18. Pfizer Pty Ltd Aricept (643)

Promotional materials entitled:
"Four reasons why Alzheimer's patients are better off with Aricept"
"The first head-to-head evidence on tolerability ARICEPT vs EXELON"

Complaint
A complaint was received from Novartis Pharmaceuticals Australia Pty Ltd alleging that a promotional materials, including an advertisement, sales aid and mailer, for Aricept by Pfizer Pty Ltd were in breach of Sections 1.1, 1.2, 1.3 and 1.7 of the Code of Conduct.

Response
A response was received from Pfizer Pty Ltd denying any breach of the Code of Conduct. Pfizer Pty Ltd maintained that there was nothing in the Code of Conduct that indicated a poster presentation was not acceptable for citation as a reference and that the advertisement did not unfairly present the respective tolerability profiles of Aricept and Exelon.

Committee ruling
It was the view of the Committee that given concerns regarding the study, particularly the lack of peer-review, it was inappropriate to base a significant comparative promotional campaign upon these results alone. The Committee reiterated its recommendation that companies should not rely upon poster presentations and abstracts that are not refereed as the basis for significant promotional claims.

The Committee acknowledged that while this data may not be defined as strictly "data on file" there was still concern that it was not reviewed via the publication process. The Committee noted that the promotional material referred to "evidence" which was only in the form of a poster presentation and that the use of this term could influence a prescribing decision given health care professional's preference for evidenced based medicine.

In addition, the Committee considered that the results of this study had been used selectively and did not represent a balanced objective view of the study's overall results. This was felt to be particularly relevant to the claims made regarding GI adverse events, which although being statistically significant, were quoted to the exclusion of other results. Concern was also expressed regarding the lack of information provided in the promotional material on the differences in dosing and titration between the products and the influence this would have on physician's perceptions of the products as measured by the study's questionnaire.

Breaches of Section 1.1, 1.3 and 1.7 were found as the Committee resolved that these claims were unbalanced and based upon a study that did not provide sufficient unequivocal evidence to support such strong comparative claims. No breach of Section 1.2 was found as the Committee noted that the references cited in the promotional material could be provided.

The Committee noted that the reasons for the discontinuation rate quoted in the material were unclear and it was possible that this claim could be inferred to be referring only to adverse events, which was not an accurate reflection of the study and was therefore in breach of Section 1.7 of the Code.

In relation the claim "higher physician satisfaction" the Committee found breaches of Sections 1.1, 1.3 and 1.7 noting that the promotional material did not provide sufficient information to determine the basis for the physician's satisfaction. The Committee considered that a reader might infer that this claim related to efficacy rather than issues such as practicalities as tested by number of patient visits etc.

Sanction
The Code of Conduct Committee determined that Pfizer 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 statements found in breach of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

Given the Committee's concerns regarding this promotional campaign was based upon insufficient evidence and the likelihood that a reader could be misled, it was resolved that Pfizer Pty Ltd should print a corrective advertisement of the same size and prominence as the original advertisement and in the same journals advising of the breaches of the Code

of Conduct. In addition, to ensure that the audience to whom it was directed received this corrective message, a corrective letter should be sent to all medical practitioners.

Appeal
Pfizer Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Pfizer Pty Ltd argued that the Code does not stipulate that peer reviewed publication is required to substantiate a major comparative claim or that sponsorship must be disclosed. Pfizer Pty Ltd contented that the tag line "make a difference" was not comparative and could be supported by the clinical and scientific 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 Appeals Committee was persuaded by the argument put forward by Pfizer Pty Ltd that the statement "make a difference" was not intended to be comparative between available treatments but was referring to the difference between the lack of and availability of a treatment for Alzheimer's disease. However, the Committee agreed with the complainant that if used inappropriately or without sufficient care this statement could imply a comparison between products. The Committee resolved to uphold this element of Pfizer Pty Ltd's appeal and to overturn the Code of Conduct Committee's decision to find breaches of Section 1.3 and 1.7.

In relation to other claims the Committee resolved to uphold the decision of the Code of Conduct Committee as no evidence had been provided to justify overturning its decision.

Sanction
The Committee resolved that the sanction to withdraw the promotional material and that it should not be used again in the same or similar format, should remain. In addition, the Committee resolved that the sanction to place a corrective advertisement as directed by the Code of Conduct Committee was an appropriate corrective action and would reach a broad audience.

The Committee did not consider that a corrective letter was required and agreed that this element of the sanction should be removed.

19. Pfizer Pty Ltd Lipitor (644)

Advertisement entitled:
"The power to protect"

Complaint
A complaint was received from Bristol-Myer Squibb Australia Pty Ltd alleging that an advertisement for Lipitor by Pfizer Pty Ltd was in breach of Sectors 1.1, 1.3, 1.3.1 and 1.5 of the Code of Conduct. Bristol-Myer Squibb Australia Pty Ltd alleged that the claims set out in the Lipitor advertisement were based on a false premise and had a serious potential for harm to patients.

Response
A letter of response was received from Pfizer Pty Ltd denying any breach of the Code of Conduct. Pfizer Pty Ltd maintained that it did not dispute the Approved Product Information for Lipitor was "as an adjunct to diet for the treatment of patients with hypercholesterolaemia" and that the lowering of cholesterol was not an end in itself. Pfizer Pty Ltd stated that there was sufficient evidence to support the claims made in the advertisement.

Committee ruling
The Committee resolved that the promotional claim "The power to protect" was not misleading and was not promoting Lipitor beyond its approved indications. The Committee concluded that the statement was general and not directly comparative to other statins. No breaches of Sections 1.1, 1.3 or 1.3.1 of the Code of Conduct were found. Further, the Committee did not consider that the word "power" implied a special merit or property for Lipitor. The claim was therefore found not to be in breach of Section 1.5 of the Code.

20. Servier Laboratories (Australia) Pty Ltd Coversyl (645)

Promotional material entitled:
"6000 patients 5 years to complete"

Complaint
A complaint was received from Aventis Pharma alleging that a promotional material, including advertisements and a mailer, for Coversyl by Servier Laboratories (Australia) Pty Ltd were in breach of Section 1.3 of the Code of Conduct. Aventis Pharma alleged that the advertising undertaken by Servier Laboratories (Australia) Pty Ltd misled prescribers about the outcomes of the PROGRESS Study and had the potential for serious implications affecting patient safety.

Response
As a non member of the APMA, Servier Laboratories (Australia) Pty Ltd agreed to have this complaint considered by the Code of Conduct Committee. Servier Laboratories (Australia) Pty Ltd maintained that the term "perindopril-based therapy" was clearly explained in the advertising material and was referenced to the study published in the Lancet publication which would provide the reader with the opportunity for clarification in the unlikely event that this was necessary.

