.2 or 12.3 of the Code of Conduct; or

b. is guilty of any act, proceeding or practice which the Board considers to be inconsistent with his position as a Member, or has acted in a manner prejudicial to the interests of the Association,

the Board may, by resolution:

i. expel the Member from the Association; or

ii. suspend the Member from membership of the Association for a specified period or until the breach for which he was suspended is remedied;

and/or

iii ratify the imposition of a fine under Section 12.3 of the Code of Conduct

13.2 *A resolution of the Board under Rule 13.1 is of no effect unless the Board, at a meeting held not earlier than 14 days and not later than 28 days after service on the Member of a notice under Rule 13.3 confirms the resolution in accordance with this rule.*

13.3 *Where the Board passes a resolution under Rule 13.1, the Secretary shall as soon as practicable, cause a notice in writing to be served on the Member:*

a. *setting out the resolution of the Board and the grounds on which it is based;*

b. *stating that the Member may address the Board at a meeting to be held not earlier than 14 days and not later than 28 days after service of the notice;*

c. *stating the date, place and time of that meeting; and*

d. *informing the Member that the Member may do either or both of the following:*

i. *attend and speak at that meeting;*

ii. *submit to the Board at or prior to the date of that meeting written representations relating to the resolution.*

13.4 *At a meeting of the Board held as referred to in Rule 13.3, the Board shall:*

a. *give to the Member an opportunity to make oral representations;*

b. *give due consideration to any written representations submitted to the Board by the Member at or prior to the meeting; and*

c. *by resolution determine whether to confirm or to revoke the resolution*

13.5 *Where the Board confirms a resolution under Rule 13.5 the Secretary shall within 7 days after that confirmation, by notice in writing, inform the Member of the fact and of the Member's right of appeal under Rule 14.*

13.6 *A resolution confirmed by the Board under Rule 13.4 does not take effect:*

a. *until the expiration of the period within which the Member is entitled to appeal against the resolution pursuant to Rule 14 where the Member does not exercise the right of appeal within that period; or*

b. *where within that period the Member exercises the right of appeal, unless and until the Association confirms the resolution pursuant to Rule 14.4.*

14. RIGHT OF APPEAL OF DISCIPLINED MEMBER

14.1 *A Member may appeal to the Association in general meeting against a resolution of the Board which is confirmed under Rule 13.4, within 7 days after notice of the resolution is served on the Member, by lodging with the Secretary a notice to that effect.*

14.2 *Upon receipt of notice from a Member under Rule 14.1, the Secretary shall notify the Board which shall convene a general meeting of the Association to be held within 21 days after the date on which the Secretary received the notice.*

14.3 *At a general meeting of the Association convened under Rule 14.2:*

a. *no business other than the question of the appeal shall be transacted;*

b. *the Board and the Member shall be given the opportunity to state their respective cases orally or in writing, or both; and*

c. *the Members present shall vote by secret ballot on the question of whether the resolution should be confirmed or revoked.*

14.4 *If, at the general meeting, the Association passes a resolution in favour of the confirmation of the resolution, the resolution is confirmed. If the resolution fails, then the resolution of the Board is revoked.*

23. DELEGATION BY BOARD TO COMMITTEE

23.1 *The Board may, by instrument in writing, delegate to one or more Committees the exercise of such of the functions of the Board as are specified in the instrument, other than;*

a) *this power of delegation;*

b) *a function which is a duty imposed on the Board by the Act or by any other law; and*

c) *the power to expel or suspend a Member as provided in Rule 13.1;*

d) *the power to impose a charge for abuse of the Code as recommended by the Code of Conduct Committee.*

23.2 *A Committee may consist of the representatives of such Member or Members of the Association as the Board thinks fit and, in the case of the Code of Conduct Committee and the Code of Conduct Appeals Committee, may also include such other persons, not being representatives of Members, as the Board considers to be suitably qualified.*

Glossary

In this Code:

"**ADRAC**" means the Adverse Drug Reactions Advisory Committee of the Australian Drug Evaluation Committee.

"**Association**" means the Australian Pharmaceutical Manufacturers Association Inc.

"**Australasian congress**" means a congress held in Australia that is organised and controlled by an Australasian (or Australian and New Zealand) College or Society, or where a College or Society in New Zealand is actively organising and has joint control over the congress with an Australian Society or College.

"**Boxed Warning**" is a mechanism adopted by the TGA for highlighting special warning statements in Product Information.

"**Brand name reminders**" means such items of low monetary value which are intended to remind healthcare professionals of the existence of a product.

"**Breach repetitions**" means when a Member repeats the same breach within a period of 12 months in the promotion of any of the Member's products.

"**Breaches where activities have ceased**" means severe breaches of this Code where the promotional activity has been completed before the breach has been found.

ange of clinical significance" is any change in the Product Information that could alter a decision to prescribe or not to prescribe the product and may include the following:

(a) Approved indications for use
(b) Precautions for use
(c) Contra-indications
(d) Warnings
(e) Adverse effects and interactions
(f) Available dosage forms
(g) Dosage regimens and routes of administration
(h) Dependence potential
(i) Reference to special groups of patients (where necessary)
(j) boxed warnings

"**Chief Executive Officer**" means that person appointed to manage the affairs of the Association in accordance with the Rules of the Association.

"**Code of Conduct Secretary**" means that person appointed by the APMA Board to act as Secretary to the Code of Conduct Committee.

"**Company Commissioned article**" means an article or series of articles which is paid for by a Member which represents the independent opinion of a third party and/or has the appearance of editorial material.

"**Company representatives**" are those persons authorised by a Member to disseminate information about a product to healthcare professionals, including medical representatives.

"**Competition**" means any activity that includes an element of chance or random selection.

"**Congress**" means an event sponsored and organised by a Society, College, university or other non-company entity.

"**Correct**" means representative of all the evaluable data.

"**Data on File**" is that body of unpublished clinical or scientific informa[illegible] held by a company. It does not include evaluated data submitted to the Department of Health and Aged Care in accordance with the Australian Guidelines for the Registration of Drugs Vol. 1 or preceding Guidelines.

"**Educational material**" means any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims.

"**Evaluated data**" means data which have been submitted as part of an application for marketing in accordance with the Australian Guidelines for the Registration of Drugs Vol 1 which form the basis for registration of a product by the Department of Health and Aged Care.

"**Full advertisement**" is the type of advertisement that is mandatory for advertising of all new chemical entities or the advertising of new indications for 24 months from the date of first advertising in medical publications, or longer at the discretion of the advertiser. These advertisements are described in Section 3.1.1 of this Code.

"**General Public**" are persons other than healthcare professionals.

"**Graphics**" means the use of any pictorial or graphical representation in promotional material, including photographs, drawings, x-rays, graphs and bar charts, but excludes any related promotional text.

"**Healthcare professions and healthcare professionals**" includes members of the medical, dental, pharmacy or nursing professions and any other persons who in the course of their professional activities may prescribe, supply or administer a medicine.

"**IFPMA**" means International Federation of Pharmaceutical Manufacturers Associations.

"**Information**" means educational facts regarding the attributes of a product.

"**Insulin delivery device**" is any device used for the administration of insulin but distributed independently from the active ingredient. The device will be listed with the TGA as a device.

"**ıustry**" means Members of the Australian Pharmaceutical Manufacturers Association Inc.

"**International congress**" means a congress held in Australia where a Society or College in an overseas country is actively organising and has joint control over the conference with an Australian Society or College.

"**Journal**" means a serial publication whose distribution is restricted to the members of the healthcare professions.

"**Literature**" means that body of published trials, findings and reviews which have appeared in medical and scientific publications.

"**Mailings**" means promotional material designed for distribution through the postal system or by private means.

"**Manufacturer**" includes the manufacturer, importer or Australian distributor of a pharmaceutical product.

"**Market research**" is the gathering of data on the scope or dimensions of a market and its components, including the needs of the customers in that market.

"**Medical claims**" includes any statement that conveys information about a disease state or the attributes of a product in respect of its therapeutic use, that is, a use for the purpose of or in connection with -

(a) preventing, diagnosing, curing or alleviating a disease, defect or injury in man;

(b) influencing, inhibiting or modifying a physiological process in man;

(c) testing the susceptibility of man to a disease or ailment; or

(d) destroying or inhibiting micro-organisms that may be harmful to man.

"**Medical content**" means that portion of promotional material which makes a medical claim.

"**Medical representative**" means a person expressly employed by a company whose main purpose is the promoting of the company's products to healthcare professionals.

"**Member**" means any person, firm or company holding Ordinary or Associate membership of the Australian Pharmaceutical Manufacturers Association Inc., as defined in the Rules of the Association.

"**Minor breach**" is a breach of this Code that has no safety implications to the patient's wellbeing and will have no major effect on how the medical profession will prescribe the product.

"**Moderate Breach**" is a breach of this Code that has no safety implications to the patient's wellbeing but may have an effect on how the medical professional will prescribe the product.

"**New chemical entity**" means a product containing an active substance which has not been previously included in a product approved for registration in Australia for human use, including new combinations, salts or esters of previously marketed substances.

"**New indication(s)**" means an additional indication for the drug which was approved by the Department of Health and Aged Care after the original registration of the drug.

"**P.B.S. availability**" means the availability of a product on the Pharmaceutical Benefits Scheme of the Commonwealth Government.

"**P.B.S. Dispensed Price**" is the current dispensed Price for Maximum Quantity for a product found in the Schedule of Pharmaceutical Benefits.

"**Post-marketing surveillance studies**" means research intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the approved Product Information.

"**duct**" means any compound and/or delivery method that is approved for registration by the Department of Health and Aged Care for human therapeutic use, PROVIDED THAT such compound has been scheduled for sale or distribution by prescription only in at least one of the States of Australia or that such compound is primarily promoted to medical practitioners for the purpose of encouraging them to prescribe or recommend usage of that compound.

"**Product familiarisation programme**" means a programme run by the company with the aim of allowing the medical profession to evaluate and become familiar with the product.

"**Product Information**" means the current Australian Approved Product Information. This Product Information must comply with the format specified in the Department of Health and Aged Care' Australian Guidelines for the Registration of Drugs Vol.1 or subsequent revision.

"**Product Manager**" means any person who is directly involved in the generation and development of promotional material. The identification of these individuals is the responsibility of the Association Representative.

"**Promotion**", "**Promotional**" or "**Promotional claim**" means any statement made by a company or company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse reactions or other cautionary aspects of the product and comparative information.

"**Promotional material**" means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.

"**Reference manual**" is a serial or monographic publication designed by its publisher to provide information in classified sequence for the purposes of ready reference to pharmacological or medical data.

"**Registration**" is the issue by the Department of Health and Aged Ca[illegible]f an AUST.R number for a product approved for marketing in Australia in accordance with the Therapeutic Goods Act and Regulations.

"**Repatriation Pharmaceutical Benefit availability**" means the availability of a product on the Repatriation Pharmaceutical Benefit Scheme of the Commonwealth Government.

"**Repeat of previous breach**" means where the same or similar breach is repeated in the promotion of a particular product of a company which had been found in breach in the preceding 24 months.

"**Rules**" means the Rules of the Association for the time being in force. See Appendix 2.

"**Satellite Meetings**" are meetings held in conjunction with international or Australasian congresses and are under the auspices of the Society/College in question.

"**Severe breach**" is a breach of this Code that will have safety implications to the patient's wellbeing and/or will have a major effect on how the medical profession will prescribe the product.

"**Starter pack**" means a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as "samples" by healthcare professionals.

"**Substantiation**" means to give reasonable grounds in support of a promotional claim. Substantiating information should conform with the requirements of Section 1.3, and must not rely solely on data on file.

"**Symposia**" means a scientific meeting sponsored by a Member as an independent event or as a satellite to a congress.

"**Technical breach**" means a breach of this Code that refers to the type size that is specified in this Code.

"**Therapeutic class**" means the classification system used for defining and grouping products in an approved reference manual.

"**rapeutic class number**" means the system of notation used in an approved reference manual.

"**Trade display**" means a display or exhibit of promotional or educational material about a product or products.

"**Trade pack**" means a package of a product which is sold by the Member.

"**Type size**" means the height of a lower case letter "o".

"**Unique**" means being the first, different from all others and the only one of its class on the Australian market.

Enclosure
2

Code of Conduct Annual Report 2000

Australian Pharmaceutical Manufacturers Association Inc.

APMA

Introduction

Welcome to the Australian Pharmaceutical Manufacturers Association (APMA) Code of Conduct Annual Report for the year ending 30 June 2000.

This report provides information regarding the activities of the APMA's Code of Conduct and Monitoring Committees for the period 1 July 1999 to 30 June 2000.

APMA anticipates that the material covered in this report provides a valuable insight into the operations of its Code of Conduct and the Committees that administer it.

Content

During the reporting period, Edition 13 of the Code of Conduct was adopted.

Edition 13 requires APMA to report on all complaints received by the Secretariat during the year. As this amendment became effective on 1 January 2000, this report is divided into two sections.

The first section includes only those complaints found in breach of the Code of Conduct between the period 1 July 1999 to 30 December 1999. The second section includes all complaints received by the APMA during the period 1 January 2000 to 30 June 2000.

At the end of this report, the text of the Sections of the Code of Conduct referred to in this report can be found.

