

MEDICINES
Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION



CODE OF
CONDUCT

2003



2002/2003 Code of Conduct Annual Report

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Welcome

Welcome to Medicines Australia's Code of Conduct Annual Report for the year ending 30 June 2003. This report provides information regarding the activities of the Code of Conduct and Monitoring Committees for the period 1 July 2002 to 30 June 2003. The material covered in this report provides a valuable insight into the operations of the Code of Conduct and the Committees that administer it and we invite you to read its content.

Commitment

Medicines Australia and its members are committed to promoting the concept of good health via the quality use of prescription medicines. As stated in the Code of Conduct, the industry recognises that medicines play a vital role in the prevention, amelioration and treatment of disease states and the industry undertakes:

- To provide medicines that conform to the highest standards of safety, efficacy and quality;
- To ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience; and
- To use professionalism in dealing with healthcare professionals, public health officials and the general public.

Medicines Australia and its member companies are committed to the National Medicines Policy including the quality use of medicines and rational prescribing, and urge that its medicines are used only in accord with the directions and advice of healthcare professionals.

The Statement of Priorities and Strategic Action Plan 2001-2003 for the Quality Use of Medicines cites four key priorities concerning information and ethical promotion of medicines:

- Disseminate and adopt objective information for all medicines, with a particular emphasis on Consumer Medicines Information;
- Coordinate activity to develop objective information;
- Include objective information in information technology developments; and
- Continue to develop standards for promoting pharmaceuticals and facilitate participation by all partners in ensuring ethical promotion of medicines.

The industry is committed to maintaining the standards set out in the Code of Conduct when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation.

Content

The Code of Conduct requires Medicines Australia to report on all complaints adjudicated by the Code of Conduct Committee and not subject to any outstanding appeals. This report therefore contains all final decisions of the Code of Conduct and Appeals Committees for the period 1 July 2002 to 30 June 2003.

Edition 14 of the Code of Conduct came into effect on 1 January 2003. Complaints in relation to activities or materials prior to this date were heard under Edition 13 of the Code. The text of the Sections of the Code of Conduct (Editions 13 and 14) referred to in the complaints can be found at the end of this report.

This report has been prepared from the minutes of the meetings of the Code of Conduct Committee and the Code of Conduct Appeals Committee and reflects the process of those meetings. As external audiences may not have the same level of understanding of the processes and provisions of the Code as those within the industry they are encouraged to contact Medicines Australia or visit the Medicines Australia website to obtain further information. Edition 14 of the Code states that "Information regarding complaints that involve activities directed towards members of the general public will be made available via the Medicines Australia website." This information will be provided in a similar format to that contained in the Code Annual Report.

Any questions relating to this Annual Report should be referred to the Secretary of the Code of Conduct Committee at Medicines Australia. Copies of the Code of Conduct can also be obtained by contacting Medicines Australia or by visiting the Medicines Australia website (www.medicinesaustralia.com.au).

SUMMARY OF RESULTS

1 JULY 2002 – 30 JUNE 2003



Medicines Australia received a total of 48 complaints for evaluation by the Code of Conduct Committee during the 12 months from 1 July 2002 to 30 June 2003. Seven of these complaints were not finalised as at 30 June 2003 due to appeals and have not been included in this report. Two complaints that were held over from the previous year and finalised in the 2002-2003 year are included in this report. This report contains details of the 36 finalised complaints considered by the Code of Conduct Committee.

The following tables are a summary of the complaints received by Medicines Australia during this period.

Complaints Analysis

Source of Complaints

Complainants	Number
Medicines Australia Member Company	28
Non-Member Company	1
Therapeutic Goods Administration	5
Healthcare Professionals	11
Consumer Organisations	1
Academics	2
Total of new complaints in 2002/2003	48

Result from Consideration of Complaints

Complaints	Number	Percentage
<i>Complaints held over from 2001/2002</i>	2	
Partial Breach	1	50%
Appeal not upheld – breach	1	50%
 <i>Complaints received in 2002/2003</i>	48	
Breach	16	33%
Partial Breach	10	21%
No Breach	8	17%
Complaint Withdrawn	5	10%
Complaint referred to a third party or not heard due to insufficient information	2	4%
Complaints held over until next reporting period	7	15%
 <i>Appeals</i>	7	
Breach	2	28%
Partial Breach	4	57%
No Breach	1	15%

Sanctions imposed on companies found in breach of the Code

Sanctions

Withdrawal of material found in breach	25
Corrective Advertisement	3
Corrective Letter	1
Fines	
\$0 – \$24,999	9
\$25,000 – \$49,999	1
\$50,000 – \$74,999	2
\$75,000 – \$99,999	1
\$100,000 – \$149,999	0
\$150,000 – \$200,000	0
Total value of fines	\$310,000

Length of Time to Resolve Complaints

	Days
Shortest	24
Longest	159
Average	59
Average for complaints without an appeal	47
Average for complaints involving an appeal	105

Performance Indicators

The Code of Conduct requires the disclosure of 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 July 2002 to June 2003 ranged from 24 to 159 days. The average number of days taken to finalise all complaints considered during this period was 59 compared with 61 the previous year. For complaints that did not go to appeal, the average number of days taken to finalise these complaints was 47 days compared to 39 in the previous year. The cause in delays in the finalisation of complaints during the year was generally in relation to finding a mutually acceptable meeting date for the subject company and complainant and the sourcing of external experts for the Code of Conduct Appeals Committee meetings.

Activities undertaken to increase awareness of the Code of Conduct

Throughout the year Medicines Australia undertook an education campaign to increase industry and stakeholder awareness of Edition 14 of the Code. Presentations were made to member and non member companies; advertising, marketing and public relations agencies; government advisory groups; conference organisers and pharmacy and medical organisations. Medicines Australia also had a trade display at the National Divisions Forum. In total Medicines Australia made presentations to 1505 individuals representing 53 organisations.