Committee ruling
The Committee was of the view that a reader of the promotional material had not been provided with sufficient information to understand the results of the trial and hence the claims referred to in the complaint could be misleading. It would be unclear to a reader that the results of the trial indicated that patients with a history of stroke or transient ischaemic attack should be treated with a combination of both Coversyl (perindopril) and indapamide. The Committee noted that the promotional material did not emphasise the need for this combination therapy but rather promoted Coversyl as the key agent that should be prescribed for patients with a history of stroke. It was the view of the Committee that the use of phrases such as "perindopril based therapy" added to the possibility that a reader may not fully understand the trial's results which suggested combination therapy rather than monotherapy with Coversyl alone.

The Committee was also concerned that the promotional material did not make it sufficiently clear that the trial's results were in relation to patients who had already suffered a stroke and agreed that statements such as "if the findings were applied widely, many millions of stroke sufferers worldwide would be spared unnecessary suffering" gave an incorrect impression regarding the treatment group that these results applied to.

At the conclusion of this discussion the Committee resolved that the material was in breach of Section 1.3 of the Code of Conduct as it was misleading and did not accurately convey the results of an interesting and valuable study.

Sanction
The Code of Conduct Committee determined that Servier Laboratories (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 statements found in breach of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

In addition, it was agreed that a corrective letter should be sent to all general practitioners. This letter should provide an accurate and balanced summary of the results of this trial. A copy of the results of the trial should be attached to this letter which should include a recommendation that prescribers read the study results.

Appeal
Servier Laboratories (Australia) Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Servier Laboratories (Australia) Pty Ltd maintained that the use of the PROGRESS study by Servier Laboratories (Australia) Pty Ltd had been appropriate and did not have the capacity to mislead.

Committee ruling
The Code of Conduct Appeal 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 Appeals Committee agreed that the phrase "perindopril-based therapy" was the appropriate terminology to describe the regimen tested via

PROGRESS. However, it was not convinced that a general practitioner would appreciate from the promotional material, that the study was investigating a regimen rather than a single product, as is the norm with most clinical trials.

The Committee agreed with the decision of the Code of Conduct Committee that the promotional material could mislead readers regarding PROGRESS and its results.

Sanction
The Code of Conduct Appeal Committee resolved that the sanction imposed by the Code of Conduct Committee was appropriate and required no amendment.

21. Aventis Pharma Tritace (647)

Promotional Material circulated to specialists

Complaint
A complaint was received from a medical practitioner alleging that promotional material for Tritace by Aventis Pharma was in breach of the Code of Conduct. Aventis Pharma was requested to respond to Sections 1.1, 1.2, 1.3 and 1.7 of the Code of Conduct. The medical practitioner alleged that the promotional material was an over interpretation of published data and an unnecessary and potentially misleading comparison between studies.

Response
A response was received from Aventis Pharma denying any breach of the Code of Conduct. Aventis maintained that the complainant's views were at odds with the findings of a peer reviewed randomised controlled trial, the HOPE Study.

Committee ruling
The Committee reviewed the HOPE paper and the selection criteria for participants in the trial noting that they probably should not have been described as either normotensive or having controlled blood pressure. The Committee also noted that it was reasonable to infer that the blood pressure reduction alone reported in the study could not account for reduced risk of strokes. It was the view of the Committee, which was supported by the Approved Product Information for Tritace, that this product was efficacious in preventing stroke in this patient population. No breach of Section 1.1 or 1.2 of the Code of Conduct was found.

In considering the comparative nature of the PROGRESS and HOPE studies, the Committee was concerned that a single result from the PROGRESS study had been used to make a comparison to the results of another trial that had a different design and objectives. Whilst acknowledging that this had been disclosed in the promotional material and that this statement was a true reflection of one of the results of the study, it was the view of the Committee that the statement was insufficient to provide the reader with a full and complete understanding of the comparison being made.

The Committee considered that the inclusion of this comparative statement "In the Progress Study, perindopril 4mg added to standard therapy failed to provide a significant reduction in risk of stroke in post stroke or post TIA stroke patients." to be unbalanced, did not provide a reader with sufficient information and was unfair. The Committee found breaches of Sections 1.3 and 1.7 of the Code.

It was the view of the Committee that in the case of complainants seeking to remain anonymous there should be negotiations through a third party (eg via the APMA) in order to establish whether there was a conflict of interest or to reach a resolution before the matter was considered by the Code of Conduct Committee.

Sanction
The Code of Conduct Committee resolved that Aventis Pharma 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 statements found in breach of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

In addition the Committee agreed that the breaches found should be considered as moderate breaches as they could influence prescribing and resolved that a $5,000 fine should be imposed.

22. Novartis Pharmaceuticals Australia Pty Ltd Famvir (651)

Famvir Genital Herpes Mailer

Genital Herpes Patient Education Leaflet and Website

Famvir Shingles Mailer

Complaint
A complaint was received from GlaxoSmithKline Australia alleging that a range of promotional items for Famvir by Novartis Pharmaceuticals Australia Pty Ltd were in breach of Sections 1.3, 1.7, 9.4 and 9.5 of the Code of Conduct. GlaxoSmithKline Australia alleged that the promotional items had the potential to mislead doctors and that the patient eduction material could be construed as advertising to the general public.

Response
A response was received from Novartis Pharmaceuticals Australia Pty Ltd denying any breach of the Code of Conduct. Novartis Pharmaceuticals Australia Pty Ltd maintained that the promotional items were consistent with the Approved Product Information and were supported by the body of clinical evidence. No attempt had been made to promote a prescription product to the general public.

Committee ruling
It was the view of the Committee that the data in the Famvir Genital Herpes Mailer was not sufficient to support a claim that inferred superiority over other treatments. The Committee therefore resolved that the claim "...once daily regimens may be more likely to allow breakthrough recurrences than twice-daily regimens..." was misleading and in breach of Section 1.3 of the Code of Conduct as it had not been qualified and could not be adequately supported.

The Committee resolved that this statement, although misleading, could not be interpreted as being directly comparative to another product. No breach of Section 1.7 was found.

The Committee was unconvinced of the accuracy of the inference in the Patient Eduction leaflet and on the website that twice-a-day therapy was more efficacious than once daily treatment. The Committee agreed that the material in the Genital Herpes Patient Education Leaflet and Website was not balanced and was in breach of Section 9.5.1 of the Code.