This report has been prepared from the minutes of the meetings of the Code of Conduct Committee, Code of Conduct Appeals Committee and Monitoring Committee, and reflects the process of those meetings. It should not be assumed that external audiences would enjoy the industry's familiarisation or understanding of these processes or the provisions of the Code of Conduct. It is therefore required that this Annual Report be kept confidential within the healthcare industry and not provided to any external audiences.

Any questions from outside the industry should be referred to the Secretary of the Code of Conduct Committee at the APMA Secretariat on (02) 9922 2699. Copies of the APMA Code of Conduct can also be obtained by contacting the APMA Secretariat or by visiting the APMA's website www.apma.com.au.

Activities

In order to improve the Code, research into the effectiveness of the current range of sanctions available to the Code of Conduct Committee was undertaken by the APMA in 1999.

As a result of this research, APMA has proposed amendments to the current range of sanctions available to the Code of Conduct Committee. The research also highlighted the need to review the current appeals process and hence revisions to the current composition of the Code of Conduct Appeals Committee and the appeals mechanism are also proposed. APMA anticipates that amendments to Edition 13 to reflect these revisions will be released in late 2000.

The success of both the Code of Conduct and Monitoring Committees can be attributed to the participation and diligence of their Chairmen and members. APMA would like to thank these individuals for their continued commitment and diligence to the APMA Code of Conduct. In particular the contribution of Mr Gaire Blunt and Mr John Baker as Chairman of the Code of Conduct and Monitoring Committee is acknowledged and greatly appreciated.

Performance indicators

Edition 13 of the Code of Conduct requires the disclosure of certain performance indicators regarding the time to consider complaints and the activities undertaken to increase healthcare professionals' awareness of the Code of Conduct.

Time to consider complaints

The time to consider and finalise the Code of Conduct complaints for the period January to July 2000 ranged from 24 to 102 days. The average number of days taken to finalise all complaints considered during this period was 53. For complaints that did not go to appeal, the average number of days taken to finalise these complaints was 42 days. Delays in the finalisation of complaints during the year include the holding over of a number of complaints to the following monthly Code of Conduct Committee meeting and the sourcing of external experts for the Code of Conduct Appeals Committee meetings.

Activities undertaken to increase healthcare professionals' awareness of the Code of Conduct

During the year, the APMA embarked upon a comprehensive educational and awareness campaign to increase stakeholder awareness of Edition 13 of the Code of Conduct.

The campaign began in February, 2000 with the official launch of Edition 13 of the Code by Parliamentary Secretary to the Minister for Health, Grant Tambling and Consumers' Health Forum Executive Director Matthew Blackmore at Parliament House, Canberra.

APMA wrote to over 200 representatives of medical and healthcare organisations and the Divisions of General Practice announcing the launch of Edition 13 of the Code, offering the opportunity to receive further information on the Code and providing them with a copy of the new Code and the Code of Conduct and Continuing Education Program (CEP) brochure.

Throughout the year, APMA provided presentations, along with Code of Conduct information kits, to external stakeholders including the Royal Australian and New Zealand College of Psychiatrists and the Royal Australasian College of Surgeons.

APMA also held trade displays at both the Australian Medical Association National Conference in May and the National Divisions of General Practice Forum in August, with over 130 delegates seeking a copy of the Code of Conduct. Over 300 Code of Conduct and Continuing Education Program brochures were inserted into delegates satchels at the AMA National conference.

In April 2000, APMA provided 28,000 Code of Conduct and Continuing Education Program brochures to general practitioners through the MIMs bi-monthly booklet.

From the outset of the campaign, APMA published advertorials in national medical and pharmacy trade journals, bulletins and pharmaceutical news to external stakeholders highlighting the Code launch, Code breaches and the APMA's Continuing Education Program Awards where the Outstanding Candidates for the Code of Conduct Module were mentioned.

APMA will continue to increase the awareness of the Code of Conduct amongst healthcare professionals and external stakeholders by providing presentations and informational kits on its Code of Conduct.

Contents

Breaches

From July 1999 to December 1999

1. Merck Sharp & Dohme (Australia) Pty Ltd Zocor (540)

Promotional material entitled:
"PBS Lipid Management Guidelines"

Promotional Letter

Complaint
A complaint was received from Bristol-Myers Squibb Australia Pty Ltd alleging that promotional material by Merck Sharp & Dohme (Australia) Pty Ltd was in breach of Sections 1.3 and 3.5.2 of the Code of Conduct. It was alleged that the promotional material inferred that Zocor was indicated for the treatment of a group of hypercholesterolaemia patients which was not supported by the Approved Product Information. Bristol-Myers Squibb Australia Pty Ltd argued that their product had a unique indication which they alone should only be allowed to promote. In addition, it was alleged that a mailing had not been accompanied by the Approved Product Information.

Response
A response was received from Merck Sharp & Dohme (Australia) Pty Ltd in which any breach of the Code of Conduct had been denied. Merck Sharp & Dohme (Australia) Pty Ltd maintained that the promotional material and letter to prescribing physicians was not misleading and, given PBAC's decision to reimburse all statins at the same level, the promotion of this decision was both accurate and appropriate.

Committee ruling
To consider this complaint appropriately the Committee enlisted the expert advice of two cardiologists and sought comment from the PBAC and TGA. Following a long and detailed discussion, the Committee found no breach of Section 1.3 of the Code of Conduct via the use of the advertisement or letter. A breach of Section 3.5.2 was found for the omission of the Product Information with the promotional letter.

2. Merck Sharp & Dohme (Australia) Pty Ltd Fosamax (541)

Advertisement entitled:
"Fosamax can help you save thousands from going to the chair. Fosamax Stops Fractures Fast"

Complaint
A complaint was received from Roche Products Pty Ltd alleging that an advertisement by Merck Sharp & Dohme (Australia) Pty Ltd was in breach of Sections 1.3, 1.5 and 1.7 of the Code of Conduct. It was alleged that claims regarding fracture reduction rates had been referenced to a single, unrepresentative reference and were misleading. In addition, the claim "Stops Fractures Fast" implied a unique action which could not be substantiated by the body of clinical evidence and inferred an unfair comparison.

Response
A response was received from Merck Sharp & Dohme (Australia) Pty Ltd in which any breach of the Code of Conduct had been denied. Merck Sharp & Dohme (Australia) Pty Ltd maintained that the claims were factual, not comparative and supported by the body of clinical evidence. In addition, Merck Sharp & Dohme (Australia) Pty Ltd maintained that the data supporting the claims were appropriate.

Committee ruling
The Committee ruled that the use of the identified claims in the advertisement by Merck Sharp & Dohme (Australia) Pty Ltd was in breach of Sections 1.3, 1.5 and 1.7 of the Code of Conduct as:

- the making of claims regarding fracture reduction rates on the available data was misleading as insufficient evidence had been presented to support the veracity of such claims
- the claims implied uniqueness and special merit which the body of literature failed to support
- the comparison made in the advertisement was not fair or capable of substantiation

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Merck Sharp & Dohme (Australia) Pty Ltd should take immediate action for the prompt withdrawal of the advertisement found in breach and should permit no further appearance of it in its present form. In addition, the claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Fine
The Committee noted that it was unlikely that the breaches found would result in any patient harm. As it was agreed that these breaches could be considered as moderate breaches, as defined by the Code of Conduct, it was resolved that a fine of $7,500 should be imposed.

Appeal
Merck Sharp & Dohme (Australia) Pty Ltd lodged an appeal against the findings and sanctions imposed by the Code of Conduct Committee. Merck Sharp & Dohme (Australia) Pty Ltd maintained that the references used in support of the claims made were appropriate and a reliable source of data. In addition, it was maintained that there was no claim that Fosamax stops fractures fastest, and therefore the claim was not comparative, rather it referred to the efficacy of Fosamax which was supported by the body of clinical evidence.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that the data and studies used in support of the claim of fracture rates were sufficient and consistent with the body of evidence and was therefore not in breach of Section 1.3 of the Code.

The Committee also agreed that the finding of a breach of Section 1.5 relating to the claim "Stops Fractures Fast" should be overturned as this statement, when used in this context, could be both supported by satisfactory evidence and would be understood by general practitioners.

The Committee were concerned that the layout of the advertisement created an implied comparison with other products and agreed that no evidence had been provided to overturn the finding that the comparison was not fair, could not be substantiated and was misleading.

The Committee then discussed the sanction imposed by the Code of Conduct Committee in light of its decision regarding the appeal. It was agreed that the breach of Section 1.7 should be considered a moderate breach. The Committee considered that it was appropriate to impose a fine for a breach of this nature and it was unanimously agreed that a fine of $5,000 was appropriate in addition to the requirement to withdraw this material.

Summary of results

1 July 1999 - 30 June 2000

APMA received a total of 44 complaints for evaluation by the Code of Conduct Committee during the 12 months from 1 July 1999 to 30 June 2000.

Of the 44 complaints received, six were withdrawn prior to review by the Committee, one complaint was referred to the Australian Self-Medication Industry (formerly the Proprietary Medicines Association of Australia), and three were returned due to the failure of companies to undertake intercompany dialogue.

The complaints received were from Government (1), members of the APMA (32), and external parties (11) including 10 complaints from healthcare professionals.

Of the complaints evaluated by the Committee, six were found not to be in breach of the Code of Conduct while 28 were found in breach.

The Code of Conduct Appeals Committee met 10 times during this period. On one occasion the findings of the Code of Conduct Committee were confirmed. On nine occasions the Committee agreed to partly uphold the appeal and on one occasion the appeal was upheld in its entirety.

The Code of Conduct Committee met 13 times during this period. The following list indicates the attendance of the external members of the Committee:

Therapeutic Goods Administration	13
Consumers' Health Forum	12
Arthritis Foundation of Australia	11
Australian Society of Clinical and Experimental Pharmacologists and Toxicologists	9
Royal Australian College of General Practitioners	9
Australian Medical Association	6

Full Members

Independent Lawyer (Chair)

Representative of the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

Representative of the Royal Australian College of General Practitioners

Representative of a Patient Support Group

Representative of the Australian Medical Association

Representative of a Consumers' Organisation

Up to three APMA Association Representatives

Up to two Medical/Scientific Directors from APMA member companies

Observers

Representative of the Therapeutic Goods Administration

Member of APMA's Marketing Committee

Advisers

Chief Executive Officer, APMA

Manager, Scientific and Technical Affairs, APMA

Code of Conduct Secretary, APMA

Code of Conduct Appeals Committee

Full Members

Independent Lawyer (Chair)

Two Representatives from the Colleges and/or Societies from the therapeutic class of the product

One APMA Association Representative

One APMA Medical/Scientific Director

Advisers

Chief Executive Officer, APMA

Code of Conduct Secretary, APMA

Breaches

From July 1999 to December 1999 continued

5. Glaxo Wellcome Australia Ltd Relenza (544)

Print advertisement entitled:
"You're more likely to go to bed with the one on the right. Your doctor can now treat influenza, consult immediately it hits."

Complaint
A complaint was received from the South Australian Department of Human Services alleging that activities undertaken by Glaxo Wellcome Australia Ltd were in breach of Sections 1.4, 1.10, 9.4, 9.5.4 and 9.5.7 of the Code of Conduct. It was alleged that an advertisement placed in the lay media was promotional, designed to encourage patients to seek a prescription for a prescription only product and raised unfounded hopes of successful treatment. In addition, it was alleged that the advertisement did not satisfy requirements for educational material and was in bad taste.

Response
A response was received from Glaxo Wellcome Australia Ltd in which any breach of the Code of Conduct had been denied. Glaxo Wellcome Australia Ltd maintained that the advertisement was not promotional and did not mention a product or references, images or product attributes that could create an association between the advertisement and a specific product. In addition, it was maintained that no convincing evidence had been provided to support the argument that the advertisement was in bad taste.

Committee ruling
The Committee found no breach of Section 9.4 of the Code of Conduct as no product name was mentioned, there were a number of options available for the treatment of influenza and hence the advertisement could not be considered as encouraging patients to seek a prescription for a specific prescription product.

The Committee did however resolve that the campaign undertaken by Glaxo Wellcome Australia Ltd was in breach of Sections 9.5.4 and 9.5.7 of the Code of Conduct as:

- the advertisement failed to include the name and city of the registered office of the supplier
- the advertisement was unbalanced and had the potential to give the reader the impression that the symptoms of influenza could be removed

The Committee found no breach of Section 1.4 of the Code as there was a majority of members of the Committee who considered the material was not in bad taste.

In relation to the alleged breach of Section 1.10 of the Code, the Committee ruled that the appearance of the material was such that it could clearly be identified as an advertisement so that no breach of Section 1.10 of the Code should be found.

Sanction
Having found breaches of the Code of Conduct the Committee resolved that Glaxo Wellcome Australia Ltd should take immediate action for the prompt withdrawal of the advertisement found in breach and should permit no further appearance of it in its present form. In addition, if the advertisement was to be used again, the comments of the Committee should be taken into consideration so that any future advertisement did not convey the same or similar messages that had been found to be in breach of the Code of Conduct.

Appeal
Glaxo Wellcome Australia Ltd lodged an appeal against the findings of a breach of Section 9.5.7 imposed by the Code of Conduct Committee. Glaxo Wellcome Australia Ltd maintained that the advertisement did not raise unfounded hopes of successful treatment and patients would not expect a "magical" cure to the symptoms of influenza.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to uphold the appeal by Glaxo Wellcome Australia Ltd and accepted that the advertisement was balanced and did not give the impression that the majority of symptoms of influenza could be removed.