Organisation	Number of Presentations
Member Companies	7
Non Member Companies	6
Industry Briefing	1
Medical/Pharmacy	6
Government	3
Consumers	2
Agencies	21
CEP Facilitators	2
Seminars	5
<i>Total number of presentations</i>	53
Total number of participants	1505

Acknowledgments

The success of both the Code of Conduct and Code of Conduct Appeals Committees can be attributed to the participation and diligence of their Chairmen and members. Medicines Australia would like to thank these individuals for their continued commitment and diligence to the Medicines Australia Code of Conduct. In particular the contribution of Mr Gaire Blunt and Mr Ian Tonking in their respective roles as chairman of the Code of Conduct and Code of Conduct Appeals Committees is acknowledged.

Medicines Australia would also like to acknowledge the invaluable support and expertise provided by Ms Fiona Woodard, Ms Deborah Monk and Ms Heather Jones.

Committee Membership

The following is the composition of the Code of Conduct and Appeals Committees:

Code of Conduct Committee

Full Members

- Independent lawyer (Chair)
- Representative of the Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Representative of the Royal Australian College of General Practitioners (RACGP)
- Representative of the Australian Medical Association (AMA)
- Representative of the Australian Divisions of General Practice (ADGP)
- Representative of a Patient Support Group (with specialist qualifications)
- Representative of a Consumers Organisation
- 3 x Medicines Australia Association Representatives (with no conflict of interest in the class of the complaint/s being heard)
- 2 x Medicines Australia Medical/Scientific Directors (with no conflict of interest in the class of the complaint/s being heard)

Observers

- Representative of the Therapeutic Goods Administration (TGA)
- A Member of Medicines Australia's Marketing Working Group (with no conflict of interest in the class of the complaint/s being heard)
- Two employees of Medicines Australia Member Companies (with no conflict of interest in the class of the complaint/s being heard)
- An observer interested in the Code process

Advisors

- Code of Conduct Secretary
- Medicines Australia Chief Executive Officer or delegate
- Medicines Australia officer responsible for Scientific and Technical Affairs

Code of Conduct Appeals Committee

Full Members

- Independent lawyer (Chair)
- Representative of the Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- One representative from the target audience to which the promotional activity has been directed eg RACGP, AMA, ADGP or consumer
- One representative from the Colleges and/or Societies from the Therapeutic class of the product
- 2 x Medicines Australia Association Representatives (with no conflict of interest in the class of the complaint/s being heard)
- Medicines Australia member company Medical/Scientific Director (with no conflict of interest in the class of the complaint/s being heard)

Advisors

- Code of Conduct Secretary
- Medicines Australia Chief Executive Officer or delegate

Medicines Australia Code of Conduct Committee

The Code of Conduct Committee met 11 times during this reporting period. The following table indicates the attendance of the external members of the Committee. Edition 14 of the Code of Conduct requires the participation of an ASCEPT member at each Committee meeting and a minimum of two Medicines Australia member company representatives to ensure a quorum of six full members.

External Organisation	Number of Meetings Attended
Australian Medical Association	7
Royal Australian College of General Practitioners	11
Australian Divisions of General Practice (ADGP became eligible to nominate a representative with the introduction of Edition 14 of the Code effective 1 January 2003)	4
Australian Society of Clinical and Experimental Pharmacologist and Toxicologists	11
Patient Support Group	8
Therapeutic Goods Administration	11
Consumers' Health Forum	8



1. Eli Lilly Evista (659)

Promotional advertisement entitled:

“One osteoporosis treatment offers a unique solution”

Complaint

A complaint was received from a healthcare professional alleging that promotional material for Evista by Eli Lilly Australia Pty Ltd (Eli Lilly) was in breach of the Code of Conduct. The complaint alleged that the claim “93% reduction in multiple vertebral fracture” was misleading. Eli Lilly was invited to respond to Section 1.3 of the Code of Conduct.

Response

A response was received from Eli Lilly denying any breach of the Code of Conduct. Eli Lilly maintained the view that the evidence was sufficient to support the claim.

Committee Ruling

The Committee found that the use of this major and influential claim “93% reduction in multiple vertebral fracture” was misleading as it was an unbalanced representation of the results of a study. The Committee noted that this finding was not the primary endpoint of the study, had been derived from a subset analysis, was selective in its positive portrayal of the results and hence was unbalanced. The data were derived from a poster presentation and did not appear to have been published in full in a peer reviewed journal. The Committee agreed that these findings would be of interest and value to prescribers but should have been provided in a more balanced and appropriate manner. The Committee unanimously agreed that the claim was misleading and in breach of Section 1.3 of the Code.

Sanction

The Committee resolved that Eli Lilly 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 conveys the same or similar meaning.

The Committee further resolved that Eli Lilly should be required to place a corrective advertisement once in each publication where this advertisement had appeared to correct the misleading claim.

Appeal

Eli Lilly lodged an appeal against the findings imposed by the Code of Conduct Committee however this was subsequently withdrawn and the corrective action as determined by the Code of Conduct Committee undertaken by the company.

2. Alcon Laboratories (Australia) Pty Ltd Travatan (664)

Promotional material entitled:

“The most powerful prostaglandin analogue”

“Confirmation Fax entitled:”

POWER ▼ CONTROL

Complaint

A complaint was received from Pharmacia Australia Pty Ltd (Pharmacia) alleging that promotional material for Travatan by Alcon Laboratories (Australia) Pty Ltd (Alcon) was in breach of Sections 1.3, 1.5 and 1.7 of the Code of Conduct. Pharmacia alleged that the claims were based on the selective and misleading use of data from a single trial, which was not designed to show non inferiority.