By a majority the Committee agreed that the inclusion of the statement "reduces the duration of post-herpetic neuralgia" which was from a trial using double the Australian approved dose for Famvir, was misleading. The Committee acknowledged that this statement in the Famvir Shingles Mailer had been qualified but considered that such a strong comparative claim based on a non-approved dosage should have been more clearly qualified or not used at all and found a breach of Section 1.3 of the Code.

Sanction
The Code of Conduct Committee resolved that Novartis Pharmaceuticals 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 statements or inferences found in breach of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

Appeal
Novartis Pharmaceuticals Australia Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Novartis Pharmaceuticals Australia Pty Ltd maintained that that the intent of the material was appropriate and reflective of the Approved Product Information.

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 Appeals Committee resolved to uphold the decisions of the Code of Conduct Committee as no evidence had been provided to justify overturning its decision.

Sanction
The Code of Conduct Appeal Committee resolved that the sanction imposed by the Code of Conduct Committee was considered appropriate and required no amendment.

23. Organon (Australia) Pty Ltd Livial and Sandrena (652)

Printed Promotional Materials:
Tissue Boxes

Complaint
A complaint was received from Wyeth Australia Pty Ltd alleging that promotional material for Livial and Sandrena by Organon (Australia) Pty Ltd was in breach of Sections 3.3.3.2 and 9.4 of the APMA Code of Conduct. Wyeth Australia Pty Ltd claimed that tissue boxes provided to Healthcare Professionals were brand name reminders not printed promotional material.

Response
A response was received from Organon (Australia) Pty Ltd denying any breach of the Code of Conduct. Organon (Australia) Pty Ltd maintained that the tissue boxes were not brand name reminders but printed promotional material and conformed to all sections of the Code in relation to printed promotional material.

Committee ruling
The Committee agreed that while tissue boxes would normally be considered as brand name reminders, these items appeared to be printed promotional material given the inclusion of a number of claims, reference to Product Information and the manner in which they had been used by medical representatives. By a majority decision, the Committee resolved that the Livial and Sandrena tissue boxes were not in breach of Sections 3.3.3.2

Some Committee members raised the issue of where the responsibility lies in advising health care professional that this material is promotional and therefore should not be displayed to the general public.

While the Committee agreed that the Livial and Sandrena tissue boxes were printed promotional material it could be argued that by using tissue boxes, normally seen as brand name reminders, this was a deliberate attempt to have these items viewed by members of the general public as they could be left in the doctors surgery or waiting rooms.

The Committee agreed that Organon (Australia) Pty Ltd was not deliberately providing material in a manner that was directed at encouraging a member of the general public to seek a prescription for a specific prescription-only medicine and no breach of Section 9.4 of the Code was found. However, the APMA was asked to consider the Committee's concerns regarding the availability of such items to members of the general public and whether the Code required some amendment.

24. Pfizer Pty Ltd Norvasc (653)

Promotional Mailer entitled:
"Why is Norvasc the most prescribed antihypertensive brand?"

Complaint
A complaint was received from Solvay Pharmaceuticals alleging that promotional material distributed by Pfizer Pty Ltd for its product Norvasc was in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct. Solvay Pharmaceuticals claimed that the promotional materials were unsupported, unbalanced, unfair and were misleading.

Response
A response was received from Pfizer Pty Ltd denying any breach of the Code of Conduct. In their response Pfizer Pty Ltd maintained that all claims could be substantiated and supported by data provided in the Approved Product Information.

Committee ruling
The Committee was of the view that the statement "most prescribed antihypertensive brand" was not a hanging comparison as 'most prescribed' could be established as being correct via the evidence referenced to this claim and therefore no breach of Section 1.7 was found.

The Committee agreed that the statement "because Norvasc has advantages that other CCBs don't" was an oversimplification of each product's possible drug interactions and that the comparison could not be adequately substantiated. It was the view of the Committee that the definitive nature of the ticks and crosses in a table in the promotional material did not allow any gradient of views other than a product either had the characteristic mentioned or did not. The Committee further noted that the use of the tick or cross implied a higher rate of drug interactions for

Zanidip that could not be supported by the available body of evidence. The Committee agreed that this claim was in breach of Section 1.1 as it could not be substantiated sufficiently, was in breach of Section 1.3 as it was unbalanced and inaccurate and in breach of Section 1.7 as it was disparaging and was not capable of substantiation.

The Committee noted that there was no evidence in the Approved Product Information for these products to warrant a claim that Norvasc was safer than Zanidip. This claim of "safe administration with β-Blockers" was found to be breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct as it could not be adequately substantiated, was misleading and a disparaging and incorrect comparison.

The Committee found the claim "no alcohol interaction" to be in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct as it could not be substantiated, was misleading and disparaging.

The Committee found the claim "use in renal impairment" was incapable of substantiation and misleading therefore breaches of Sections 1.1 and 1.3 of the Code were found.

The Committee was not satisfied that sufficient evidence existed that would support such a definitive comparison as indicated by a tick or a cross, between the products based on missed dose protection. The Committee considered that a head-to-head trial would be the only way in which adequate support could be obtained for such a claim. This claim was found to be in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct as it could not be adequately substantiated, was misleading and made a disparaging comparison that could not be substantiated.

A majority of members of the Committee considered that the comparison between Norvasc and Zanidip "proven benefits in coronary artery disease", presented in this form, was misleading and disparaging, as there was some evidence to suggest that Zanidip did have a positive cardiovascular safety profile. By a majority decision a breach of Sections 1.1, 1.3 and 1.7 was found as it was considered that insufficient evidence existed to substantiate this strict via a tick or cross comparison which was misleading and disparaging.

The Committee considered that the claim "extensive clinical experience'" was too definitive and did not allow a reader to understand the amount of evidence and experience available for each product. It was agreed that although there was more clinical experience with Norvasc, there was still a substantial body of clinical evidence for Zanidip that this comparison failed to inform. The Committee resolved that breaches of Sections 1.3 and 1.7 should be found as the claim was misleading and a disparaging comparison.

The Committee discussed each company's product support programme noting that although the Norvasc program was more patient focussed, both programmes could be described as assisting patients in the treatment of hypertension. As this comparison was definitive and suggested that no patient support programme existed for Zanidip when this was not the case the Committee found that it was false. The Committee found breaches of Sections 1.1, 1.3 and 1.7 as the comparison could not be adequately substantiated, was false and a misleading and disparaging comparison.

The Committee resolved that a breach of Section 1.3 should be found as the claim, "98% of Norvasc patients were maintained on the starting dose of 5mg" without adequate qualification regarding the evidence to support it, was misleading.