The Code of Conduct Appeals Committee resolved that the sanctions imposed in relation to the finding of a breach of Section 9.5.7 by the Code of Conduct Committee should be removed.

6. Bristol-Myers Squibb Australia Pty Ltd Serzone (547)

Brochure entitled:
"Depression Awareness Journal Issue 8, August 1999"

Editorial entitled:
"Depression, anxiety and sleep"

Article entitled:
"Serzone Broadening horizons in antidepressant therapy."

Complaint
A complaint was received from a medical practitioner alleging that an editorial and article in which it had not been acknowledged as having been sponsored by Bristol-Myers Squibb Australia Pty Ltd, was deceptive and would breach the Code of Conduct.

Response
A response was received from Bristol-Myers Squibb Australia Pty Ltd in which any breach of the Code of Conduct had been denied. Bristol-Myers Squibb Australia Pty Ltd maintained that although the journal was supported by it, the article about Serzone had been written by an independent medical writer and therefore was not an advertisement for the product. In addition, it was maintained that the journal was not promotional material, rather a vehicle for expressing facts and opinions of various authors independent of the sponsoring company. Evidence was also provided that confirmed that the editorial had been the views of the brochure's editor and not that of Bristol-Myers Squibb Australia Pty Ltd.

Committee ruling
The Committee ruled that the article should be considered as a Company Commissioned Article sponsored by Bristol-Myers Squibb Australia Pty Ltd. Breaches of Sections 3.1.4.1, 3.1.4.2, 3.1.4.3 and 1.10 of the Code of Conduct were found as:

- the article had neither been identified as a Company Commissioned Article nor had the company responsible for its insertion been identified
- Bristol-Myers Squibb Australia Pty Ltd had failed to include any statement regarding the total sponsorship of the journal
- the promotional material was not clearly distinguishable as such

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3. Roche Products Pty Ltd Rocaltrol (542)

Advertisement entitled:
"Will your osteoporosis treatment still be effective in Y2K? Yes. If your patients are still taking it."

Complaint
A complaint was received from Merck Sharp & Dohme (Australia) Pty Ltd alleging that an advertisement by Roche Products Pty Ltd was in breach of Sections 1.3 and 1.7 of the Code of Conduct. It was alleged that comparative claims regarding patient compliance with other osteoporosis treatments were disparaging. In addition, it was alleged that the claims made were insufficiently supported by the references cited and did not conform to the body of clinical evidence.

Response
A response was received from Roche Products Pty Ltd in which any breach of the Code of Conduct had been denied. Roche Products Pty Ltd maintained that the claims made were accurate, fully supported by the clinical evidence and body of literature. In addition, Roche Products Pty Ltd believed that the practical evidence regarding dosage and administration were important and determined long-term compliance and hence efficacy in the clinical setting.

Committee ruling
The Committee ruled that the use of comparative claims in the advertisement by Roche Products Pty Ltd was in breach of Sections 1.3 and 1.7 of the Code of Conduct as the claims made were not based on sufficiently similar evidence to support their use and had been unfair and disparaging.

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Roche Products Pty Ltd should take immediate action for the prompt withdrawal of the advertisement found in breach and should permit no further appearance of it in its present form. In addition, the claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Fine
The Committee noted that it was unlikely that the breaches found would result in any patient harm. As it was agreed that these breaches could be considered as moderate breaches, as defined by the Code of Conduct, it was resolved that a fine of $7,500 should be imposed.

4. Bristol-Myers Squibb Australia Pty Ltd Pravachol (543)

Tabbed card entitled:
"Unique Indication, Average Cholesterol Levels Post MI. A positively different range of indication and reimbursement for heart attack survivors."

Adhesive sheet entitled:
"Qualifying criteria for lipid-lowering drugs."

Complaint
A complaint was received from Parke Davis Pty Ltd alleging that a tabbed card and an adhesive sheet used by Bristol-Myers Squibb Australia Pty Ltd were in breach of Sections 1.3 and 1.5 of the Code of Conduct. It was alleged that the promotional material inferred a unique range of indications and reimbursements that was contrary to a decision of a previous Code of Conduct Committee complaint (Zocor (540)). It was also alleged that the use of the term "unique indication" was a hanging comparator and a breach of Section 1.5.

Response
A response was received from Bristol-Myers Squibb Australia Pty Ltd in which any breach of the Code of Conduct had been denied. Bristol-Myers Squibb Australia Pty Ltd maintained that Pravachol had been granted a unique indication which is not available to, and cannot be claimed by, any other product. In addition, it was maintained that the listing of the statin drugs in the material, when taken into consideration with the current Product Information, was accurate and not in breach of the Code.

Committee ruling
The Committee agreed that, although Pravachol may have been granted a different and additional specific approved indication, it could not be described as a "different range of indication and reimbursement for heart attack survivors". By a majority decision the Committee ruled that the claims made by Bristol-Myers Squibb Australia Pty Ltd were in breach of Sections 1.3 and 1.5 of the Code of Conduct as:

- the inference of a "unique indication" was incorrect and did not preclude other statins being prescribed for the treatment of hypercholesterolaemia measured by cholesterol levels of greater than 4.0mmol/L and with a history of myocardial infarction
- the range of indication and reimbursement was applicable to all statins, as decided by the PBAC

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Bristol-Myers Squibb Australia Pty Ltd should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its present form. In addition, the claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Appeal
Bristol-Myers Squibb Australia Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Bristol-Myers Squibb Australia Pty Ltd maintained that the claims regarding a unique indication and a unique subsidisation for Pravachol were accurate and supported, as no other statin had received an indication or PBS subsidisation for the treatment of patients with previous myocardial infarction and normal cholesterol levels.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that Pravachol had been given a unique indication in terms of its legal definition and that understood by the industry. The finding of a breach of Section 1.5 was overturned.

The Code of Conduct Appeals Committee agreed that no evidence had been provided to overturn the finding that the claims of a unique reimbursement and that other statins have no right to a subsidy in similar circumstances was misleading.

The Code of Conduct Appeals Committee agreed that the sanction imposed by the Code of Conduct Committee was appropriate and should not be amended.

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Response
A response was received from Novo Nordisk Pharmaceuticals Pty Ltd denying any breach of the Code of Conduct and advising that the promotional material in question had been withdrawn for use. Novo Nordisk Pharmaceuticals Pty Ltd acknowledged the error in the graph, although maintained that the location of the Kliogest logo was not intended to be read as promoting Kliogest for an unapproved indication of reduction in mortality. In addition, Novo Nordisk Pharmaceuticals Pty Ltd maintained that the images of products used were real size and had not been enlarged.

At the time of this complaint Novo Nordisk Pharmaceuticals Pty Ltd was not a member of the APMA.

Committee ruling
The Committee ruled that the use of promotional material used by Novo Nordisk Pharmaceuticals Pty Ltd was in breach of Sections 1.1, 1.3 and 1.3.1 of the Code of Conduct as:

- information in graphs regarding study results was incorrect and misleading
- the inclusion of mortality data promoting an unapproved indication was false and not supported by the body of clinical evidence

No breach of Section 1.1 or 1.3.1 was found regarding the location of the reference to a reduction in mortality by HRT and the position of the Kliogest logo nor was a breach of Section 1.7 found regarding the images of the products in the material.

Sanction
The Committee resolved that Novo Nordisk Pharmaceuticals Pty Ltd should permit no further appearance of this material in its present form. In addition, the claims and graphs found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning

Fine
It was agreed that the breaches found could be considered as moderate breaches, as defined by the Code of Conduct, and a fine of $5,000 was imposed.

10. Merck Sharp & Dohme (Australia) Pty Ltd Fosamax (553)

Promotional material entitled:
"Fosamax can help you save thousands from going to the chair. Fosamax stops fractures fast."

Complaint
Three letters of complaint were received from Roche Products Pty Ltd alleging that Merck Sharp & Dohme (Australia) Pty Ltd had failed to comply with the Code of Conduct Committee's direction to withdraw advertisements for Fosamax which had been found in breach of the Code of Conduct. This activity was alleged to be in breach of Section 11.3 of the Code as it had resulted in a repeat of a previous breach.

Response
A response was received from Merck Sharp & Dohme (Australia) Pty Ltd describing the actions taken by it following the finding of a breach of the Code of Conduct pursuant to complaint Fosamax (541). Merck Sharp & Dohme (Australia) Pty Ltd maintained that all publications of the advertisement which had not passed their cancellation deadline had been withdrawn. However, it was noted that as relevant staff had been absent from the office, Merck Sharp & Dohme (Australia) Pty Ltd had been unable to cancel the appearance of some advertisements previously found in breach.

Committee ruling
The Committee ruled that the behaviour of Merck Sharp & Dohme (Australia) Pty Ltd in failing to prevent the continued use of material was in breach of Sections 11.3 and 12.1.1 and a repeat of a previous breach of the Code of Conduct as:

- the requirement to complete the action to withdraw the advertisements found in breach within five working days had not been complied with
- the Committee considered that Merck Sharp & Dohme (Australia) Pty Ltd had the ability to withdraw the relevant advertisements or replace them with other advertisements
- the absence of relevant staff should not have delayed the appearance of the advertisements previously found in breach.

Sanction
The Code of Conduct Committee resolved that a fine of $10,000 should be imposed for the repeat of a previous breach found.

11. Sanofi-Synthelabo Australia Pty Limited Plavix (555)

Promotional material & Dear Doctor letter entitled:
"Introducing Plavix. Prevents significantly more ischaemic events than aspirin"

Complaint
A complaint was received from Boehringer Ingelheim Pty Ltd alleging that the use of several claims and graphs in promotional material by Sanofi-Synthelabo Australia Pty Limited was in breach of Section 1.3 of the Code of Conduct. It was alleged that claims made regarding reduction in ischaemic events (myocardial infarctions, ischaemic stroke and vascular death) inferred that Plavix significantly reduces the risk in each of these categories, which was considered misleading. In addition, it was alleged that data from two separate studies had been combined to imply Plavix's superiority to aspirin, which could not be supported, and results from graphs had been extrapolated to imply that Plavix provided significant risk reduction benefits over aspirin that were incorrect and misleading.

Response
A response was received from Sanofi-Synthelabo Australia Pty Limited in which any breach of the Code of Conduct had been denied. Sanofi-Synthelabo Australia Pty Limited maintained that the promotional material consistently referred to the composite endpoint of myocardial infarction, ischaemic stroke and vascular death as reported in the study rather than individual endpoints. In addition, it was maintained that it was appropriate to combine the results of two studies and that the claims regarding Plavix's risk reduction rate over aspirin had been supported by an accurate clinical reference.

Committee ruling
The Committee ruled that the use of claims and graphs in the promotional material by Sanofi-Synthelabo Australia Pty Limited was in breach of Section 1.3 of the Code of Conduct as:

- claims made regarding reduction in ischaemic events had not disclosed nor clarified the cluster or composite

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Sanction
Having found breaches of the Code of Conduct, the Committee discussed an appropriate sanction. It was resolved that the breaches found could be described as "moderate", as defined by the Code of Conduct. The Committee was particularly concerned regarding the non-disclosure of the support given to the journal by Bristol-Myers Squibb Australia Pty Ltd and the way in which the Company Commissioned Article had breached the provisions of the Code. The Committee resolved that a fine of $5,000 should be imposed for the breaches found.

7. Mundipharma Pty Limited OxyContin (549)

Promotional material entitled:
"Steve is a prisoner to lower back pain. He is also a prisoner to the drugs he takes – six doses through the day – and through the night. Five years ago, Steve lost his job when he took time off because of the pain. He hasn't worked since – forced into early retirement. He has tried surgery, physical therapy, acupuncture and even spiritual healers. If only his doctor knew about OxyContin tablets."

Complaint
A complaint was received from a medical practitioner alleging that the use of promotional material by Mundipharma Pty Limited was in breach of Sections 1.3 and 1.4 of the Code of Conduct, as representations of the person in the material as a "prisoner" to back pain were in bad taste. In addition, it was alleged that claims made regarding the use of opioids for first line therapy in chronic pain management were incorrect and misleading.

Response
A response was received from Mundipharma Pty Limited in which any breach of the Code of Conduct had been denied. Mundipharma Pty Limited maintained that OxyContin had been approved by the Therapeutic Goods Administration for the treatment of chronic severe non-malignant and malignant pain and the context of the recommendation in the material was for patients with chronic severe pain not responding to other treatments. In addition, it was maintained that Mundipharma Pty Limited had no intention of promoting OxyContin as first line therapy.

Committee ruling
The Committee ruled that the use of the identified statements in the promotional material by Mundipharma Pty Limited was in breach of Section 1.3 of the Code of Conduct as:

- statements overstated the attributes of OxyContin and promised more than the product could reasonably be expected to deliver
- the statement "OxyContin is the one to start and stay with" implied that OxyContin is first line therapy, which is contrary to the approved indications for the product and was therefore considered potentially misleading
- statements used in an unqualified manner in the material may encourage excess usage of OxyContin in a non-cancer context and therefore was inappropriate and misleading

No breach of Section 1.4 was found for the use of the images included in the promotional material.