Response

A response was received from Alcon denying any breach of the Code of Conduct. Alcon maintained that much of the complaint was unfounded due to the analytical approach taken by Pharmacia.

Committee ruling

The Committee was of the opinion that the data did not support the use of the word ‘consistently’ across the whole 12 months. It would appear to only be of significance at one point on the graph and that this is not sufficient to make a generalised statement. It considered the oversimplification of complex data did not provide a balanced and accurate reflection of the results. Through the use of unsubstantiated and inaccurate data the Committee found that the use of the word ‘consistently’ in the promotional claim “consistently lower IOP results” to be in breach of Sections 1.3 and 1.7 of the Code.

The Committee was also of the view that the claims “Travatan provides consistently lower trough pressures – even at 12 months” and “Travatan provides the most powerful control at trough” were not an accurate reflection of the data and the use of the words ‘most powerful’ was a ‘hanging’ comparative and therefore the claims were in breach of Sections 1.3 and 1.7 of the Code.

The Committee also questioned the use of very small asterisks used in the promotional material. The minute size made it difficult for a reader to recognise it and make the connection between it and the notes at the edge of the graph.

The Committee also expressed some reservations about the racial demographics of the study and their applicability to the Australian population.

The Committee found that the graph entitled “More patients respond to Travatan and significantly more patients respond to Travatan than Xalatan” should be referenced to the appropriate study. The claims were found to be in breach of Section 1.3 of the Code as the material had the potential to mislead prescribers.

The Committee agreed that while this graph may be correct for a single trial, Alcon should not use this invitro data for a major promotional claim and was therefore in breach of Section 1.3 of the Code.

Confirmation Fax

As the confirmation fax contained previously mentioned claims it was therefore in breach of Sections 1.5 and 1.7 of the Code.

Sanction

The 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 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 conveys the same or similar meaning.

The Committee also resolved that Alcon should send a corrective letter to all healthcare professionals and print a corrective advertisement correcting the misleading and incorrect claims made in the promotional item.

Alcon was also required to pay a fine of \$10,000.

Appeal

Alcon lodged an appeal against the findings of the Code of Conduct Committee. Alcon maintained that there was sufficient data to support the claims. Alcon claimed that the TGA had deemed the population to be relevant and the Code of Conduct Committee had erred in some decisions unrelated to the complaint by Pharmacia.

Committee ruling

The Code of Conduct Committee had determined that the claim “The most powerful prostaglandin analogue” was a breach of Section 1.5 and 1.7 of the Code as it could not be substantiated and was considered as a “hanging comparative”. The Code of Conduct Appeals Committee agreed that a breach of Section 1.7 of the Code on the basis that this claim was a “hanging comparative” which had not been raised in the original complaint should not have been found and agreed to uphold Alcon’s appeal against this finding. It was the view of the Committee that the data presented to it did not provide sufficient unequivocal evidence to support such a strong and comparative claim. The Appeal Committee agreed with the conclusion of the Code of Conduct Committee that it could not be substantiated and resolved not to uphold the appeal against a finding of a breach of Section 1.5 of the Code.

The Appeal Committee concurred with the Code of Conduct Committee’s findings that the data did not provide sufficient justification for a prominent promotional claim “Consistently lower IOP Pressure” that would be interpreted by a reader as stating that Travatan was clinically superior to Xalatan in terms of intra-ocular pressure. The Committee considered that this inference was both misleading based on the study’s results and a disparaging and inaccurate comparison. On this basis the Appeal Committee agreed to uphold the decision of the Code of Conduct Committee to find a breach of Sections 1.3 and 1.7 of the Code.

The Appeals Committee considered that the claim “Travatan provides consistently lower trough pressure – even at 12 months” and the accompanying graph reinforced the impression of clinically significant outcomes at a rate and for a period that could not be fully supported by the provided data.

In relation to the claim “Travatan provides the most powerful control at trough” the Appeals Committee agreed that as the complainant raised no complaint based on an argument of “hanging comparator” no breach of Section 1.7 of the Code should be found based on this reason alone. The Committee also could not concur that this claim was based on inaccurate data. However, the Appeals Committee did concur with the Code of Conduct Committee’s decision in relation to its concerns regarding the evidence used to support this claim and the use of a qualifying device and statement and agreed that this was the basis of the Committee’s findings rather than on an assertion that the data itself was inaccurate.

In relation to a breach of Section 1.3 of the Code the Appeals Committee agreed with the Code of Conduct Committee that the level of supporting data was not sufficient to support a clearly promotional and comparative claim that inferred clinical superiority. The Appeal Committee agreed to uphold the Code of Conduct Committee’s decision to find a breach of Section 1.3 of the Code as this statement was misleading as it could not be adequately substantiated.

While the Code of Conduct Committee found a breach of Section 1.3 of the Code as the claims “More patients respond to Travatan and significantly more patients respond to Travatan than Xalatan” had the potential to mislead prescribers based on inadequacies in the graph, the Appeals Committee did concur with the spirit of the Code of Conduct Committee’s concerns but could not agree that this was a valid basis to find a breach of Section 1.3 of the Code as it had not been raised in the complaint and resolved that the appeal against a finding of a breach of Section 1.3 of the Code should be upheld.

In relation to the Code of Conduct Committee’s decision to find a breach of Section 1.3 of the Code as the claim “Travatan is the most potent prostaglandin analogue” was misleading and insufficient evidence had been provided to support it, the Appeals Committee resolved to uphold the finding of the Code of Conduct Committee that this claim was misleading and in breach of Section 1.3 of the Code.