Having found numerous breaches in the comparisons made in the table, the Committee unanimously agreed that the claim "because Norvasc has advantages that other CCBs don't" was in breach of Sections 1.1 and 1.7 as it could not be substantiated and was a misleading comparison.

Sanctions

Given the Committee's concerns regarding the number and severity of the breaches found in this promotional item and the likelihood that prescribers could be misled, the Committee resolved that Pfizer 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 of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

- be required to send a corrective letter to all general practitioners advising of the breaches of the Code of Conduct and correcting the misleading and incorrect claims contained in this promotional item.
- be required to print a corrective advertisement that should appear as a half page advertisement in an edition of Australian Doctor and Medical Observer advising of the breaches of the Code of Conduct and correcting the misleading and incorrect claims made in the promotional item.
- should pay a fine of $50,000 for the breaches found as the Committee considered that this promotional item, and in particular the misleading table, may have a real effect on the prescribing of the two products featured.

25. Pfizer Pty Ltd Aricept (654)

Journal Advertisement entitled:
"Alzheimers is a thief. Aricept is a gift"

Promotional Mailer entitled:
"Some gifts are beyond value"

Complaint
A complaint was received from Janssen-Cilag Pty Ltd alleging that promotional material for Aricept by Pfizer Pty Ltd was in breach of Section 1.2 of the Code of Conduct. Janssen-Cilag Pty Ltd claimed that the advertisements and the mailer used a poster presentation as the sole reference or a poster and data on file as the reference for support of the claims. Pfizer Pty Ltd was also requested to respond to Sections 1.3 and 1.7 of the Code of Conduct.

Response
A response dated 13 March 2002 had been received from Pfizer Pty Ltd denying any breach of the Code of Conduct. Pfizer Pty Ltd claimed that the claims made were correct and could be substantiated.

Committee ruling
The Committee reiterated the recommendations of a previous Code of Conduct Committee that companies should not rely upon poster presentations and abstracts that may not be adequately refereed or subsequently published, as the basis for significant promotional claims.

It was the view of the Committee that given these concerns, particularly the lack of a peer-review study, it was inappropriate to base a comparative promotional campaign upon these results alone. The Committee noted that the promotional material referred to "evidence" which was only in the form of a poster presentation and that the use of this term could influence a prescribing decision given health care professional's preference for evidence based medicine.

The Committee also noted that Pfizer Pty Ltd funded this study. The Committee noted its preference for such sponsorship to be disclosed in order for prescribers to be fully aware of the study's funding source.

The Committee concluded a breach of Section 1.3 should be found as there was inadequate substantiation in relation to the claim made regarding reduction in care giving times which may lead to a prescriber being mislead. No breaches of Sections 1.2 or 1.7 of the Code were found.

Sanction
The Committee resolved that Pfizer 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 of the Code should not be used again in their present form or in a manner that conveyed the same or similar meaning.

Appeal
Pfizer Pty Ltd lodged an appeal against the findings imposed by the Code of Conduct Committee. Pfizer Pty Ltd maintained that the poster presentation reflected the results of a credible and significant study and that its use satisfied the list of examples listed in the Explanatory Notes of Section 1.3. Pfizer Pty Ltd also claimed that the provision of important information via a poster presentation was accepted within the medical community and the prohibition of such communication.

Committee ruling
The Code of Conduct Appeal Committee discussed the current Code provisions and the ability to use poster presentations to support promotional claims. It was noted that the current edition of the Code did not prohibit the use of such evidence however companies should ensure that sufficient detail is

provided via the poster presentation so that prescribers are not misled and have sufficient information to substantiate the claims being made. The lack of peer review was also cited by the Code of Conduct as an issue that should be considered by companies wishing to use poster presentations to ensure that the poster could be cited as verifiable and credible evidence to support the claims being made.

The Committee agreed with the original decision that the poster presentation did not provide sufficient information that would afford the average reader with confidence that the claim being made was correct or appropriate. Members of the Committee reviewed the poster presentation in detail and were not confident that a prescriber would be able to ascertain sufficient information to be assured that the claim made was correct and relevant to their practice of medicine.

The Committee unanimously agreed that the decision of the Code of Conduct Committee to find a breach of Section 1.3 should stand and the appeal should not be upheld.

Sanction
The Code of Conduct Appeal Committee resolved that the sanction imposed by the Code of Conduct Committee was considered appropriate and required no amendment.

26. Roche Products Pty Ltd Xenical (655)

Television feature entitled:
"Linda's Story"

1800 Direct Response Telephone Number

Patient Education Booklet

Complaint
A complaint was received from the Therapeutic Goods Administration (TGA) advising that it had received a letter of complaint alleging that a television feature was promoting a prescription product direct to consumers. The TGA had forwarded this letter to the APMA as a complaint under its Code of Conduct. This complaint was provided to Roche Products Pty Ltd which was requested to respond to Sections 9.1, 9.2, 9.4, 9.5, 10 and 10.1 of the Code of Conduct.

Response
A response was received from Roche Products Pty Ltd denying any breach of the Code of Conduct. Roche Products Pty Ltd claimed that the overarching objective of its activities was to raise awareness of the increasing problem of obesity and encourage people to take responsibility and effective course of action, which was to see their general practitioners.

Committee Ruling
Some members of the Committee considered that the television feature "Linda's Story" was promoting a specific product to the general public as the script mentioned "a scientifically proven treatment" although not mentioning the product by name. This reference, and the need to consult a doctor, convinced these members of the Committee that this feature would lead a consumer to contact a doctor in search of a prescription for the product referred to by "Linda".

Other members of the Committee considered that although approaching promotion of a prescription product, as the feature did not mention a product by name and only inferred a product, this feature should not be considered as promotion.

In relation to the 1800 Direct Response Telephone Number the Committee considered that the provision of a doctor's contact details in this instance was acceptable providing the doctors had given their permission and that the doctor's information was current and an accurate reflection of their wish to remain on this database. The Committee also expressed some concern regarding the definition of obesity used in the script for the telephone response (>30 BMI) which it considered may not lead to the correct referral to a general practitioner for consumers with a BMI of 25-29.

The Committee was of the view that the operators of the 1800 number were being required to provide diagnostic advice in determining who should go to their doctor via the discussion of a caller's BMI. Given that the operators were providing information or advice regarding the diagnosis of a disease the Committee found a breach of Section 9.1 of the Code.