Sanction
The Committee had been advised that Mundipharma Pty Limited had already withdrawn the advertising and promotional material. Having found breaches of the Code of Conduct, the Committee resolved that the material should not be used again in its present form or in a manner that conveys the same or similar meaning.

8. Bristol-Myers Squibb Australia Pty Ltd Pravachol (551)

Tabbed card entitled:
"Unique Indication, Average Cholesterol Levels Post MI, A positively different range of indication and reimbursement for heart attack survivors."

Adhesive sheet entitled:
"Qualifying criteria for lipid-lowering drugs."

Complaint
A complaint was received from Parke Davis Pty Ltd alleging that the use of promotional material by Bristol-Myers Squibb Australia Pty Ltd represented a repeat of previous breaches of Sections 1.3 and 1.5 as defined by the Code of Conduct. This material included claims regarding a unique reimbursement and indication for Pravachol (see Pravachol (543)).

Response
A response was received from Bristol-Myers Squibb Australia Pty Ltd describing the actions taken by it to remove the material from use following the finding of a breach of the Code of Conduct pursuant to complaint Pravachol (543). Bristol-Myers Squibb Australia Pty Ltd maintained that they had taken every effort to ensure the material found in breach had been withdrawn.

Committee ruling
The Committee ruled that the behaviour of Bristol-Myers Squibb Australia Pty Ltd in failing to prevent the continued use of material, which continued to be in breach of Section 1.3 of the Code of Conduct, was a repeat of a previous breach as:

- sufficient time had been available to Bristol-Myers Squibb Australia Pty Ltd to ensure that all of its representatives and employees were advised that the material should be withdrawn
- it could not be accepted that difficulty in communicating with its staff was sufficient to avoid the requirements of the Code of Conduct

Sanction
The Code of Conduct Committee resolved that a fine of $12,500 should be imposed for the finding of a repeat of a previous breach. The Committee recommended that Bristol-Myers Squibb Australia Pty Ltd reassess its communications with its employees to ensure that such a situation did not re-occur.

9. Novo Nordisk Pharmaceuticals Pty Ltd Kliogest (552)

Promotional material entitled:
"Natural HRT for the way she wants to be tomorrow"

Complaint
A complaint was received from Wyeth Australia Pty Limited alleging that the use of promotional material by Novo Nordisk Pharmaceuticals Pty Ltd was in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct. It was alleged a graph containing information regarding study results was incorrect and misleading and the location of a reference to a reduction in mortality by HRT and the position of the Kliogest logo, implied a decrease in mortality with Kliogest. In addition, it was alleged that images of competitor products in the material were misrepresented and therefore disparaging.

Breaches

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had been withdrawn. The content of this letter would be approved by the Chairman of the Code of Conduct Committee.

13. Pfizer Pty Limited Zoloft (560)

Promotional brochure entitled:
"Zoloft...a suitable choice for elderly patients. Zoloft Three problems, One tablet, One solution."

Complaint
A complaint was received from SmithKline Beecham (Australia) Pty Limited alleging that a promotional brochure for Zoloft by Pfizer Pty Limited was in breach of Sections 1.3 and 1.7 of the Code of Conduct as statements made regarding efficacy and safety of SSRI's inferred a positive attribute to Zoloft that was incorrect and disparaging. In addition, it was alleged that claims made regarding psychomotor and anticholinergic effects of a competitor's product were directly misleading and not representative of the body of clinical evidence.

Response
A response was received from Pfizer Pty Limited in which any breach of the Code of Conduct had been denied. Pfizer Pty Limited advised that an agreement had been reached between the two companies to withdraw the material. However, the material had regrettably reappeared since then. In its defence, Pfizer Pty Limited maintained that the claims made in the material were fully supported by the body of clinical evidence.

Committee ruling
The Committee ruled that the use of identified claims in the brochure by Pfizer Pty Limited were in breach of Section 1.7 of the Code of Conduct as:

- clinical relevance had not been established nor supported by acceptable evidence
- claims inferred a positive attribute to Zoloft that was possibly incorrect and therefore represented an unfair comparison
- the claims were unbalanced and presented unfair comparisons to a competitor product

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Pfizer Pty Limited should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of this material in its present form. In addition, the claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning

Fine
In addition, given the implication of benefits that these claims incorrectly inferred, the Committee agreed that they should be considered as a moderate breach. It was agreed that a fine of $10,000 should be imposed.

14. Searle, A Division of Monsanto Australia Limited Lomotil (561)

Promotional advertisement entitled:
"Lomotil", The powerful diarrhoea stopper is now S3"

Complaint
A complaint was received from Janssen-Cilag Pty Ltd alleging that an advertisement for Lomotil by Searle, A Division of Monsanto Australia Limited was in breach of Sections 1.1, 1.3, 1.5 and 1.7 of the Code of Conduct as claims regarding efficacy and Lomotil's superiority over other available treatments were misleading, contrary to the Product Information and the body of clinical evidence. In addition, it was alleged that the claim regarding market share for Lomotil could not be substantiated.

Response
A response was received from Searle, A Division of Monsanto Australia Limited in which any breach of the Code of Conduct had been denied. Searle, A Division of Monsanto Australia Limited maintained that claims regarding efficacy were correct and fully supported by the Product Information. In addition, it was maintained that no comparative efficacy claims had been made nor implied.

Committee ruling
The Committee ruled that the use of the identified claims in the advertisement by Searle, A Division of Monsanto Australia Limited was in breach of Section 1.3 of the Code of Conduct as no evidence had been provided to substantiate market share claims and was therefore considered misleading.

No breach of Sections 1.1, 1.5 and 1.7 were found as the Committee was not convinced that the efficacy claims used could infer the superiority suggested by the complainant or the negative comparisons to other treatments.

Sanctions
Having found a breach of the Code of Conduct, the Committee resolved that Searle, A Division of Monsanto Australia Limited should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of this material in its present form. In addition, the claim found in breach should not be used again in its present form or in a manner that conveys the same or similar meaning.

Corrective advertisement
Given the number of times this advertisement had appeared since 1998 and its current use in November 1999 the Committee considered that it was appropriate that the marketplace be advised of this breach. It was agreed that a corrective advertisement should be placed by Searle, A Division of Monsanto Australia Limited in "Australian Pharmacist" advising of this breach of the Code of Conduct and correcting the false impression regarding market share.

This corrective advertisement should:

- be the same size as the advertisement in the November 1999 "Australian Pharmacist"
- appear once in this journal
- appear in the same or similar location within the journal as the November advertisement
- be entitled "Corrective Advertisement"
- contain a crossed out image of the original advertisement found in breach
- correct the false impression possibly gained from the original advertisement regarding market share
- be approved before publication by the Chairman of the Code of Conduct Committee

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nature of the reported benefits and hence were unbalanced and misleading

- the claims could mislead the reader into considering that Plavix significantly reduces the risk in each of the clinical categories
- the combination of results from two different trials with different protocols and inclusion criteria was inappropriate and led to a result which may not reflect the overall risk reduction
- the statement used to portray claims of relative risk reduction in Plavix over aspirin were not supported by the Product Information, were misleading and had been used without the support of clinical data

Sanction
The Committee resolved that Sanofi-Synthelabo Australia Pty Limited should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of this material in its present form. In addition, the claims and graphs found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Corrective letter
Given the Committee's concerns regarding the number of breaches found in the promotional material and the possibility that readers may be misled, the Committee resolved that a corrective letter should be sent to all recipients of the promotional material found in breach. The content of this corrective letter, which would be approved by the Chairman of the Committee, should identify the breaches found and correct any misleading impressions that could have been gained from them.

Appeal
Sanofi-Synthelabo Australia Pty Limited lodged an appeal against the findings and sanctions imposed by the Code of Conduct Committee. Sanofi-Synthelabo Australia Pty Limited maintained that the results of the study used in support of the claims made were both statistically and clinically significant, the comparison of the results of the two studies were appropriate and the promotional material clearly discriminated between the composite outcomes of using Plavix and the outcomes for individual endpoints.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that the results quoted were appropriate and therefore the claim regarding reduction in ischaemic events was not misleading and not in breach of Section 1.3. In relation to the breach regarding not discriminating between "events" and "cluster events", the Committee were not convinced by the arguments presented by Sanofi-Synthelabo Australia Pty Limited that these claims would not mislead.

The Code of Conduct Appeals Committee resolved that the finding of a breach of Section 1.3 relating to the combination of the results of two studies should be overturned as the combination of the two studies was considered appropriate. However, it was agreed that the depiction of these results was in breach of Section 1.3.

In addition, the Code of Conduct Appeals Committee resolved that the finding of a breach of Section 1.3 relating to a statement used to portray claims of relative risk reduction in Plavix over aspirin should be overturned as evidence had been provided to support its use.

The sanction imposed by the Code of Conduct Committee was amended and the requirement for a corrective letter was removed. The requirement to withdraw the material found in breach and the inability to use this material again remained.

12. Novo Nordisk Pharmaceuticals Pty Ltd Kliovance (558)

Product Familiarisation Programme & Market Research Activity

Complaint
A complaint was received from a general practitioner alleging that an invitation to participate in a "research project" for Kliovance by Novo Nordisk Pharmaceuticals Pty Ltd was inappropriate. It was alleged that the payment offered for the completion of the work was excessive and inappropriate.

Response
A response was received from Novo Nordisk Pharmaceuticals Pty Ltd in which any breach of the Code of Conduct had been denied. Novo Nordisk Pharmaceuticals Pty Ltd maintained that only those doctors that had expressed an interest in participating in the programme were provided with the questionnaire and the payment had not been offered as an inducement to prescribe, rather as compensation for the completion of activities. In addition, Novo Nordisk Pharmaceuticals Pty Ltd apologised for any offence that might be taken by their programme.

At the time of this complaint Novo Nordisk Pharmaceuticals Pty Ltd was not a member of the APMA.

Committee ruling
The Committee agreed that the activity should be considered in two parts, firstly, a Product Familiarisation Programme (PFP) to introduce prescribers to Kliovance and secondly as a Market Research Activity to obtain information from prescribers.

The Committee ruled that the Product Familiarisation Programme was in breach of Sections 8.2.1 and 8.2.4 of the Code of Conduct as:

- offering payment to healthcare professionals participating in PFP's and the provision of three months free supply of Kliovance were not permitted

In addition, the Committee ruled that the Market Research Activity was in breach of Sections 8.3.1 and 8.3.2 of the Code of Conduct as:

- the activity had not been clearly identified as Market Research and the cumulative payment of any amounts, particularly in the case of multiple payments, was considered excessive

Sanction
Having found breaches of the Code of Conduct, the Committee discussed an appropriate sanction. It was noted by the Committee that a letter had been sent to prescribers advising that "Recruitment has now concluded". The Committee considered that this communication did not sufficiently clarify that such an activity was inappropriate and in breach of the Code of Conduct. It was therefore resolved that in addition to the immediate cessation of this activity in its current form, Novo Nordisk Pharmaceuticals Pty Ltd should be required to write to all prescribers who may have been exposed to this activity advising them that it had been found in breach of the Code of Conduct and

Breaches

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- graphs and figures used inferred the possibility of chronic treatment with Clexane which was contrary to the Approved Product Information
- insufficient responsibility had been shown in ensuring evidence was available that could support claims of chronic treatment with Clexane being made at the time of release
- data contained inaccuracies that were considered false
- graphs and comparative statements could not be supported by statistically significant data or the Product Information and were considered disparaging and misleading
- graphs used relied solely on data on file

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Rhone-Poulenc Rorer Australia Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. The items found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Fine
As it was considered that these breaches could be considered as severe breaches, as defined by the Code of Conduct, it was resolved that a fine of $15,000 should be imposed.

The Committee noted that although Rhone-Poulenc Rorer Australia Pty Ltd had agreed to withdraw this material, it had been appropriate to consider this complaint given the number and significance of the breaches found.

17. Alcon Laboratories (Australia) Pty Ltd Betoptic S (566)

Promotional brochure entitled:
"Betoptic S Three views on visual protection. It's time to re-focus Glaucoma is a multi-factorial disease... choose a multi-factorial therapy."

Promotional advertisement entitled:
"Betoptic S – Three views on visual protection."

Complaint
A complaint was received from Pharmacia & Upjohn Pty Limited alleging that a promotional brochure by Alcon Laboratories (Australia) Pty Ltd for Betoptic S was in breach of Sections 1.1 and 1.3 of the Code of Conduct. It was alleged that statements inferring neuroprotective properties for Betoptic S were solely supported by an animal study and implied that Betoptic S exhibited this property which was unqualified, misleading and not supported by the body of clinical evidence or Approved Product Information. In addition, it was alleged that claims regarding pulsatile ocular blood flow were false and misleading.

Response
A response was received from Alcon Laboratories (Australia) Pty Ltd in which any breach of the Code of Conduct had been denied. Alcon Laboratories (Australia) Pty Ltd advised that the material in question had been withdrawn and would not be used again.