Confirmation Fax

The Committee agreed with the comments made by the Code of Conduct Committee that this document contained the claim previously considered under Claim 1 and was therefore in breach of Section 1.3 of the Code. The appeal against the finding of a breach of Section 1.7 of the Code for the use of this claim was upheld.

Sanction

Having upheld several issues in the Alcon appeal the Appeals Committee resolved that it was appropriate to consider the sanction imposed by the Code of Conduct Committee. The Committee agreed that the original sanction determined by the Code of Conduct Committee should remain with the exception of the corrective advertisement that was determined to be excessive.

3. Mundipharma Oxycontin (669)

Advertisement on Medical Director entitled:

“Don’t let pain interrupt your patient’s life”

“MS Contin, MS Mono. Discover a range of products to suit everybody”

Complaint

A complaint was received from a healthcare professional alleging that promotional material for Oxycontin, MS Contin and MS Mono by Mundipharma Pty Ltd (Mundipharma) was in breach of the Code of Conduct. Mundipharma was invited to respond to Sections 1.1 and 1.3 of the Code of Conduct. The healthcare professional alleged that the material was sending a misleading message to general practitioners and that the promotion was inappropriate for apparently well elderly people.

Response

A response was received from Mundipharma denying any breach of the Code of Conduct. Mundipharma advised that it always endeavoured to promote its products ethically, responsibly and in accordance with the Code of Conduct.

Committee ruling

In relation to the claim “Don’t let the pain interrupt your patient’s life” the Committee was of the view that the person in the promotional material could be experiencing severe pain associated with any medical disorder or illness, not necessarily a headache. The essential criterion for these products is that they help keep people active. The Committee was of the opinion that the visual in this instance was not misleading and therefore the material was not found in breach of Sections 1.1 and 1.3 of the Code.

While the visual accompanying the claim “Discover a range of morphine products to suit everybody” may have been designed with the intent to provide a snapshot of what these people may wish they could do, it may lead to an assumption that the product is suitable for everybody without recourse to the strict conditions under which it may be prescribed. By a majority decision, the Committee resolved that the visual presentation for MS Contin and MS Mono had the potential to mislead prescribers and encourage broader use of this product than was appropriate and was therefore in breach of Sections 1.1 and 1.3 of the Code.

Sanction

The Committee resolved that Mundipharma 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 conveys the same or similar meaning.

4. CSL Limited Fluvax (670)

Brochure for the general public entitled:

“Can you afford the flu”

Complaint

A complaint was received from a healthcare professional alleging that promotional material for Fluvax by CSL Limited (CSL) was in breach of the Code of Conduct. The healthcare professional alleged that the material was misleading and unbalanced and was in breach of Sections 1.1 and 1.3 of the Code of Conduct. Subsequently CSL was also requested to respond to Sections 9.4 and 9.5 of the Code as the advertisement was available in pharmacies, places of employment and general practitioners waiting rooms.

Response

A response was received from CSL denying any breach of the Code of Conduct. CSL maintained that the content of the brochure fully complied with all sections of the Code and was designed to raise community awareness regarding the public health importance of immunisation against influenza, and to inform and educate the general public.

Committee ruling

The Committee discussed the content of the brochure “Can you afford the flu” and whether it was a balanced public education document or the promotion of a prescription only product to the general public. The Committee noted that the NHMRC Guidelines recommended people to be vaccinated if they wish to reduce their risk on contracting an episode of flu and therefore it may be appropriate to provide this type of information to members of the general public.

While the brochure contained information on the risks of getting the flu, some members of the Committee were concerned that the content focussed more on the financial impact rather than the possible benefits of vaccination. A minority of the Committee suggested that the document would have been of greater utility had it included information on any possible side effects of flu vaccination as it could not be considered balanced without this information. These Committee members were also concerned that there was an overstated inference on the effectiveness of flu vaccination in the over 65 age group and that the key target groups that should be vaccinated had not been sufficiently highlighted.

The majority of the Committee however, agreed that CSL had created an acceptable educational document. Importantly the document clearly stated that people should consult their doctor for further information if they were considering being vaccinated. The Committee also noted that a website address had been provided which contained further information that could be used as a reference point prior to making the decision to consult a medical practitioner. By a majority the Committee determined that there was no breach of Sections 1.1, 1.3, 9.4 or 9.5 of the Code.

5. Alcon Laboratories (Australia) Pty Ltd Travatan (672)

Television news item entitled:

“Cure for blindness”

Complaint

A complaint was received from a healthcare professional alleging that a television story for Travatan by Alcon Laboratories (Australia) Pty Ltd (Alcon) was in breach of Sections 9.4 and 9.5.7 of the Code of Conduct. The healthcare professional alleged that the product was not shown or discussed in the context of other available glaucoma treatments thereby suggesting that Travatan may be a unique treatment for glaucoma or blindness. It was alleged that this television piece could be seen as the promotion of a prescription product to the general public.

Response

A response was received from Alcon denying any breach of the Code of Conduct. Alcon maintained that it did not have control over the manner in which a television station may put together a story and that depending on their source of information the accuracy may vary. Alcon acknowledged that some of the material used was disappointing and that it was beyond the information included in the Alcon media release which made no suggestion that Travatan was unique or had unique qualities.

Committee ruling

The Committee was of the opinion that while companies do not always have control over the headlines used by the media or how they format a story, they have control over their advertising agencies that undertake the educational campaigns. Companies providing healthcare professionals to contribute commentary in a program should make every effort to ensure that they are made aware of the requirements of the Code of Conduct. While the Code allows for comment by independent healthcare professionals, the Committee was concerned that those interviewed in the Travatan stories may have been sponsored by Alcon.