The Committee considered that the information contained in the Patient Education Booklet was unbalanced as it concentrated on prescription medications as the solution to weight loss rather than emphasising other options such as lifestyle changes and then moving to medication if necessary. Although

noting the need for exercise the Committee was not convinced that a reader would consider that a lifestyle change incorporating exercise should be the first step in a weight loss program.

The Committee noted that the booklet concentrated on one type of prescription medicine and implied the unsuitability of other prescription medicines. The Committee considered that this emphasis was unbalanced. The Committee did acknowledge however, that the booklet provided some useful information that would be beneficial for consumers.

By a majority decision the Committee found that the combination of the television feature that referred to availability of prescription medicines and the unbalanced nature of the booklet, was sufficient to find a breach of Section 9.4 as this material encouraged patients to seek a prescription for a prescription-only product.

The Committee found the material in the booklet to be in breach of Section 9.5 of the Code as it was not balanced. The Committee considered that the booklet should have included information on lifestyle changes including diet as a first step in any weight loss program before the option of prescription only products are considered. The booklet should also have been accurate and balanced in its description of other prescription medicines that may be available for weight loss. A breach of Section 9.5 of the Code was found.

Whilst no breach of the Code was found in relationship to Section 10, concern was expressed over the role and independence of a doctor being enlisted by a particular company and that name being provided to a consumer.

Sanction
The Committee considered that the breaches found would not cause patient harm and that in some instances the provision of information about diseases or conditions and their treatments were appropriate and outweighed any potential risks.

The Code of Conduct Committee resolved that Roche Products Pty Ltd 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. Care should be taken so that any new materials did not convey the same or similar meaning. The Committee considered that balanced consumer information on obesity, including comment on lifestyle and dietary issues, would be beneficial.

27. Abbott Australasia Pty Ltd Reductil (656)

Promotional material entitled:
"Introducing the simple new approach to effective weight management"

Complaint
A letter of complaint was received from Roche Products Pty Ltd alleging that promotional material for Reductil by Abbott Australasia Pty Ltd was in breach of Sections 1.1 and 1.3 of the Code of Conduct. Roche Products Pty Ltd claimed that the advertisement carried claims which were inaccurate, incorrect and/or not fully supported by the Reductil Product Information.

Response
A letter of response was received from Abbott Australasia Pty Ltd denying any breach of the Code of Conduct. Abbott Australasia Pty Ltd claimed that the advertisement did not compare Reductil with any competitor product but focussed on educating prescribers about Reductil in relation to its mode of action with a focus on the benefits of long term sustainable weight loss.

Committee ruling
The Committee considered the data provided to support the claim "Reductil prevents decline in energy expenditure during weight loss" and agreed that the statement was sufficiently in line with the general body of available data and the Approved Product Information so as not to be in breach of Sections 1.1 or 1.3 of the Code.

The Committee agreed that the claim "The Reductil 10 - 20 - 30 patient support program combines therapy and behaviour modification to achieve sustainable weight loss" could be supported and should not be considered as misleading and no breach of Section 1.3 of the Code was found.

The Committee agreed with Abbott Australasia Pty Ltd's substantiation for the statement noting "Long-term Reductil-induced weight loss provides sustained

improvement in HDL and triglycerides" reflected similar comments in Reductil's Approved Product Information, therefore no breach of Sections 1.1 or 1.3 of the Code was found.

The Committee noted that Abbott Australasia Pty Ltd had already corrected the statement "Minimal Cardiovascular Effects" in recent advertising and correspondence reminding physicians of the need to monitor their patients' blood pressure and heart rate as recommended in the Reductil Product Information.

However, the Committee agreed with Roche Products Pty Ltd that as currently stated this claim could not be adequately supported and was misleading given the body of clinical evidence and the cardiovascular warning in Reductil's Product Information. The Committee was unsure what a reader would imply via the term "minimal" which added to the Committee's reasoning to find a breach of Section 1.1 and 1.3.

By a majority decision the Committee agreed that the use of "simple" in the claim "Introducing the simple new approach to effective weight management" was easily understood and was found not to be in breach of Section 1.3 of the Code.

Sanction
The Code of Conduct Committee resolved that Abbott Australasia 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 current form. The claim found in breach should not be used again in its present format or in a manner that conveyed the same or similar meaning.

28. GlaxoSmithKline Australia Augmentin (657)

Promotional material entitled:
"Clinical failure at 32,000ft"

Complaint
A complaint was received from Aventis Pharma alleging that promotional material for Augmentin by GlaxoSmithKline Australia was misleading to prescribers and relied on incorrect comparison of in-vitro data to support a claim of clinical superiority and was therefore in breach of Sections 1.3 and 1.7 of the Code of Conduct.

Response
A response was received from GlaxoSmithKline Australia denying any breach of the Code of Conduct. GlaxoSmithKline Australia responded that the purpose of the promotional material was to inform doctors of recent resistance data as part of the responsible prescribing of antibiotics. GlaxoSmithKline Australia considered that resistance was an important issue for doctors to consider when choosing an antibiotic, if one was warranted.

Committee ruling
A majority of Committee members considered the claim "Augmentin delivers first time" was not unreasonable in the context, would not confuse or mislead a reader and was qualified by a statement referring to resistance to amoxycillin. It was also agreed that the claim was merely a statement that did not infer any comparison and hence could not be considered as a hanging comparator. By a majority decision, no breach of Sections 1.3 or 1.7 was found.

The majority of Committee members considered that the included graph was accurate, had been clarified with a qualifying statement regarding extrapolating in vitro activity to clinical response and hence would not be likely to mislead. The Committee considered that the provision of this type of information was important for prescribers and did not agree with the complainant that it inferred an unsupportable clinical superiority. By a majority decision, no breach of Sections 1.3 or 1.7 of the Code of Conduct was found. The Committee agreed however, that it would be preferable, that the use of the qualifying statements "In vitro activity does not imply clinical response" should be made more prominent.

29. Merck Sharp & Dohme (Australia) Pty Ltd Fosamax (658)

Advertisement entitled:
"Once a week"

Advertorial Feature entitled:
"Treating Osteoporosis"

Behaviour of a medical representative

Complaint
A complaint was received from Aventis Pharma alleging that promotional material for Fosamax by Merck Sharp & Dohme (Australia) Pty Ltd was in breach of Sections 1.3 and 1.7 of the Code of Conduct and that the behaviour of one of its medical representatives was in breach of Sections 4.1 and 4.4 of the Code of Conduct.

Response
A letter of response was received from Merck Sharp & Dohme (Australia) Pty Ltd denying any breach of the Code. Merck Sharp & Dohme (Australia) Pty Ltd also requested that the complaint relating to allegations made by an unknown general practitioner should not be considered by the Code of Conduct Committee as no opportunity had been allowed to discuss this matter with Aventis Pharma nor had the identity of the prescriber or medical representative been disclosed.