Committee ruling
The Committee ruled that the use of the identified graphs and claims in the material by Alcon Laboratories (Australia) Pty Ltd were in breach of Sections 1.1 and 1.3 of the Code of Conduct as:

- statements and graphs gave an incorrect impression regarding Betoptic S and could not be supported by available evidence or the Approved Product Information
- the supporting data was either pre-clinical or from limited clinical evidence and considered inadequate
- claims made had solely relied upon the Product Information which was considered inappropriate
- the statements used could infer an incorrect interpretation of the benefits of Betoptic S and could not be supported by the evidence provided

Sanction
The Committee resolved that Alcon Laboratories (Australia) Pty Ltd should take immediate action to ensure that all material containing these claims was withdrawn and that no further appearance of it in its present form should be permitted. The claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Corrective advertisement & letter
In addition, as the Committee resolved that the promotional campaign inferred that the use of Betoptic S would result in better outcomes which could not be supported, it was requested that a corrective advertisement be placed once in the same journals in which the claims found in breach had been published. The content of this advertisement would be approved by the Chairman of the Code of Conduct Committee. In addition, it was agreed that a corrective letter, the content of which would be approved by the Chairman, should be sent to all specialists who may have been provided with this material.

Appeal
Alcon Laboratories (Australia) Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Alcon Laboratories (Australia) Pty Ltd maintained that the claims and statements made were factual and could be supported by appropriate clinical findings. In addition, it was maintained that the promotional items met the requirements of the Code about use of animal or laboratory data.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that sufficient evidence had been provided to support the claims made regarding the effect of Betoptic S on pulsatile ocular blood flow. The decision to find a breach of Sections 1.1 and 1.3 was overturned.

The Code of Conduct Appeals Committee agreed that no evidence had been provided to overturn the finding that statements and graphs relating to neuroprotective properties had the capacity for readers to be misled and therefore a breach of Section 1.3 of the Code should remain.

The Committee also agreed that the decision of the Code of Conduct Committee to rely upon the Product Information to support claims was appropriate and resolved that the breach of Section 1.1 of the Code should remain.

The sanction imposed by the Code of Conduct Committee was amended and the requirement for a corrective advertisement

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15. Novartis Pharmaceuticals Australia Pty Limited Lamisil (562)

Promotional mailer entitled:
"Only one person can change this to this. You !"

Complaint
A complaint was received from a general practitioner alleging that a campaign by Novartis Pharmaceuticals Australia Pty Limited for their product Lamisil was inappropriate, as claims of onychomycosis being a "highly contagious disease" were incorrect. In addition, as doctors were invited to be included on a list to treat patients, it was considered that the competitive nature of general practice may encourage prescribers to rely positively on the campaign and encourage them not to prescribe in accord with the PBS guidelines for this product.

Response
A response was received from Novartis Pharmaceuticals Australia Pty Limited in which any breach of the Code of Conduct had been denied. Novartis Pharmaceuticals Australia Pty Limited maintained that onychomycosis is a highly contagious condition and this claim was supported by the body of evidence. In addition, it was maintained that doctors who chose to be included on the list compiled as a service to patients who did not have a general practitioner, were under no obligation to prescribe Lamisil. Furthermore, Novartis Pharmaceuticals Australia Pty Limited considered that the campaign was ethical and had sought approval of it from various external organisations including the Medical Board of NSW, the AMA and the APMA.

Committee ruling
The Committee ruled that the claim identified in the awareness campaign by Novartis Pharmaceuticals Australia Pty Limited was in breach of Section 1.3 of the Code of Conduct as insufficient evidence had been provided to substantiate claims of a "highly contagious" nature of onychomycosis and it was therefore considered misleading.

The Committee considered the ethics of the campaign and resolved that the activity was in breach of Section 10 of the Code of Conduct as it was inappropriate to supply the names of practitioners to patients based upon this campaign, hence the activity did not conform to professional standards of ethics.

The Committee could not agree that the campaign had the intent of encouraging doctors to prescribe Lamisil outside of PBS guidelines, hence no breach of the Code of Conduct was found in relation to this claim.

Sanction
Having found breaches of the Code of Conduct the Committee resolved that Novartis Pharmaceuticals Australia Pty Limited should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its present form. The claim found in breach should not be used again in its present form or in a manner that conveys the same or similar meaning.

Appeal
Novartis Pharmaceuticals Australia Pty Limited lodged an appeal against the findings imposed by the Code of Conduct Committee maintaining that the matter before the Committee was not the promotion of Lamisil, rather a disease awareness campaign relating to the disease onychomycosis. It was considered that as there was no promotion of a product as defined by the Code, it should not be the subject of a Code of Conduct complaint.

Novartis Pharmaceuticals Australia Pty Limited responded to the issues raised by the Code of Conduct Committee, maintaining that the claim of "highly contagious" could be supported and was accurate. Furthermore, the scientific content of the campaign had been approved by a member of the Scientific Advisory Committee of the Australasian College of Dermatologists. In addition, it was maintained that the campaign was of the highest ethical standard and did not constitute any improper behaviour, as all relevant regulatory bodies, including the AMA, were consulted openly during the development of the disease awareness campaign and none of these bodies raised any concern.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that as the claim of "highly contagious" was not product related it did not fall within the definition of "promotion" or Section 1.3 of the Code. The finding of a breach of Section 1.3 was overturned.

The Committee resolved to uphold the decision of the Code of Conduct Committee relating to the ethics of the campaign as no evidence had been provided to justify overturning its decision. The sanction imposed by the Code of Conduct Committee was considered appropriate and required no amendment.

16. Rhone-Poulenc Rorer Australia Pty Ltd Clexane (563)

Promotional brochure entitled:
"Should Clexane Become The Standard of Care in Acute Coronary Syndromes ?"

Complaint
A complaint was received from Pharmacia & Upjohn Pty Limited alleging that a promotional brochure by Rhone-Poulenc Rorer Australia Pty Ltd for Clexane was in breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code of Conduct. It was alleged a number of graphs and claims were misleading, inaccurate and not supported by the Approved Product Information and statements made inferred superiority of Clexane over other products which was considered incorrect and disparaging. In addition, graphs inferred the promotion of Clexane for an indication which was contrary to that of the Approved Product Information.

Response
A response was received from Rhone-Poulenc Rorer Australia Pty Ltd in which any breach of the Code of Conduct had been denied. Rhone-Poulenc Rorer Australia Pty Ltd maintained that the use of the promotional brochure had ceased prior to the submission of the complaint and they had also acknowledged that some minor amendments needed to be made in the interests of clarity. In addition, it was maintained that the material was accurate and fully supported by the body of clinical evidence.

Committee ruling
The Committee ruled that the use of the graphs and claims identified in the material by Rhone-Poulenc Rorer Australia Pty Ltd was in breach of Sections 1.1, 1.2, 1.3, 1.3.1 and 1.7 of the Code of Conduct as:

- the claims were inaccurate and inferred superiority over other products that could not be supported, hence were considered misleading and disparaging

Results

From January 2000 to June 2000

20. AstraZeneca Pty Ltd Losec (569)

Tele-marketing Activity

Complaint
A complaint was received from a general practitioner alleging that contact by a telemarketing company appointed by AstraZeneca Pty Ltd to advise of a change to the availability of Losec was inappropriate.

Response
A response was received from AstraZeneca Pty Ltd in which any breach of the Code of Conduct had been denied. AstraZeneca Pty Ltd maintained that they had employed a teleservices company to contact medical practitioners to inform them that Losec capsules were to be removed from the PBS. The intent of the exercise had not been promotional, but rather to warn doctors of the potential risk of writing a prescription that could not be filled.

Committee ruling
In order to give the matter full consideration, the Committee obtained the script used by the telemarketing company and the instructions given to it by AstraZeneca Pty Ltd to determine whether the activity was promotional or informational as defined by the Code of Conduct.

The Committee considered this complaint by examining Sections 4.7 and 10 of the Code and it was agreed that, given the wide definition of medical representative, it was possible to include the company appointed by AstraZeneca Pty Ltd in this definition if it could be determined that its purpose was promotional.

The Committee ruled that the statements made by the telemarketing company were not promotional but informational, and therefore no breach of Section 4.7 was found. Given that market research had been undertaken by AstraZeneca Pty Ltd indicating that knowledge regarding the unavailability of Losec capsules was not high within medical practitioners, the Committee considered it appropriate for such information be made available to medical practitioners.

The Committee discussed the use of telemarketing companies by APMA members and referred to Section 10 of the Code to determine whether this activity fell within this provision. It was agreed that Section 10 of the Code did not encompass this type of activity and therefore no breach had occurred.

However, the Committee suggested that guidelines be developed that reflected the need that, where such activities were to be undertaken, they should not cause any inconvenience or concern to the medical practitioner. Since this decision, APMA has developed provisions to reflect such behaviour which will be included in the latest edition of the Code.

21. Pharmacia & Upjohn Pty Limited Fragmin (570)

Promotional brochure entitled:
"Graduate towards optimal patient care in unstable coronary artery disease".

Complaint
A complaint was received from Rhone-Poulenc Rorer Australia Pty Ltd alleging that a promotional brochure for Fragmin by Pharmacia & Upjohn Pty Limited was in breach of Sections 1.1, 1.2, 1.3, 1.5, 1.7 and 2 of the Code of Conduct. It was alleged the material contained a number of errors, statements that inferred that Fragmin is the optimal care in unstable angina which could not be supported by the body of clinical evidence and was disparaging to competitor products. In addition, it was alleged that Pharmacia & Upjohn Pty Limited had repeatedly used Product Information which omitted the Therapeutic Goods Administration (TGA) required bold warning.

Response
A response was received from Pharmacia & Upjohn Pty Limited in which any breach of the Code of Conduct had been denied. Pharmacia & Upjohn Pty Limited acknowledged that the inclusion of an incorrect graph was an oversight although they maintained that the statements made were accurate, balanced and fully supported by the body of clinical evidence. In addition, it was maintained that the TGA approved warning was included in the Approved Product Information and highlighted with asterisks as required by the APMA Code of Conduct however, the warning had not been bolded and such an oversight would be rectified in subsequent promotional materials.

Committee ruling
The Committee ruled that the use of the identified statements and claims made by Pharmacia & Upjohn Pty Ltd were in breach of Sections 1.1, 1.3, 1.7 of the Code of Conduct as:

- the non-inclusion of statistical significance of the results on a graph was considered misleading and disparaging
- statements regarding the results of studies including competitor products were incorrect, misleading and disparaging

The Committee was not convinced that certain claims complained of could be considered to imply that Fragmin was the optimal care in unstable coronary artery disease and found no breach of Section 1.3, 1.5 or 1.7 of the Code of Conduct.

The Committee also found the alleged breach of Section 1.2 of the Code not made out, given that it was unreasonable to require that a company be aware of all published comment or material regarding a trial.

The Committee resolved that the inclusion of the incorrect Product Information with the promotional material was in breach of Section 2 of the Code of Conduct.

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Pharmacia & Upjohn Pty Limited should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of them in their present form. The statements found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

22. Eli Lilly Australia Pty Ltd Evista (571)

Promotional advertisement entitled:
"Now you can stop wishing. Evista prevents more than fractures"

Complaint
A complaint was received from Schering-Plough Pty Limited alleging that an advertisement for Evista by Eli Lilly Australia Pty Ltd was in breach of Sections 1.3 and 1.3.1 of the Code of Conduct. It was alleged claims of risk reduction in breast cancer were false and misleading and claims of prevention of more than fractures implied additional benefits to Evista that was contrary to the approved indications.

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was removed, although the requirement to send a corrective letter to all specialists who had been exposed to the material remained.

18. Bristol-Myers Squibb Australia Pty Ltd Iscover (567)

Promotional brochures & Product Familiarisation Programme entitled:
"Iscover clean, simple Ischaemic cover. Introducing an important advance for patients at risk of Heart Attack and Ischaemic Stroke."

Monograph entitled:
"Iscover Scientific Monograph"

Complaint
A complaint was received from Boehringer Ingelheim Pty Ltd alleging that promotional material and material used in a Product Familiarisation Programme by Bristol-Myers Squibb Australia Pty Ltd for Iscover was in breach of Section 1.3 of the Code of Conduct. It was alleged that data from two separate studies using different statistical analyses had been used to imply a significant benefit when using Iscover which could not be supported by one of the studies. Graphs had been used that implied that Iscover provided significant risk reduction benefits over aspirin that were incorrect and misleading and claims of efficacy of Iscover over aspirin which was considered to be exaggerated and misleading.

Furthermore, it was alleged that these claims were similar or the same as those found in breach of the Code of Conduct regarding the product Plavix (555).

Response
A response was received from Bristol-Myers Squibb Australia Pty Ltd in which any breach of the Code of Conduct had been denied. Bristol-Myers Squibb Australia Pty Ltd maintained that claims and graphs used were accurate and supported by the current body of clinical evidence. In addition, it was maintained that statements regarding the effectiveness of Iscover over aspirin were valid, supported scientifically and consistent with the Approved Product Information.

Committee ruling
The Committee discussed the combination of data, the use of the relative risk reduction, claims of an additional benefit and the lack of support for such claims in the Product Information. Given the previous decision of the Code of Conduct Appeals Committee relating to a similar complaint against the promotion of Plavix, the Committee considered that they were obliged to follow the decision of that Committee not to find breaches of Section 1.3.