The Committee viewed the various television stories as a marketing campaign to encourage a patient to seek a prescription only product from their healthcare professional rather than a general public education activity. The Committee found the material to be in breach of Sections 9.4 and 9.5 of the Code.

Sanction

The Committee resolved that Alcon should pay a fine of \$45,000.

Appeal

Alcon lodged an appeal against the findings of the Code of Conduct Committee. Alcon asserted that the media statement and associated press conference were in compliance with the Code and that there was no prohibition in the Code for providing a pack shot or even having the product available to the media to photograph themselves.

Committee ruling

The Committee was of the view that the media release, which did not seem to conform with the requirements of Section 9.2 of the Code, (i.e. inclusion of the trade name, a launch date and possible promotional and comparative claims) combined with the disclosure to members of the general public that this product was also freely available from ophthalmologists, had the effect of promoting a prescription medicine to the general public and was a breach of Section 9.4 of the Code as determined by the Code of Conduct Committee.

In addition, the Appeals Committee confirmed the Code of Conduct Committee's decision that these activities also resulted in a breach of Section 9.5.7 of the Code, as they would stimulate the demand for this prescription only product.

In resolving not to uphold this appeal the Committee concurred with the original Committee that no company can control the media but encouraged companies to ensure that any activities directed to members of the general public are educational and should not have the effect of being promotional.

Sanction

Having being requested by Alcon to review the magnitude of the fine imposed by the Code of Conduct Committee and having upheld the findings of breaches, the Committee considered whether the sanction imposed by the Code of Conduct Committee was appropriate.

The Appeals Committee resolved that the fine should be reduced to \$7,500.

6. Pfizer Pty Ltd Lipitor (673)

Slide Rule entitled:

“Total cholesterol reduction guide”

Complaint

A complaint was received from Bristol-Myers Squibb Pharmaceuticals (Bristol-Myers Squibb) alleging that a “slide rule” produced by Pfizer Pty Ltd (Pfizer) was promoting a product outside its approved indication and was in breach of Sections 1.1 and 1.3.1 of the Code of Conduct. Bristol-Myers Squibb stated that no statin other than Pravachol was at the time of the complaint indicated in patients with normal cholesterol levels and that Pfizer’s claim may lead to confusion in the minds of physicians.

Response

A response was received from Pfizer denying any breach of the Code of Conduct. The Pfizer response stated that there were two fundamental issues in the complaint. Firstly, the definition of hypercholesterolaemia and “normal cholesterol levels” and secondly, the Therapeutic Goods Administration (TGA) approval for Pravachol and other statins. Pfizer also asserted that the slide rule statement was correct and supported by the medical profession and the TGA.

Committee ruling

The Committee agreed that Pravachol had a unique indication for the treatment of patients with previous myocardial infarction including those who have normal (4.0-5.5mmol/L) serum cholesterol while Lipitor was indicated for the treatment of hypercholesterolaemia. The Committee was satisfied that data must have been provided, reviewed and accepted by the Australian Drug Evaluation Committee (ADEC) and the TGA that had made the granting of this unique indication possible. It was also noted that by the wording of Pravachol’s indication a numeric definition of normal cholesterol in patients with previous myocardial infarction had been created. Although not agreeing or disagreeing that this was the best or worst definition of normal cholesterol, it was contained in Pravachol’s Product Information and therefore had relevance in terms of the promotion of products in accord with the Code of Conduct.

The Committee considered that the use of the sentence “Projected Lipitor dose to obtain this reduction” adjacent to the Slide Rule’s window at the baseline cholesterol level of 4.1-5.5mmol/L was recommending that Lipitor was effective at reducing cholesterol in patients with this serum level. By a majority decision, the Committee found that the Lipitor Slide Rule had the potential to mislead prescribers as it was promoting the use of Lipitor outside its approved indication and could not be supported by its Product Information. Breaches of Sections 1.1 and 1.3 of the Code were found.

Sanction

The Committee resolved that Pfizer 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 made again in its present format or in a manner that conveys the same or similar meaning.

Appeal

Pfizer lodged an appeal against the findings of the Code of Conduct Committee arguing that the slide rule provided guidance on the dose of Lipitor likely to be required to reduce total cholesterol from a range of levels to target readings desirable in individuals and includes recommendations for commencement within a range of 4.1 to 5.5mmol/L.

Committee ruling

The Committee was of the view that it was not in a position to initiate change by the PBAC or the TGA and that the Committee’s responsibility in this instance was to decide whether in their opinion the Lipitor slide rule was in breach of Sections 1.1 and 1.3.1 of the Code for promoting a product outside the approved Product Information.

Members agreed that the TGA had confirmed the indication and the definition of ‘normal’ as applying to Pravachol’s indication only and not to Lipitor or any other product. However, they were also of the view that the TGA had not defined hypercholesterolaemia. Members considered the position that if there are no defined numerical figures for hypercholesterolaemia according to the TGA and Lipitor is approved for hypercholesterolaemia then Pfizer is not promoting outside the approved Product Information (PI). However, it may be outside the Bristol Myers Squibb qualifying criteria for Lipid lowering products.

The Committee noted that the Schedule of Pharmaceutical Benefits does also state that:

“Patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility”.

Members of the Committee agreed that Bristol Myers Squibb had presented evidence to the TGA for a specific indication and that if other companies had similar evidence it was open to them to submit it to the TGA for an amendment to their PI. The TGA would then be in a position to recognise new studies and data and consider the issues of safety and efficacy.

While acknowledging all these factors, members of the Committee were of the view that the Lipitor slide rule did not promote Lipitor outside its PI and that the starting point of 4.1 did not promote the prescribing of the product for patients with post myocardial infarction (MI) and a cholesterol level of between 4.0– 5.5mmol/L. It was the opinion of the Committee that healthcare professionals were in a position where they would take all the relevant factors into consideration before prescribing the most appropriate product for their patient.