Committee ruling
The Committee agreed that the quoted study did not provide sufficient evidence to support a claim regarding superior tolerability as it only inferred a trend or a possibility of superiority rather than proof of this benefit. This was considered misleading and in breach of Section 1.3 of the Code of Conduct.

The Committee agreed that the statement "overall clinical and laboratory adverse event profiles were very similar across treatment groups" could not be considered as a comparison with other forms of Fosamax or other bisphosphonates and hence resolved to find no breach of Section 1.7 of the Code.

Although the advertorial material could have been made clearer, the Committee did not agree that the content of the advertorial represented a breach of either Section 1.3 or 1.7 of the Code.

As no details of the medical representative or doctor had been provided by Aventis Pharma, the Committee resolved that it should not consider this aspect of the complaint.

Sanction
The Committee 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 current form. The claim found in breach should not be used again in its present format or in a manner that conveyed the same or similar meaning.

30. Alcon Laboratories (Australia) Pty Ltd Travatan (660)

Product Monograph entitled:
"Travatan (Travoprost) Eye Drops 0.004%"

Promotional material entitled:
"Power - Control"

Complaint
A complaint was received from Allergan Australia Pty Ltd alleging that promotional material for Travatan by Alcon Laboratories (Australia) Pty Ltd was in breach of Sections 1.3 and 1.7 of the Code of Conduct. Allergan Australia Pty Ltd alleged that the material incorrectly characterised the active species of Lumigan and that through the use of claims implied greater potency when compared to other products.

Response
A response was received from Alcon Laboratories (Australia) Pty Ltd denying any breach of Sections 1.3 and 1.7 of the Code Conduct. Alcon Laboratories (Australia) Pty Ltd maintained that the data in the promotional material was clearly pharmacological and not clinical and that no claims or suggestions about the clinical efficacy of Lumigan were made in the monograph. It also refuted the assertion that the material claimed that PBS listing was certain.

Committee ruling
The Committee was not convinced that a reader of

the table comparing the functional activity of various agents would be misled. As there was no inference that the table was making a comparison to Lumigan no breach of Section 1.3 of the Code was found.

The Committee noted that given the current PBS listing system it would be unlikely that Alcon Laboratories (Australia) Pty Ltd could be assured that it would gain PBS listing for Travatan effective on 1 August, 2002 when this material was released.

Whilst it is up to the health professional to make a decision on the most appropriate treatment, they must also make a decision whether it is better to prescribe subject to the possibility of having to change products if the product is not PBS listed and the patient can no longer afford the product, or prescribe a product that is already listed and guaranteed of supply via the PBS. Some members of the Committee considered that health professionals should be in a position to make this fact known to the patient at the time of the prescribing.

As the meaning of the seal was unclear and seemed to infer that PBS listing was guaranteed, the Committee, by a majority decision found its use in breach of Section 1.3 as it was misleading.

The Committee agreed that the claim "More patients respond to Travatan" was a hanging comparative. Alcon Laboratories Pty Ltd had previously acknowledged this breach of Section 1.7 and had agreed to withdraw the claim.

Sanction
The Code of Conduct Committee resolved that Alcon Laboratories (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 current form. The claims found in breach should not be used again in their present format or in a manner that conveyed the same or similar meaning.

31. GlaxoSmithKline Australia Seretide (661)

Advertisement entitled:
"Control asthma like never before"

Poster Presentation entitled:
"Seretide (fluticasone propionate 250µg salmeterol 50µg bd shows nocturnal and exacerbation benefits over budesonide 800µg + eformoterol 12µg bd"

Medical Director Conversion Chart entitled:
"How to upgrade your Becotide and Becloforte patients"

Complaint
A complaint was received from AstraZeneca Pty Ltd alleging that claims made for Seretide by GlaxoSmithKline Australia in various promotional materials were not capable of substantiation and that the conversion chart was likely to inappropriately influence prescribers' choice. AstraZeneca Pty Ltd alleged that the materials were therefore in breach of Sections 1.1, 1.3, 1.7 and 3.10.11 of the Code of Conduct.

Response
A response was received from GlaxoSmithKline Australia denying any breach of Sections 1.1, 1.3, 1.7 and 3.10.11 of the Code of Conduct. GlaxoSmithKline Australia claimed that the promotional materials were supported by cited references and represented the body of evidence on the subject.

Committee ruling
The Committee discussed the use of the words "reduces exacerbations" noting that the evidence to support this claim was in the form of a comparison rather than the measurement of any reduction in exacerbations. The poster presentation used the words "a trend towards fewer exacerbations" although it also claimed that there were "significantly fewer exacerbations per patient with Seretide". The Committee noted that these two statements might cause confusion amongst prescribers.

The Committee did not agree with the complainant that the phrasing "night time asthma symptoms and awakenings" suggested two distinct variables and

were satisfied that this statement could be supported.

The Committee found no breach of Sections 1.1, 1.3 or 1.7 as on balance it considered that the statements made could be supported and were not misleading. However the Committee did recommend that some qualification be made to the claim regarding exacerbations to clarify the source of the evidence to support this claim and limit its ability to be generalised.

The Committee was not convinced that the statement "So to prevent and control asthma in one breath, switch to Seretide" would be read as a call to switch patients from a combination of budesonide and eformoterol to Seretide based on a study that was not a switch study. The Committee was of the view that doctors would not be likely to be misled. No breaches of Sections 1.1 or 1.3 of the Code were found.

In relation to the Medical Director Conversion Chart the Committee agreed that it was important that information regarding alternate products be provided to prescribers if it was known that a product was to be withdrawn. In this instance the Committee was satisfied that the placement of the conversion chart was appropriate as it was after the decision to prescribe Becotide or Becloforte had been made by a prescriber. The Committee also noted that there was an option for the prescriber not to proceed to the Conversion Chart should they wish. The Committee did however consider that a single button that directed the prescriber to the A-Z Directory on the first screen advising of the discontinuation of Becotide and Becloforte would be of assistance to prescribers. This did not result in a breach of the Code as the ability to access the Conversion Chart would be of benefit to prescribers and patients.

32. Pharmacia Australia Pty Ltd Xalatan (662)

Brand Name Reminder:
"Coconut Rough chocolate with Xalatan name and logo"

Complaint
A complaint was received from Alcon Laboratories (Australia) Pty Ltd alleging that a brand name reminder for Xalatan by Pharmacia Australia Pty Ltd Australia Pty Ltd, which included pictorial images, could be considered promotional. Alcon Laboratories Pty Ltd alleged that the image was promotional and was in breach of Section 3.3.3.2 of the Code of Conduct.