However, the Committee ruled that the use of the identified graphs and claims in the material by Bristol-Myers Squibb Australia Pty Ltd were in breach of Section 1.3 of the Code of Conduct as:

- graphical representations of data were inaccurate and therefore misleading
- the use of claims relating to the efficacy of Iscover over aspirin were without adequate qualification and potentially misleading

Sanction
Having found breaches of the Code of Conduct, the Committee discussed the severity of the breaches and an appropriate sanction. The Committee resolved that Bristol-Myers Squibb Australia Pty Ltd should take immediate action for the prompt withdrawal of the promotional materials found in breach and should permit no further appearance of them in their present form. The statements and presentations found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

19. Galderma Australia Pty Ltd Loceryl (568)

Promotional advertisement entitled:
"Onychomycosis. Paint it Dead"

Promotional mailer entitled:
"STEP ON IT!"

Complaint
A complaint was received from Novartis Pharmaceuticals Australia Pty Limited alleging that a promotional mailer and an advertisement used by Galderma Australia Pty Ltd for Loceryl was in breach of Sections 1.1, 1.3 and 3.1.1.4 of the Code of Conduct. It was alleged claims implied an additional benefit of the product that could mislead a reader by implying that Loceryl's use is simple and convenient which could neither be supported by the Approved Product Information, literature or data on file. In addition, it was alleged that the evidence used to reference the term "cure" was inadequate and misleading and failure to disclose the PBS dispense price in the advertisement did not meet the requirements of the Code.

Response
A response was received from Galderma Australia Pty Ltd in which any breach of the Code of Conduct had been denied. Galderma Australia Pty Ltd maintained that the claims were accurate and fully supported by the Approved Product Information and body of clinical evidence. In addition, it was maintained that Galderma Australia Pty Ltd had not claimed a "cure" rather the term "mycological cure" had been used to clarify the claim. Galderma Australia Pty Ltd advised that the PBS dispensed price would be added to future material.

At the time of this complaint Galderma Australia Pty Ltd was not a member of the APMA.

Committee ruling
The Committee ruled that the use of identified claims in the material by Galderma Australia Pty Ltd was in breach of Sections 1.3 and 3.1.1.5 as:

- the term "cure" had been used without proper clarification and hence was considered unbalanced and misleading
- Galderma Australia Pty Ltd had failed to include the PBS dispensed price in the advertisement

The Committee was not convinced that certain claims complained of could be considered to imply an additional benefit of Loceryl and found no breach of Section 1.1 and 1.3 of the Code of Conduct.

The Committee also found the alleged breaches of Section 1.1 and 1.3 of the Code not made out, given that it was possible to consider the treatment as simple and convenient.

Sanction
Having found breaches of the Code of Conduct the Committee discussed an appropriate sanction. The Committee resolved that Galderma Australia Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of them in their present form. The claim found in breach should not be used again in its present form or in a manner that conveys the same or similar meaning. The omission of the RPBS price should be immediately corrected in future promotional material.

Results

From January 2000 to June 2000 continued

Complaint
A complaint was received from Merck Sharp & Dohme (Australia) Pty Ltd alleging that promotional material for Celebrex by Searle, A Division of Monsanto Australia Limited and Pfizer Pty Limited were in breach of Sections 1.2, 1.3, 1.5 and 1.7 of the Code of Conduct. It was alleged a claim that inferred Celebrex is indicated for arthritis was misleading and inaccurate and the use of the word "safely" without qualification was unbalanced, potentially misleading and contrary to the Approved Product Information. In addition, it was alleged that a number of other claims and statements were inaccurate, misleading and disparaging to competitor products and referenced only to data on file.

Furthermore, it was alleged that the Approved Product Information for Celebrex included a statement inferring attributes of safety which had not been approved by the Therapeutic Goods Administration (TGA).

Response
A response was received from Searle, A Division of Monsanto Australia Limited and Pfizer Pty Limited in which any breach of the Code of Conduct had been denied. The companies maintained that the claim that Celebrex is indicated for arthritis is qualified and fully supported by references and the use of the word "safely" did not imply absolute safety, but rather is appropriately qualified by the word "delivered". In addition, it was maintained that other claims and statements mentioned were consistent with and supported by the Approved Product Information and the body of clinical evidence.

Furthermore, Searle, A Division of Monsanto Australia Limited and Pfizer Pty Limited refuted any breach of the Code of Conduct regarding the inclusion of a promotional statement in the Product Information.

Committee ruling
The Committee ruled that the use of the identified claims and statements by Searle, A Division of Monsanto Australia Limited and Pfizer Pty Limited was in breach of Sections 1.3, 1.2, 1.5 and 2.1.2 of the Code of Conduct as:

- the tagline of "safely delivered" gave a false impression regarding the safety of the product and hence was considered misleading and inadequately qualified
- the combination results from two different studies in the manner presented could be considered misleading
- the use of data on file alone to support claims relating to side effects was inappropriate
- claims made, although sourced to the Product Information, were not clear in terms of comparisons and supporting data and hence could be considered misleading
- the inclusion of a promotional claim within the Product Information was contrary to the requirements of the Code
- statements made were not qualified to state that Celebrex was not indicated for general pain relief

No breach of Section 1.7 of the Code of Conduct was found as the Committee resolved that evidence could be provided that supported the claim "with significantly less risk of adverse GI events".

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Searle, A Division of Monsanto Australia Limited and Pfizer Pty Limited should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of them in their present form. The claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Fine
As it was agreed that these breaches could be considered as moderate breaches, as defined by the Code of Conduct, it was resolved that a fine of $10,000 should be imposed.

Appeal
Searle, A Division of Monsanto Australia Limited and Pfizer Pty Limited lodged an appeal against the findings imposed by the Code of Conduct Committee. It was maintained that combining the data from two different studies is appropriate and justified. In addition, it was maintained that a large body of data supported the statements and claims in question and these data included evaluated data, the Product Information and peer reviewed publications.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that the presentation of the combination of results of the two studies was not misleading nor was in breach of Section 1.3 of the Code. Having reviewed the studies and similarity of results of both the osteoarthritis and rheumatoid arthritis, the Committee agreed that, although it might have benefited from the depiction of osteoarthritis and rheumatoid arthritis results separately, the graph in question did not have the capacity to mislead.

The Code of Conduct Appeals Committee resolved that no evidence had been provided to overturn the finding that the quoting of "data on file" as the sole substantiating information for claims relating to side effects was not in breach of Section 1.2 of the Code of Conduct.

The Committee then discussed the sanction imposed by the Code of Conduct Committee in light of its decision regarding the appeal. It was agreed that the sanction imposed by the Code of Conduct Committee was appropriate and should not be amended.

25. Merck Sharp & Dohme (Australia) Pty Ltd Vioxx (574)

Promotional brochure entitled: *"The World of Relief is About to Change..."*

Complaint
A complaint was received from Searle, A Division of Monsanto Australia Limited alleging that a promotional brochure for Vioxx by Merck Sharp & Dohme (Australia) Pty Ltd was in breach of Sections 1.1, 1.3, and 1.7 of the Code of Conduct. It was alleged that claims extending beyond the terms of the approved indications for Vioxx were misleading and not supported by the Approved Product Information, claims of safety and efficacy were not supported by the body of clinical evidence and failed to disclose reference to cautionary statements regarding interactions. In addition, it was alleged that claims relating to safety information applicable to a competitor product were not applicable to Vioxx and hence considered misleading and disparaging. The misrepresentation of the approved dosing regime for Celebrex was also considered to be misleading.

Response
A response was received from Merck Sharp & Dohme (Australia) Pty Ltd in which any

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Response
A response was received from Eli Lilly Australia Pty Ltd in which any breach of the Code of Conduct had been denied. Eli Lilly Australia Pty Ltd maintained that the claim of reduction of breast cancer was correct and accurate and was not promoted as an indication, rather presented as information to clinicians. In addition, it was maintained that the claim of "prevents more than fractures" was not false nor misleading and was consistent with the Approved Product Information and the body of clinical evidence.

Committee ruling
The Committee ruled that the use of identified claims made by Eli Lilly Australia Pty Ltd were in breach of Section 1.3 of the Code of Conduct as:

- the claim of "prevents more than fractures" could not be supported by the Approved Product Information and incorrectly inferred an unqualified benefit that could not be substantiated satisfactorily
- the claim regarding risk reduction in breast cancer inferred a greater benefit than the evidence supported

The Committee ruled that the inclusion of this statement should not be considered as promoting an unapproved indication and therefore no breach of Section 1.3.1 of the Code was found.

Sanction
Having found breaches of the Code of Conduct, the Committee resolved that Eli Lilly Australia Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. The claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Appeal
Eli Lilly Australia Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Eli Lilly Australia Pty Ltd maintained that the claims of risk reduction in breast cancer were clinically achievable and new data to support this claim had been submitted to the TGA for inclusion in the Evista Product Information. In addition, it was maintained that the claim of "prevents more than fractures" is accurate, supported by the body of clinical evidence and is not misleading.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that the use of the claim regarding risk reduction in breast cancer was appropriate and did not contradict the Product Information. The Committee therefore resolved to overturn the decision to find a breach of Section 1.3 of the Code.

The Committee discussed the claim of "prevents more than fractures" and agreed that no evidence had been provided to overturn the finding that the claim inferred benefits that were not supported by the Product Information.

The sanction imposed by the Code of Conduct Committee was considered to be appropriate. The Code of Conduct Appeals Committee noted that a claim regarding the prevention of more than fractures may possibly be made in the future, although it would need to be appropriately qualified so as not to mislead or infer benefits that could not be supported by the Product Information.

23. Glaxo Wellcome Australia Ltd Pritor (572)

Promotional advertisement entitled:
"It's also the peak hour for heart attack and stroke"

Complaint
A complaint was received from Bristol-Myers Squibb Australia Pty Ltd alleging that an advertisement for Pritor by Glaxo Wellcome Australia Ltd was in breach of Section 1.3 of the Code of Conduct. It was alleged the juxtaposition of the headline in the advertisement implied that Pritor was an effective agent for the prevention of stroke and myocardial infarction which was considered false and misleading. In addition, it was alleged that a statement made regarding Pritor being the first angiotensin II antagonist to be available on the PBS without an authority listing was incorrect and misleading.

Response
A response was received from Glaxo Wellcome Australia Ltd in which any breach of the Code of Conduct had been denied. Glaxo Wellcome Australia Ltd maintained that the advertisement was clearly for an antihypertensive and did not claim an indication for heart attack and stroke. In addition, Glaxo Wellcome Australia Ltd acknowledged the error of the claim for Pritor to be the first angiotensin II antagonist to be available on the PBS without an authority listing, however, considered that this claim would not have a major impact on a doctor's decision to prescribe.

Committee ruling
The Committee ruled that the statement referring to "heart attack and stroke" should not be considered promotion of Pritor for the prevention of heart attack and stroke and therefore was not in breach of Section 1.3 of the Code of Conduct.

The Committee ruled that the use of the identified statement made by Glaxo Wellcome Australia Ltd regarding Pritor's PBS listing was in breach of Section 1.3 of the Code of Conduct as it was incorrect.

Sanction
Having found a breach of the Code of Conduct the Committee resolved that Glaxo Wellcome Australia Ltd should ensure that no such occurrence of this breach was repeated and that it should review its internal procedure to ensure compliance with the Code of Conduct.

24. Searle, A Division of Monsanto Australia Limited & Pfizer Pty Limited Celebrex (573)

Promotional brochure entitled:
"This will change the way you treat arthritis. Celebrex. Powerful relief, safely delivered."

Promotional advertisements entitled:
"New Celebrex
Powerful relief, safely delivered."

"Potentially the most exciting therapeutic advance in the treatment of inflammation and pain since the advent of NSAIDs."

"It will change the way you treat arthritis"

Product Information – Celebrex

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considerable and lengthy frustration did they make a direct approach to a select group of patients who were already using the product and who had gained benefit from it. Pfizer Pty Limited maintained that no breach of the letter nor the spirit of the Code of Conduct had occurred.

Committee ruling
Although no Section of the Code of Conduct had been identified as potentially being breached, the Committee examined Sections 1.4, 9.4 and 9.5 of the Code.

The Committee resolved that no breach of Section 9.4 was made out, given that the letter could not be considered promotional nor encouraging members of the general public to seek a prescription for Aricept.

In relation to Section 9.5 the Committee agreed that this activity did not fit easily within this Section which dealt with patient education and not political lobbying.

In relation to Section 1.4 the Committee considered that the sending of this letter in this particular circumstance to patients could withstand the test regarding good taste, therefore no breach of this Section was found.

The Committee considered that this complaint was sufficiently important for the APMA to consider whether the Code should not be modified to prevent such activities in the future.

27. Pharmacia & Upjohn Pty Limited Caverject (576)

Promotional advertisement entitled:
"To be sure... Happy St Patrick's Day from Caverject."

Complaint
A complaint was received from a medical practitioner alleging that an advertisement for Caverject by Pharmacia & Upjohn Pty Limited was in breach of Sections 1.3, 1.5 and 3.1 of the Code of Conduct. It was alleged the headline "to be sure" conveyed a claim of 100 percent efficacy for Caverject which was considered misleading. In addition, the headline inferred a special merit for the product that could not be substantiated. It was also alleged that the advertisement did not meet the required type size as defined by Section 3.1 of the Code of Conduct.

Response
A response was received from Pharmacia & Upjohn Pty Limited in which any breach of the Code of Conduct had been denied. Pharmacia & Upjohn Pty Limited maintained that the word "sure", taken in isolation, implied some level of confidence or certainty however, at no time was it stated or implied 100 percent success rate for Caverject. In addition, it was acknowledged that the body of the disclosure information in the advertisement was not 2mm in height although noted that there appeared to be some ambiguity between Section 2 and Section 3 of the Code with regard to required type sizes.