Having considered the appeal, the Committee was of the view that Pfizer Pty Ltd was not in breach of Sections 1.1 and 1.3 of the Code and that their appeal should be upheld.

Sanction

Having upheld the appeal the Committee resolved that the sanction imposed by the Code of Conduct Committee should be removed.

7. Bristol-Myers Squibb Pharmaceuticals Pravachol (674)

Promotional material entitled:

“Important change to Pravachol Post MI indication”

“Pravachol – indicated and reimbursed like no other statin”

Complaint

A complaint was received from a healthcare professional alleging that promotional material by Bristol-Myers Squibb Pharmaceuticals (Bristol-Myers Squibb) was misleading and incorrect. The healthcare professional claimed that material promoting Pravachol was confusing as it suggested that patients with a previous myocardial infarction who have cholesterol levels of between 4.0 and 5.5 mmol/L can only receive PBS reimbursement for Pravachol. Bristol-Myers Squibb was invited to respond to Sections 1.1 and 1.3 of the Code of Conduct.

Response

A response was received from Bristol-Myers Squibb denying any breach of the Code of Conduct. Bristol Myers Squibb contended that while the doctor may be expressing his concern in relation to the Therapeutic Goods Administration (TGA) clarification of indications with which he may not agree, the approved Product Information was a legal document that contained indications based on the submission of data from a sponsor and in the patient group under discussion, a numerical definition did exist. Bristol-Myers Squibb was of the view that if the healthcare professional believed that the numerical values of cholesterol levels did not serve to clarify indications he should either request the sponsors of other statins to submit data upon which safety and efficacy analyses can be performed to enable them to gain registration in the patient group under discussion or place an enquiry with the authorities responsible for the administration of the ARTG.

Committee ruling

The Committee referred to the recent amendment to the approved indication for Pravachol which stated that “Pravachol is indicated in patients with previous myocardial infarction including those who have normal (4.0-5.5 mmol/L) serum cholesterol levels” and the PBS listing restrictions for statins. The Committee stated its concern that the differences between TGA approved indications and reimbursement restrictions on the PBS were the cause of confusion within the medical profession.

The Committee noted previous information provided to it advising that the Australian Drug Evaluation Committee (ADEC) had clarified that “normal” could be quantified as 4.0-5.5 mmol/L serum cholesterol levels. It also noted that the current PBS listing for statins and the differences in reimbursement for statins based on the included qualifying criteria and the notation that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but was outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

The Committee agreed that the information provided in the promotional material was capable of substantiation and was in accord with Pravachol’s Product Information and its PBS listing. No breach of Section 1.1 of the Code was found.

The majority of the members of the Committee however found that although the promotional material could have been made clearer, the information was factual, represented the current approved TGA indication and PBS listing and would be of value to prescribers and therefore no breach of Section 1.3 of the Code was found.

8. Bristol-Myers Squibb Pharmaceuticals Pravachol (675)

Promotional material entitled:

“Important change to Pravachol Post MI indication”
“Pravachol – indicated and reimbursed like no other statin”

Complaint

A complaint was received from Pfizer Pty Ltd (Pfizer) alleging that promotional material for Pravachol by Bristol-Myers Squibb Pharmaceuticals (Bristol-Myers Squibb) was in breach of Sections 1.1, 1.3, 1.3.1, 1.5 and 1.7 of the Code of Conduct. Pfizer alleged that the activities of Bristol-Myers Squibb in promoting their amended indication was causing confusion within the medical community as to the terms under which a statin may be prescribed and attract reimbursement under the Pharmaceutical Benefits Scheme (PBS).

Response

Bristol-Myers Squibb maintained that the Therapeutic Goods Administration (TGA) had approved a change to the registered post MI indication for Pravachol to include “Patients with previous myocardial infarction including those with normal (4.0-5.5mmol/L serum cholesterol” and that the TGA approval also included a statement that “it does serve to clarify the meaning of “normal cholesterol” and it also reflects the data that were provided in support of the indication.

Committee ruling

By a majority the Committee accepted that Pravachol’s approved Product Information provided a definition of “normal” that was 4.0-5.5 mmol/L cholesterol serum levels and that this had been accurately depicted in the promotional material and no breach of Sections 1.1 or 1.3 of the Code was found.

In relation to the reference to patients who experienced unstable angina rather than the approved indication which stated patients with previous myocardial infarction and the statement of “history of unstable angina” and the approved indication of

“unstable angina”, the Committee considered this wording was appropriate, reflective of the approved indication and did not have the capacity to mislead. No breach of Section 1.3.1 of the Code was found.

By a majority the Committee found the statement “Pravachol indicated and reimbursed like no other statin” and the graph entitled “PBS Reimbursement” were not in breach of Section 1.7 of the Code, as it was determined that the information provided was correct and not disparaging.

By a majority decision no breach of Section 1.5 of the Code was found in relation to the tag line “positively different”. The Committee considered that the tag line was meaningless puffery that did not infer a direct comparison with other products.

The Committee commented on the footnote on the “Evidence based medicine: Pravachol and Lipitor” table and noted Bristol-Myers Squibb’s views on why it had not included the GREACE Study ie. that it was not a head to head or placebo controlled trial. The Committee also noted that Bristol-Myers Squibb had indicated that this promotional material would not be used in the same format again. The Committee also discussed the timing of the release of the GREACE study and the release of the promotional material.