Response
A response was received from Pharmacia Australia Pty Ltd denying any breach of the Code of Conduct. Pharmacia Australia Pty Ltd alleged that the complaint was frivolous in nature and not within the spirit of the Code.

Committee ruling
The Committee noted that the name Xalatan with the accompanying two arrows had been used in other Xalatan material. The Committee agreed that under the requirements of Section 3.3.3 of the Code, the Xalatan brand name reminder did not breach the Code, as it did not contain any promotional claim or statement.

33. CSL Ltd Flomax (663)

Promotional Material entitled:
"Treat BHP/LUTS without lowering blood pressure"

Complaint
A complaint was received from a medical practitioner alleging that promotional material for Flomax by CSL Ltd was false and misleading and therefore in breach of Section 1.3 of the Code of Conduct.

Response
A response was received from CSL Ltd denying any breach of the Code of Conduct. CSL Ltd maintained that the promotional card was neither false nor misleading and that the medical representative provided accurate and appropriate information to the medical practitioner.

Committee ruling
The Committee noted that the claim made in the promotional material "Treat BHP/LUTS without lowering blood pressure" did not seem to accurately reflect the graph referring to clinically relevant cardiovascular side effects. By a majority the Committee found the promotional material to be misleading and therefore in breach of Section 1.3 of the Code.

Sanction
The Committee resolved that CSL 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 current form. The claim found in breach should not be used again in its present format or in a manner that conveyed the same or similar meaning.

34. Novartis Pharmaceuticals Australia Pty Ltd Zelmac (665)

Promotional Mailout entitled:
"Symptom relief for Irritable Bowel Syndrome is here"

Complaint
A letter was received from a medical practitioner alleging that promotional material for Zelmac by Novartis Pharmaceuticals Australia Pty Ltd was in breach of Sections 1.1, 1.3 and 1.3.1 of the Code of Conduct as the promotional material could be misinterpreted by medical practitioners that Zelmac was indicated for males and females.

Response
A response was received from Novartis Pharmaceuticals Australia Pty Ltd denying any breach of the Code of Conduct. Novartis Pharmaceuticals Australia Pty Ltd maintained that there was no deliberate intention to mislead doctors into believing that Zelmac could be prescribed for men and that the Approved Product Information was included with the mailer.

Committee ruling
The Committee agreed that while the Approved Product Information that accompanied the promotional material clearly stated that Zelmac was approved for use in females only, the promotional material included pictures of both males and females.

The Committee found that Novartis Pharmaceuticals Australia Pty Ltd had a responsibility to ensure that its promotional material was compliant with the Approved Product Information and the Code. By implication the promotional piece was advocating the use of Zelmac in people of either gender which is contrary to the Approved Product Information. The Committee therefore found that the promotional material was in breach of Sections 1.1, 1.3 and 1.3.1 of the Code.

Sanction
Having found a breach of the Code of Conduct the Committee considered an appropriate sanction. The Committee resolved that Novartis Pharmaceuticals 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 current form. The inference found in breach should not be used again in its present format or in a manner that conveyed the same or similar meaning.

35. Aventis Pharma Rulide (666)

Promotional Mailer entitled:
"Rulide has excellent clinical success in RTIs"

Complaint
A complaint was received from GlaxoSmithKline Australia alleging that promotional material for Rulide by Aventis Pharma was in breach of Sections 1.3 and 1.7 of the Code of Conduct. GlaxoSmithKline Australia alleged that there was little or no evidence to support the Rulide claims which were also disparaging. GlaxoSmithKline also alleged that these claims constituted a repeat breach.

Response
A response was received from Aventis Pharma denying any breach of the Code of Conduct and alleging that the complaint was an attempt to thwart legitimate commercial activities. Aventis Pharma maintained that the claims were appropriate and capable of substantiation.

Committee ruling
The Committee agreed that the more usual coverage of antimicrobials for respiratory tract infections related to infections of the lower respiratory tract (ie chest/ lungs). The Committee considered the inference that atypical pathogens are important across the board ie upper and lower respiratory tract, did not reflect the current scientific evidence or such publications as the Antibiotic Guidelines.

By a majority the Committee found the mailer to be

in breach of Section 1.3 of the Code as it had the potential to mislead prescribers by the implication that Rulide should be prescribed for all RTIs including all URTIs.

Sanction
The Committee resolved that Aventis Pharma 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 current form. The claim found in breach should not be used again in its present format or in a manner that conveyed the same or similar meaning.

Although the Committee found Aventis Pharma in breach of Section 1.3 in relation to this complaint, it was of the view that this breach did not constitute a repeat breach.

36. AstraZeneca Pty Ltd Oxis Turbuhaler (667)

Promotional Materials entitled
"Eformoterol is the only long acting beta-agonist indicated for PRN use"
"Faster Relief"

Complaint
A complaint was received from GlaxoSmithKline Australia alleging that promotional material for Oxis Turbuhaler by AstraZeneca Pty Ltd was in breach of the Code of Conduct. The complaint alleged that the claims in relation to Oxis Turbuhaler were inaccurate and misleading and were therefore in breach of Sections 1.1 and 1.3 of the Code of Conduct.

Response
A response was received from AstraZeneca Pty Ltd denying any breach of the Code of Conduct. AstraZeneca Pty Ltd maintained that the claims in the promotional material quoted the approved PRN (Pre re nata – as circumstances may require) indications and dosage and were not inaccurate or misleading.

Committee ruling
In relation to the claim "No safety issues were identified in either group and eformoterol was as well tolerated as terbuline" the Committee determined that the patients involved were clearly identified and that the approved use was stated on the promotional material. The Committee found no breach of Sections 1.1 or 1.3 of the Code in relation to inaccurate or misleading claims. The Committee also found no breach of Section 1.3 of the Code in relation to the claim "eformoterol is fast acting".

The Committee was in agreement that the use of the statement "as a reliever medication" did not imply that it should be used for the relief of acute exacerbations. The Committee found no breach of Sections 1.1 or 1.3 of the Code in relation to inaccurate or misleading claims.

The Committee agreed that the claims in relation to the "reduced risk of severe exacerbations and fewer inhalations" were not generalised and were clearly referenced. The claims were not found in breach of Sections 1.1 or 1.3 of the Code.