Furthermore, Pharmacia & Upjohn Pty Limited questioned the ability of an employee of a member company to raise a complaint with the APMA regarding a competitor product given that inter-company dialogue had not been undertaken.

Committee ruling
Before considering the substance of the complaint, the Committee discussed the appropriateness of an employee of a competing pharmaceutical company lodging a complaint in their own name and the lack of any dialogue between the complainant and the subject company. The majority of members of the Committee felt that it was inappropriate for an employee of a competitor company to raise such a complaint as the individual and company were not divisible. It was also considered inappropriate that no dialogue had been undertaken between the complainant and the company involved. The Committee asked that the APMA review the provisions of the Code of Conduct to determine how such complaints should be considered in the future.

Without any clear guidance from the Code of Conduct regarding these types of complaints, on this occasion the Committee resolved that it should consider this complaint and discussed each aspect raised in the letter of complaint.

The Committee found no breach of Section 1.3 and 1.5 of the Code of Conduct as it was considered that the phrase "to be sure" would not be interpreted as a guarantee of 100 percent level efficacy.

The Committee resolved that a technical breach of Section 3.1.2.3 of the Code of Conduct had occurred via the use of an incorrect sized font for the required disclosure information. It was noted that Section 3.1 required that this information should appear in a type size of not less than 2mm as measured by the font's capital letter.

Sanction
Having found a technical breach, the Committee resolved that Pharmacia & Upjohn Pty Limited should take immediate action to ensure that no further breaches of Section 3.1.2.3 occurred via the use of an incorrect font size.

28. Wyeth Australia Pty Limited Premarin & Premia (577)

Promotional material entitled:
"Multiple oestrogen HRTs, Premarin and Premia, offer multiple benefits for treating the whole woman."

Promotional advertisement entitled:
"Think you know all there is to know about Premarin and Premia? Think again."

Promotional advertisement entitled:
"Dentists are excited about the benefits Premarin and Premia could offer beyond those expected from HRT."

Complaint
A complaint was received from Novo Nordisk Pharmaceuticals Pty Ltd alleging that promotional material for Premarin and Premia by Wyeth Australia Pty Limited was in breach of Sections 1.1 and 1.3 of the Code of Conduct. It was alleged Premarin and Premia had been promoted as being potentially beneficial for a range of unapproved indications by providing a list of current research areas. In addition, it was alleged that the medical content included in the promotional material was incorrect and not supported by the Approved Product Information and available evidence.

Response
A response was received from Wyeth Australia Pty Limited in which any breach of the Code of Conduct had been denied. Wyeth Australia Pty Limited maintained that the intent of the material was not to represent that Premarin and Premia offered benefits not offered by other hormone therapies. In addition, it was maintained that claims were fully supported by the Approved Product Information and the body of clinical evidence and care had been taken in all material to distinguish between proven benefits and topics in research.

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breach of the Code of Conduct had been denied. Merck Sharp & Dohme (Australia) Pty Ltd maintained that the claims were fully qualified by the indications and claims of comparative efficacy and safety were fully qualified and substantiated. In addition, it was maintained that claims of limited drug interactions were accurate and a relevant point of comparison and the claims relating to the difference in dosing regimes between Vioxx and Celebrex were appropriate.

Committee ruling
The Committee ruled that the use of identified claims and statements made by Merck Sharp & Dohme (Australia) Pty Ltd were in breach of Sections 1.3 and 1.7 of the Code of Conduct as:

- statements regarding the GI safety of Vioxx, without appropriate qualification, were overly positive and had the capacity to mislead
- statements had the capacity to mislead readers to think that the safety profile of Vioxx was better than the evidence provided
- claims inferred a lower risk of potential drug interactions than was supported by the Product Information and were considered misleading and disparaging
- claims could infer greater concern regarding other COX-2 inhibitors than clinical experience indicated and hence was considered misleading and an inaccurate comparison
- statements implied a positive benefit of Vioxx over other COX-2 specific inhibitors which could not be substantiated
- the omission of certain interactions and the lack of prominence of others in the material was unbalanced
- the heading of "providing 24 hour pain relief" had not been qualified nor referenced and was considered misleading

No breach of Section 1.3 of the Code of Conduct was found as the Code of Conduct Committee resolved that evidence had been provided to the satisfaction of the Committee that supported the claim "A New World of GI Safety in Pain Relief".

Sanction
Having found breaches of the Code of Conduct, the Committee discussed an appropriate sanction. The Committee discussed whether any of the breaches found had the capacity to cause patient harm. It was the view of the Committee that the lack of balance regarding statements on drug interactions and sulfonamide allergy which had been found in breach could impact upon patient safety. The Committee acknowledged that information regarding this new type of treatment should be provided to prescribers but in a way that was accurate and balanced.

Given the Committee's concerns that a prescriber may be misled by the information contained in the promotional material, it was resolved that Merck Sharp & Dohme (Australia) Pty Ltd should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. The claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Corrective letter
In addition, the Committee agreed that a corrective letter should be sent to each prescriber that had been exposed to this material. The content and format of the corrective letter would be determined by the Committee or its Chairman and Merck Sharp & Dohme (Australia) Pty Ltd should provide APMA with a list of the prescribers contacted and a mailing list providing sufficient detail to determine that each prescriber had been sent this corrective letter.

Fine
As it was agreed that these breaches could be considered as moderate breaches, as defined by the Code of Conduct, it was resolved that a fine of $10,000 should be imposed.

Appeal
Merck Sharp & Dohme (Australia) Pty Ltd lodged an appeal against the findings and sanctions imposed by the Code of Conduct Committee. Merck Sharp & Dohme (Australia) Pty Ltd maintained that the material was designed for specialist physicians and had not been distributed to general practitioners. It was considered that the specialists would have a high level of familiarity with NSAIDs, in particular the issue of adverse reactions. In addition, it was maintained that the claims for benefits of Vioxx over other COX-2 specific inhibitors encompassed other agents rather than just Celebrex alone.

Committee ruling
The Code of Conduct Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that

- the statements regarding the safety profile of Vioxx to other NSAIDs did not have the capacity to mislead and therefore were not in breach of Section 1.3 of the Code
- the claims inferring greater concern regarding other COX-2 inhibitors were correct and could be substantiated, therefore were not in breach of Sections 1.3 and 1.7 of the Code.

The listing of medicines without clinical evidence of interactions could be substantiated as additional information had been provided later in the material and its availability had been highlighted to readers. The decision to find a breach of Section 1.3 of the Code was overturned.

Having partly upheld the appeal, the Committee discussed the sanction imposed by the Code of Conduct Committee and it was agreed that the requirement for a corrective letter was no longer necessary. However the Committee agreed that a fine of $10,000 imposed for the breaches found was appropriate and should remain.

26. Pfizer Pty Limited Aricept (575)

Dear Patient Letter

Complaint
A complaint was received from the Pharmaceutical Benefits Advisory Council (PBAC) in which concerns regarding an activity by Pfizer Pty Limited in relation to Aricept were stated. PBAC was concerned that sending letters to patients encouraging them to lobby Members of Parliament to support the PBS listing of this product was inappropriate and unethical.

Response
A response was received from Pfizer Pty Limited in which any breach of the Code of Conduct had been denied. Pfizer Pty Limited maintained that the letter did not constitute promotion to the general public or induce patients to seek prescriptions of Aricept for themselves or others. In addition, Pfizer Pty Limited maintained that they had been seeking the listing of Aricept on the PBS for some time and only after

Results

From January 2000 to June 2000 continued

Fine
The Committee also considered that a fine of $15,000 should be imposed on Boehringer Ingelheim Pty Ltd for the breaches found as it was agreed that this promotional material was not of a standard that was demanded of industry via APMA's Code of Conduct.

Appeal
Boehringer Ingelheim Pty Ltd lodged an appeal against the findings and sanctions imposed by the Code of Conduct Committee. Boehringer Ingelheim Pty Ltd disputed the finding of the Committee that a severe breach had occurred due to the potential that the claims contained within the material might lead to out of indication use and potential patient harm.

Committee ruling
The Code of Conduct Appeals Committee reviewed the material considered to be in breach of the Code of Conduct to determine whether evidence had been provided to it to overturn the decision of the Code of Conduct Committee.

The Code of Conduct Appeals Committee resolved to partly uphold the appeal by accepting that the combination of the results from two studies was appropriate and the source of data had been disclosed hence the presentation was not misleading nor in breach of Section 1.3 of the Code. The Committee did not find the graph to be misleading, falsely based or disparaging and hence resolved to overturn the decision to find a breach of Section 1.7.

The Committee also agreed that the finding of a breach of Section 1.3 relating to the unfair representation of results of a study should be overturned.

In relation to the finding that claims inferred an unapproved indication, the Committee agreed that no evidence had been provided to justify the overturning of its decision.

Having partly upheld the appeal, the Committee discussed any possible patient harm that might result from the remaining breaches. It was agreed that the risk of any patient harm would be negligible and possibly non-existent. The Committee was satisfied that as the brochure included an abridged Product Information which stated its approved use, any risk of patient harm would be minimised. On this basis the Committee agreed that there was no need for corrective action and resolved to remove the requirement for a corrective letter.

In relation to the fine it was agreed that it should be reduced to $5,000 as it was apparent that Boehringer Ingelheim Pty Ltd had considered the material carefully before its release and had, on the whole, taken reasonable steps to avoid any breach of the Code of Conduct.

30. Pfizer Pty Limited Zoloft (582)

Promotional advertisement and brochure entitled:
"The pick of the bunch. Zoloft for depression."

Company Commissioned article entitled:
"Mental Health Foundation of Australia. SSRI's: The Australia Perspective – Are All SSRIs the same ?"

Presentation to healthcare professionals entitled:
"Zoloft vs SSRI"

Complaint
A complaint was received from SmithKline Beecham (Australia) Pty Limited alleging that promotional material for Zoloft by Pfizer Pty Limited was in breach of Sections 1.2, 1.3, 1.3.1, 1.5 and 1.7 of the Code of Conduct. It was alleged that the promotion of Zoloft for the use of social phobia/social anxiety was outside of the approved indications and the claim of "pick of the bunch" inferred superiority over other products that was unqualified and inappropriate. In addition, it was alleged that certain claims constituted a repeat breach given the decision of the Code of Conduct Committee pursuant to complaint Zoloft (560).

Response
A response was received from Pfizer Pty Limited in which any breach of the Code of Conduct had been denied. Pfizer Pty Limited maintained the headline "pick of the bunch" was justified, supported by the reference and adequately qualified. The alleged promotion of Zoloft for the treatment of social phobia/social anxiety related to educational material directed primarily to patients and their families, that made no reference to Zoloft. In addition, it was maintained that the alleged repeated breach of the Code of Conduct related to material devoid of promotional content and product logos and had been distributed prior to finding certain claims in breach of Section 1.7. Pfizer Pty Limited advised that no further distribution had taken place and hence no repeat breach should be established.

Committee ruling
The Committee ruled that the use of the identified claims and statements made by Pfizer Pty Limited were in breach of Sections 1.3, 1.3.1 and 1.7 of the Code of Conduct as:

- a linkage between the use of the sunflower motif and Zoloft existed which had been used on educational material for conditions in which Zoloft was not approved
- claims implied the promotion of an unapproved indication for Zoloft
- omission of dosage for competitor products was misleading and disparaging
- inferences of a possible increase in the severity of side effects with increased dose could give a false impression regarding a product and could not be supported to the satisfaction of the Committee

The Committee resolved that, as it was not convinced that the average reader of the claim "pick of the bunch" would infer a meaning of superiority, no breach of the Code had occurred via its use.

The Committee resolved that breaches were of sufficient similarity to previous breaches to find their use a repeat of a previous breach.

Sanction
Before discussing an appropriate sanction for the breaches found the Committee discussed whether there was any potential for patient harm. The Committee agreed that the claims made were not sufficient to create the potential for patient harm.

The Committee then discussed the possibility of prescribing outside the approved indications for Zoloft that may result from this material and the finding of repeat breaches. The Committee determined that it was appropriate that some corrective action was required and agreed that a corrective letter to all prescribers that may had been exposed to this promotional material was appropriate. A draft corrective letter had been developed by the Committee and provided to Pfizer Pty Limited who would be given the opportunity to comment upon it, however the clear intent to correct the breaches found must remain.

From January 2000 to June 2000 continued

Furthermore, Wyeth Australia Pty Limited maintained that some of the same promotional material had been submitted to the APMA's Monitoring Committee however no concerns had been raised as a result of this review.

Committee ruling
The Committee discussed the non-provision of the Monitoring Committee's determination regarding this material to Wyeth Australia Pty Limited which had indicated some concern. It was agreed that the lack of the availability of this information to Wyeth Australia Pty Limited had denied them the opportunity to modify their conduct but did not ameliorate the company's requirement to comply with the Code of Conduct at all times. On this basis it was agreed that the Committee should consider the complaint.