The Committee was not convinced that Bristol-Myers Squibb had provided sufficient reason or evidence to justify the non-inclusion of material referred to by Pfizer which could have made this table more comprehensive and balanced. By a unanimous decision the Committee resolved that a breach of Section 1.7 of the Code should be found as the table was not reflective of the available data and represented a disparaging comparison to other products.

Sanction

The Committee resolved that Bristol-Myers Squibb 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 table found in breach should not be used again in its present format or in a manner that conveyed the same or similar meaning.

9. Pfizer Pty Ltd Viagra (676)

Advertising material entitled:

“What qualifies me to talk about erection problems”

Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that an advertisement for Viagra by Pfizer Pty Ltd (Pfizer) may be in breach of the Code of Conduct. Pfizer Pty Ltd was invited to respond to this complaint in terms of possible breaches of Sections 9.4 and 9.5 of the Code of Conduct.

Response

A response was received from Pfizer denying any breach of the Code of Conduct. Pfizer maintained that the campaign was intended to remove a perceived stigma from a common condition which many men cannot bring themselves to discuss. Pfizer asserted that there was no direct or indirect reference to Viagra in the advertisement and that erectile dysfunction was often considered by men as distressing due to its effects on relationships and while the advertisement was not distinctly educational it fulfilled the requirements of the Code of Conduct in that it encouraged members of the general public to seek further information from their healthcare professional.

Committee ruling

The Committee agreed that the advertisement did not include the name of any prescription product or make any claim that could be considered promotional. The Committee acknowledged that due to the media coverage surrounding this advertisement and the naming of the product by the media, the public may have an awareness that Viagra is indicated for

erectile dysfunction. However as no product was mentioned in the material, there was no linkage between the advertisement and a specific prescription medicine and there were a number of treatments that could be prescribed or recommended to treat this condition, no breach of Section 9.4 of the Code was found.

The Committee agreed that the material before it was sufficiently generic to meet the requirements of the Code and hence no breach of Section 9.5 of the Code should be found, however some concern was expressed regarding the true educative value of such material and whether it fell comfortably within the current provisions of the Code.

10. Organon (Australia) Pty Ltd Livial (677)

Letter to doctors re findings of the Women's Health Initiative Trial (WHI) entitled:

“HRT and Media Attention”

Complaint

A complaint was received from Novo Nordisk Pharmaceuticals Australia Pty Ltd (Novo Nordisk) alleging that a letter to doctors by Organon (Australia) Pty Ltd (Organon) was in breach of Sections 1.3 and 3.5.2 of the Code of Conduct. Novo Nordisk alleged that the Organon letter to Australian physicians discussed Livial's effects on cardiovascular and breast parameters in an exclusively favourable light and insinuated that there were no negative effects on these conditions.

Response

A response was received from Organon denying any breach of the Code of Conduct. Organon maintained that the content of the letter to healthcare professionals was factually correct and supported by the cited publications. Organon also asserted that it was made clear which evidence was available from the company and which areas were subject to further study.

Committee ruling

The Committee was of the view that there was no unequivocal evidence in the Product Information or via the literature that would support a statement that the overall cardiovascular effect of Livial may be beneficial. Although Organon may have some data to this effect the Committee considered it was premature to use this data as it had not been approved by the Therapeutic Goods Administration (TGA) via inclusion in the Product Information (PI). It was further noted that the PI included a reference to cardiovascular or cerebrovascular disorders which added to the Committee's concerns regarding these promotional statements which did not make it clear that this product should not be used for women in which it was contraindicated. As the Committee considered that these statements were misleading and could not be supported by sufficient evidence, the Committee resolved that the use of these statements was in breach of Section 1.3 of the Code.

In relation to the statements “Livial improves fibrinolysis and does not adversely affect blood clotting” and “Clinical studies have identified no increased incidence of venous thrombotic or arterial events with Livial compared with placebo” the Committee was of the view that these were consistent with the PI and no breach of Section 1.3 of the Code of Conduct was found.

The Committee agreed that while Organon had acknowledged the fact that a copy of the Livial PI should have been sent with the letter, the omission was a serious error on the part of the company and a breach of 3.5.2 of the Code was found.

Sanction

The Committee resolved that Organon Pty Ltd should take immediate action for the prompt withdrawal of the promotional materials found in breach and should permit no further appearance of it in their present form or in a manner that conveys the same or similar meaning.

It was also resolved that Organon should pay a fine of \$10,000.

11. Boehringer Ingelheim Pty Ltd Mobic (678)

Promotional material entitled:

“Introducing Mobic Works like a NSAID Behaves like a COX-2”

Complaint

A complaint was received from Pharmacia Australia Pty Ltd (Pharmacia) alleging that promotional material for Mobic by Boehringer Ingelheim Pty Ltd (Boehringer Ingelheim) was in breach of Sections 1.3, 1.7 and 3.1 of the Code of Conduct. Pharmacia alleged that the linked statements were intended to be read as an overall claim on behalf of Mobic and that no clinically relevant basis for the claim “introducing a COX-2 with a difference” was available.

Response

A response was received from Boehringer Ingelheim stating that due to the time lapse in communication between the two companies none of the promotional pieces referred to in the complaint were still in use.

Committee ruling

The Committee was of the view that it was appropriate to classify Mobic as behaving like a COX-2. The Committee was satisfied that the statements were consistent with the Product Information (PI) and therefore not in breach of Sections 1.3 or 1.7 of the Code. However, the Committee noted that although in isolation these statements may not breach the Code it was possible that the use of these statements linked to other promotional claims may add to a breach of the Code. The Committee also noted that Boehringer Ingelheim had advised Pharmacia that these statements were no longer in use. No breach of Sections 1.3 and 1.7 of the Code were found.

The Committee resolved that as claims of superior GI tolerability could not be easily compared it was misleading by inferring a clinical benefit that was not appropriately supported and was in breach of Section 1.3 of the Code.