Monitoring Report
1 July 2001 - 30 June 2002

Although committed to the ongoing review of promotional material and activities, due to the relocation of the Medicines Australia office to Canberra and staff changes with the Medicines Australia national office, the Monitoring Committee did not meet during the year. In addition to the Committee meeting in the new financial year, other mechanisms are being considered by Medicines Australia to enhance its monitoring activities. These will be reported upon in next year's Code of Conduct Annual Report.

1. Nature and Availability of Information and Claims

1.1 Responsibility

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 Product Information. 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 Member 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 reasonable 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.

1.4 Good Taste

Promotional material (including graphics and other visual representations) should conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

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.

1.9 Medical Ethics

Doctors' names or photographs must not be used in any way that is contrary to medical ethics.

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 Product Information.

Wherever required, Product Information must appear in a type size of not less than 1 mm 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 Full Disclosure Product Information

2.1.1. With the exception of full advertisements*, full disclosure Product Information must accompany all promotional material for a period of 24 months from the date of first advertising of a new chemical entity* in Australia or longer, at the discretion of the advertiser.

3. Promotional Material*

For products that have a "Boxed Warning" included in their Approved Product Information, all promotional material must include the Boxed Warning or include a prominent statement drawing attention to the Boxed Warning.

3.3.1 Printed promotional material

3.3.1.3 The use of full disclosure Product Information is mandatory for promotion of all new chemical entities for 24 months from the date of first advertising, or longer at the discretion of the Member. Abridged disclosure Product Information may be used subsequent to that period.

3.3.3 Brand name reminders*

3.3.3.2 Brand Name Reminders are not to contain any promotional claims/and or statements.

3.10 Advertising in Electronic Prescribing Software Packages

The following provisions are applicable to advertising included in electronic prescribing software packages. Advertisements for products covered by this Code can be included in electronic prescribing software.

3.10.11 The company shall not negotiate or accept any offer from a software manufacturer to achieve a preferential presentation of its own product or a less favourable presentation of a competitor's product in a way that could reasonably be held as likely to influence the prescriber's choice.

4. Medical Representatives

4.1 Medical Representatives must only use promotional material, which conforms to the provisions of Section 3 of this Code. Verbal statements made about a product must comply with the provisions of Section 1 of this Code.

4.3 Medical Representatives should possess sufficient medical and technical knowledge to present information on the company's products in an accurate current and balanced manner and should be cognisant of all provisions of this Code.

4.4 Medical Representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.

4.6 Medical Representatives should ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as not to cause inconvenience. The wishes of an individual doctor, or the arrangements in force at any particular establishment, must be observed by Medical Representatives.

5. Product Starter Packs*

Care should be exercised by Members that the distribution of Starter Packs is carried out in a reasonable manner. There are a number of State Laws which control the supply and storage of products.

5.1 Starter Packs of products may only be supplied at their request to medical practitioners, dentists and hospital pharmacists for use in accordance with Section 5.2.

Product Information and Consumer Medicine Information, when available, should be offered at the time of distribution or included in the product pack.

5.2 Starter Packs should only be supplied to medical practitioners, dentists and hospital pharmacists when required for any of the following reasons:

(a) for immediate use in the surgery for relief of symptoms, or
(b) for the use of alternative treatments, prior to a prescription being written, or
(c) for after hours use, or
(d) for gaining familiarisation with products.

6. Trade Displays

General Principle

Trade displays are important for the dissemination of knowledge and experience to the healthcare professions. The prime objective in organising such displays should be the enhancement of medical knowledge. Where hospitality is associated with Symposia and congresses, it should always be secondary to the main purpose of the meeting.

6.4 Product information for products being promoted must be available from the display stand.

7. Travel and Sponsorship

7.1 The following applies to Members sponsoring delegates travelling FROM or WITHIN Australia to Symposia and/or congresses:

- Travel may be subsidised provided the meeting is directly related to the healthcare professional's area of expertise.
- Travel should generally be by Economy or Business Class. First Class travel should only be used for international travel and then only in exceptional circumstances.
- A reasonable level of accommodation expenses may be covered.
- Expenses for family or travelling companion(s) should not be paid by the sponsoring Member.

7.3 The Symposia's focus should be on scientific and medical matters and hospitality should be kept to a minimum level.

7.4 Where Members undertake sponsorships such support must be able to withstand public and professional scrutiny, and conform to professional standards of ethics and good taste.

9. Communications with the General Public

9.1 General Inquiries

Inquiries regarding the use of products must be handled by appropriately qualified personnel. Requests from individual members of the public for information or advice on the diagnosis of disease or choice of therapy must always be refused and the inquirer recommended to consult their doctor.

9.2 Media Statements

9.2.1 A media release issued directly, or through conferences for the lay media to announce a new product or major indication approval to the public, will be allowed if the product has been registered for use in Australia and the medical profession has been supplied with the appropriate information.

The written media release must be confined to the use of the Australian Approved Name of the product, approved indications and Therapeutic Class. No reference to the launch date must be made and no promotional claims or comparisons to other products made.

9.2.2 No other promotional media releases are permitted except under Section 9.2.1. but it is acceptable to respond to an inquiry.

9.3 General Media Articles

General media articles concerning specific prescription products must not be initiated by Members of the industry. However, information on medical conditions is allowed.

Members should not attempt to encourage the publication of general media articles or their content with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

9.4 Promotion to the General Public

It is the intention of the Code that prescription products be promoted only to healthcare professionals. Non-promotional material used in patient education must not contain material which could be regarded as advertising to the general public.

Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only product is unacceptable.

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.

9.5.1 The educational material should be current, accurate and balanced.

9.5.2 The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.

9.5.3 Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.

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.

10. Relations with Healthcare Professionals

Members may choose to support, initiate or become involved in activities with healthcare professionals. Such involvement either by financial or other means must be able to successfully withstand public and professional scrutiny, and conform to professional standards of ethics and of good taste.

10.1 Entertainment

Entertainment or other hospitality offered to healthcare professionals should be appropriate, secondary to the educational content and in proportion to the occasion; its cost should not exceed that level which the recipients might reasonably be expected to incur for themselves under similar circumstances.

- Inappropriate financial or material benefits, including inappropriate hospitality, should not be offered to healthcare professionals to influence them in their prescribing or dispensing of pharmaceutical products.

11. Administration of the Code

The administration of the Code shall be supervised by the Code of Conduct Committee, (hereinafter referred to as The Committee) which will be responsible to the APMA Board. Expert advice may be sought externally by the Committee in reaching a decision as to whether or not a breach has occurred.

11.1 Procedures

The following procedures shall apply in the event of the APMA receiving information alleging contravention by a Member of the Code of Conduct.