The Committee ruled that the use of identified claims and statements made by Wyeth Australia Pty Limited were in breach of Section 1.1, 1.3.1 and 1.7 of the Code of Conduct as:

- claims had the capacity to mislead readers into thinking that the product provided benefits that had not been supported by some evidence
- the manner in which beneficial effects were listed had suggested that these benefits were clinically proven and should be influential when considering a product to prescribe

The Committee ruled that, although the disclosure of research areas in appropriate forum should not be prevented, in this instance the Committee was concerned that the overall impact was promotional and it was likely that a reader may conclude that the areas of research had already established a clinically proven benefit that would influence the decision to prescribe. This was considered unbalanced, unsubstantiated and had the capacity to mislead and was therefore in breach of Section 1.3.1 of the Code of Conduct.

Sanction
Having found breaches of the Code of Conduct, the Committee discussed an appropriate sanction for what it considered a strong promotional campaign that did not adequately distinguish between promotion and education. The Committee however considered that there was little or no chance of patient harm likely to result from this campaign.

Following this discussion, and in light of the Committee's earlier discussion regarding the unavailability of the Monitoring Committee minutes, it was resolved that Wyeth Australia Pty Limited should take immediate action to ensure that all material containing these claims was withdrawn and that no further appearance of them in their present form should be permitted. The claims and presentations found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

29. Boehringer Ingelheim Pty Ltd Persantin SR (578)

Promotional mailer entitled:
"Adding NEW Persantin SR to aspirin doubles her protection against secondary stroke."

Complaint
A complaint was received from Sanofi-Synthelabo Australia Pty Limited alleging that a direct mailing to medical practitioners for Persantin SR by Boehringer Ingelheim Pty Ltd was in breach of Sections 1.3 and 1.7 of the Code of Conduct. It was alleged claims of superiority for Persantin SR over competitor products for the prevention of vascular events were not consistent with the purpose of the material to promote usage in secondary stroke prevention, nor appropriate as Persantin SR is not approved for such an indication. It was alleged that these comparative claims were misleading and inappropriate.

Response
A response was received from Boehringer Ingelheim Pty Ltd in which any breach of the Code of Conduct had been denied. Boehringer Ingelheim Pty Ltd, maintained that there was no attempt to mislead healthcare professionals that Persantin SR is approved for the prevention of other secondary events such as myocardial infarction or peripheral vascular disease. In addition, Boehringer Ingelheim Pty Ltd agreed to further clarify graphs to minimise any potential misinterpretation.

Committee ruling
The Committee ruled that the use of the identified claims and statements made by Boehringer Ingelheim Pty Ltd were in breach of Sections 1.3, 1.3.1 and 1.7 of the Code of Conduct as:

- the graphical combination of data from two studies in the manner presented was inappropriate, misleading and disparaging
- graphs inferred that Persantin SR was approved for the treatment of vascular events which was contrary to the Approved Product Information
- claims and analysis did not fairly represent results of a study nor were they supported by the Approved Product Information and hence had the capacity to mislead
- claims of "considerably greater" and lack of clarification regarding "risk reduction" were considered misleading and inappropriately disparaging

Sanction
The Committee considered that as this material was a direct mailing, prescribers would not have the opportunity to discuss the claims made directly with representatives of Boehringer Ingelheim Pty Ltd.

The Committee considered that there may be a chance of patient harm resulting from the promotion if this product was prescribed as a consequence of the claims made regarding reduction in vascular events which had not been proven or included in the approved product indications. The Committee further considered that this material might be influential in changing medical practitioners' prescribing habits. Hence, it was agreed that the breaches found should be considered as serious breaches, as defined by the Code of Conduct.

Withdrawal
Having found breaches of the Code of Conduct, the Committee resolved that Boehringer Ingelheim Pty Ltd should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its present form. The claims and graphs found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Corrective letter
In addition, given the Committee's concerns regarding the inappropriateness of the claims made and the graphs included in the promotional material, their possible impact on prescribing habits and patient safety, it was agreed that a corrective letter was appropriate. The Committee agreed that the content of the letter should include acknowledgment of the breaches found and a summary of the primary results of the studies. The final content of this letter would be approved by the Chairman of the Code of Conduct .

Monitoring

Monitoring Committee Annual Report

The Monitoring Committee has been formed to review promotional material for compliance with the provisions of the Code of Conduct, provide relevant advice on current marketing practices to the APMA and, if deemed necessary, submit any complaints as a result of its findings to the APMA Code of Conduct Committee.

Member companies are required to submit to the Monitoring Committee selected types of promotional material used during a nominated period for the product category under review. Other reviews may also be undertaken throughout the year on request from the APMA, its Marketing, Code of Conduct or Monitoring Committees.

The Monitoring Committee consists of the following members:

Permanent Members

Chairman – consulting industry representative with Code of Conduct experience

One member of the Royal Australian College of General Practitioners

One member of the Australian Medical Association

One member of the APMA Secretariat

Rotating Members

One expert in a particular therapeutic category, generally representative of the relevant College or Society

One member of a relevant patient support group

One Medical Director of an APMA member company

One Marketing Director of an APMA member company

If, following a review of the submitted material, the Committee considers that a Code of Conduct issue has arisen, the company in question is contacted and asked to state whether the determination of the Committee is correct and give any answer or explanation deemed necessary. The Committee considers this response and either provides relevant advice on compliance with the Code of Conduct to the company or, if necessary, refers the matter to the Code of Conduct Committee as a complaint.

Activities

Review of Therapeutic Categories

The Monitoring Committee reviewed four therapeutic categories (a total of 170 pieces of promotional material) during the 12 months from 1 July 1999 to 30 June 2000.

As the review of Dermatological products had not been finalised at the time of the release of last year's report these results are as follows. A total of 67 pieces of promotional material were reviewed, resulting in 97% compliance with the Code of Conduct.

During the 1999/2000 year, companies were required to submit promotional material for Systemic Hormonal Preparations, Gonadal Hormones, Genito-Urinary and Sensory Organ products. The review of Systemic Hormonal Preparations resulted in 81% compliance, while the review of Genito-Urinary Products resulted in 93% compliance. The review of Gonadal Hormones resulted in 86% compliance.

The review of Sensory Organ products had not been finalised at the time of the printing of this report. The results of this review will be included in next year's Annual Report.

Advice regarding compliance with the Code of Conduct was provided to those companies where the Committee raised concerns regarding potential breaches of the Code of Conduct.

Proposed Therapeutic Reviews for 2000/2001

Anti-Infectives for Systemic Use

The next category for review by the Monitoring Committee is the General Anti-Infectives for Systemic Use. Companies will be required to submit all promotional material for the period between June to August 2000 with the review taking place in mid September 2000.

Company Sponsored Websites and the Internet

With the increasing use of the Internet by companies for the provision of information about prescription medicines and the adoption of new provisions in Edition 13 of the Code relating to the Internet, APMA may consider undertaking a review of company sponsored Websites in 2000/2001 to ensure compliance with Section 3.9 of the Code of Conduct.

From January 2000 to June 2000 continued

The Committee also resolved that Pfizer Pty Limited should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of them in their present form. The claims found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

Fine

The Committee unanimously considered that the imposition of a fine for the breaches found, particularly the repeat breach, was appropriate. It was agreed that as the breaches found could be considered as moderate, a fine of $5,000 for the incorrect promotion of unapproved indication via the video and a fine of $10,000 for the breaches in the promotional brochure was imposed.

In addition, the Committee agreed that a fine of $10,000 should be imposed for the finding of a repeat of a previous breach.

Glossary

3.1.1 Full advertisement*

3.1.1.1 A full disclosure advertisement must contain the following within the body of the advertisement.

(a) The brand name of the product

(b) The Australian Approved Name(s) of the active ingredient(s)

(c) The name of the supplier and the city, town or locality of the registered office

3.1.1.2 A full advertisement must also contain either:

(d) An approved indication or indications for use together with the dosage and method of use

(e) A succint statement of the contraindications, precautions and side effects, including any boxed warnings that may appear in the full Product Information.

(f) A clear and unambiguous statement for prescribers to review the Product Information before prescribing

(g) A statement to the effect that full disclosure Product Information is available on request from the manufacturer

or

Section (f), (g) and

(h) the Product Information

3.1.2.3 Reminder Advertisement

A reminder advertisement must also contain either:

(a) the content of Section 3.1.1.2 (d) and (e)

or

(b) the location of the Product Information within the same publication either via reference to the location of the Product Information or via a Product Information index

or

(c) the location of a full advertisement contained within the same publication via reference to an advertisers index

3.5 Mailings*

3.5.2 The full or abridged disclosure Product Information as applicable must be included in all mailings where promotional claims are made.

8. Research

The following provisions apply to Market Research*, Product Familiarisation Programmes* and Post-Marketing Surveillance Studies*, whether the research is carried out directly by the manufacturer or by an organisation acting under its direction.

8.2 Product Familiarisation Programmes (PFPs)

8.2.1. Members should not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.

8.2.4. Starter packs may be supplied free of charge for these programmes but must still comply with Section 5 of the Code of Conduct.

8.3.2 Market Research

Any payment must be kept to a minimum and should not exceed a level commensurate with the work involved.

9.5 Patient Education

It is acknowledged that members of the general public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The purpose of such information should be educational and should encourage patients to seek further information or explanation from the appropriate healthcare professionals.

In addition, the following criteria should be satisfied.

9.5.4 The educational material must include the name and the city, town or locality of the registered office of the supplier of the material, but the location of such information should not be given prominence.

9.5.7 On all occasions the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes of successful treatment or stimulating the demand for prescription of a particular product.

11.3 Administration of the Code (Edition 12 including amendments adopted on 1st June 1999)

In the event of the Subcommittee requiring a member to cease or withdraw a promotional activity, the Member shall at once comply with the Subcommittee's ruling pending any appeal against the decision of the Committee pursuant to the Rules of the Association. A promotional activity thus suspended shall not be reactivated before the appeal process has been concluded, nor shall any other promotional activity thus suspended be recommenced during the period in question.

12.1.1 Sanctions (Edition 12 including amendments adopted on 1st June 1999)

The requirement that the subject company take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code, within five working days of being notified of the Subcommittee's decision. Written notification of this action must be provided to the APMA within five working days.

Glossary

1.1 Responsibility (Edition 12 including amendments adopted on 1st June 1999)

It is the responsibility of Members, their employees and their medical/technical advisers to ensure that medical content* included in all promotional material* is correct*, fully supported by the Product Information, literature* or "Data on File"*, where the latter do not conflict with the former. Activities of company representatives* must comply with the Code at all times.

(Edition 13)
It is the responsibility of Members, their employees and their medical/technical advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct*, fully supported by the Product Information, literature* or "Data on File"* or appropriate industry source, where the latter do not conflict with the former. Activities of company representatives* must comply with the Code at all times.

1.2 Provision of Substantiating Data

Further to the information supplied or generally available, the manufacturer will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

Substantiating information must not rely solely on data on file.

Data cited in promotional material in support of a claim, including "data on file" or "in press", must be made available to healthcare professionals and industry companies upon request.

Where this material is not available through standard library services, it must be made available without delay.

1.3 False or Misleading Claims

Information, medical claims* and graphical representations about products must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

Information, claims and graphics* must be capable of substantiation*, such substantiation being provided without delay at the request of health professionals.

1.3.1 Unapproved products and indications

Products that have not been approved for registration by the Department of Health and Aged Care must not be promoted. However, samples of unapproved products may be displayed and educational material* made available at International Congresses* and Australasian Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.

1.5 Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique* or has some special merit, quality or property unless this can be substantiated. The word "safe" must not be used without qualification.

1.7 Comparative Statements

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis or in any other way. "Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc - must not be used.

"Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2.

1.10 Distinction of Promotional Material

Promotional material must be clearly distinguishable as such.

2. Product Information

Certain types of promotional material described in Section 3 must be accompanied by either full or abridged disclosure Product Information.

Wherever required, Product Information must appear in a type size of not less than 1mm on a background sufficiently contrasting for legibility. Major headings should be easily identifiable.

Product Information must not be overprinted or interspersed with promotional phrases or graphics and must clearly identify any recent change of clinical significance*.

2.1.2 Full Disclosure Product Information

Where a Product Information document has been approved by the Department of Health and Aged Care, that document must be used in full without alteration unless such alteration is approved by the Department of Health and Aged Care. When used to accompany promotional material, it should appear under the heading "Approved Product Information".

3.1.4 Company Commissioned articles*

3.1.4.1 Company commissioned articles must be identified as such in a type size of not less than 2mm.

3.1.4.2 The Member which is responsible for the insertion of the Company Commissioned Article must be clearly identified at either the top or the bottom of the Company Commissioned Article in a type size of not less than 2mm.

3.1.4.3 Company Commissioned Articles must conform to all relevant provisions of Section 1 of this Code.

3.1.1.5 Full Advertisement

If a full advertisement contains a claim or statement regarding PBS availability or cost, the current PBS dispensed price* must be included with the mandatory text required for this type of advertisement as detailed in Section 3.1.1.1. If a specific indication is being promoted the price or prices relevant to this indication should be disclosed. If no specific indication is being promoted the price of all presentations should be listed.

3.1 Journal Advertising (Edition 13)

Journal Advertising must conform with the requirements of one or other of the following categories. The information required for Sections 3.1.1, 3.1.2 and 3.1.3 shall appear in each publication in a type size of not less than 2mm as measured by the font's capital letter, and should appear on a background sufficiently contrasting for legibility. The orientation of the text should be the same as that of the main text of the advertisement.