The Committee considered that the term “safety profile” used in the claim “a well documented safety profile” would benefit from greater clarification and explanation. By a majority decision, the Committee considered that without further explanation regarding the term “safety profile” this claim was misleading and in breach of Section 1.3 of the Code. No breach of Section 1.7 of the Code was found as the Committee did not consider this statement to be a disparaging comparison.

As Boehringer Ingelheim had acknowledged that the claim “A low incidence of GI perforations, obstructions and bleeding” was a hanging comparator and was inadequately referenced a breach of Sections 1.3 and 1.7 of the Code was found.

The Committee found that the claim “No evidence of increased risk of cardiovascular or thrombotic events” was inadequately referenced and related only to data on file. The Committee was concerned that by implication this statement was claiming that Mobic was superior to the COXIBs but this was unclear. The Committee resolved that a breach of Section 1.3 of the Code should be found as this statement was misleading and that as this statement did not declare the comparator to which this claim was being made it should be considered as a hanging comparator and therefore in breach of Section 1.7 of the Code.

The Committee resolved that the statement “The COX-2 with a difference” was misleading as it implied a benefit that could not be substantiated. A breach of Section 1.3 of the Code was found. The Committee also considered that a breach of Section 1.7 of the Code should be found as the claim was disparaging to another group of products.

The Committee considered that as the PI supported the statement “TGA approved as a COX-2 selective inhibitor” and no breach of Section 1.3 of the Code was found.

The Committee was not convinced that the graphs “% COX-1 inhibition at therapeutic COX-2 inhibition in a human whole blood plasma” and “The concentration of Mobic sufficient to inhibit COX-2 by 80% produced only 25% inhibition of COX-1” were misleading and was satisfied that the title of the graph provided clarification that the results were from whole blood assay and the axis was clearly named. No breach of Section 1.3 of the Code was found.

In relation to the claim “Fewer adverse events” the Committee considered that the graph was not misleading as it was an accurate reflection of the Product Information. No breach of Section 1.3 of the Code was found.

By a majority the Committee resolved that as the statement “Independent evaluation by NICE concluded: No differences were demonstrated in efficacy of GI adverse events between Mobic, celecoxib and rofecoxib.” was an accurate quotation and NICE was a credible source of information, it should not be considered as misleading and no breach of Section 1.3 of the Code was found.

The Committee did not find that the statement “COX-2 selectivity with superior GI tolerability to standard NSAIDs” was misleading as it could be supported by the Product Information and evidence provided. No breach of Section 1.3 of the Code was found.

On balance the Committee considered that although clumsy the claim “No evidence of increased risk of CV, renal or thrombotic adverse events compared to standard NSAIDs” was not misleading and found no breach of Section 1.3 of the Code.

Sanction

The Committee resolved that Boehringer Ingelheim 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 or in a manner that conveys the same or similar meaning.

It was also resolved that Boehringer Ingelheim should pay a fine of \$15,000.

12. AstraZeneca Pty Ltd Nexium (679)

Promotional material entitled:

“A new experience in power. A feeling of freedom (from symptoms of GORD)”

Complaint

A complaint was received from Pharmacia Australia Pty Ltd (Pharmacia) alleging that promotional material for Nexium by AstraZeneca Pty Ltd (AstraZeneca) was in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct. Pharmacia alleged that certain claims were not based upon direct head-to-head studies but an attempt to extrapolate conclusions from disparate studies.

Response

A response was received from AstraZeneca denying any breach of the Code of Conduct. AstraZeneca maintained that it was critical to take into account the wealth of well-designed clinical studies which had specifically investigated the comparative efficacy of compounds to understand the issues pertinent to comparative claims regarding efficacy and that this body of evidence supported the comparative efficacy claims for Nexium.

Committee ruling

The Committee viewed the statements “A new experience of power. A new feeling of freedom” and “It’s got the power” as advertising ‘puffery’ with little or no meaning and found them not to be in breach of Sections 1.1 and 1.3 of the Code.

The Committee agreed that while not actually contradicting the approved Product Information (PI), the claims “... greater healing power than either omeprazole or lansoprazole” should include the dosages of each product to aid the clarity of the claim and its understanding by prescribers. On balance the Committee considered that the claim could be supported and was not misleading however encouraged AstraZeneca to consider clarifying its meaning. The Committee considered that AstraZeneca should ensure that prescribers were not confused regarding the appropriate dosages for initiation and healing however found no breaches of Section 1.1 or 1.3 of the Code.

The Committee agreed that insufficient evidence was available to support the significant promotional claim “Nexium heals more patients faster” and a breach of Section 1.3 of the Code was found.

The Committee agreed that the inclusion of the comparative statement “Nexium is better than Losec in controlling the amount of acid produced in your stomach” in material provided with the starter pack was in breach of Section 9.5 and 9.5.7 of the Code.

Sanction

The Committee resolved that AstraZeneca 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 or in a manner that conveys the same or similar meaning.

Appeal

An appeal was received from AstraZeneca maintaining that there was evidence from two large prospective randomised studies that supported the claims in the promotional material.

Committee ruling

The Appeals Committee agreed to uphold the decision of the Code of Conduct Committee in finding a breach of Section 1.3 of the Code. Members were of the view that the Nexium material should be made more applicable to the target audience which in this case was general practitioners and that AstraZeneca should include a reference to all four grades of eosophagitis and remove the word ‘faster’ from their promotional material.

Sanction

Having upheld the decision of the Code of Conduct Committee the Appeals Committee was of the view that the sanction imposed by the Code of Conduct Committee should remain.

13. Bayer Australia Limited Adalat Oros (680)

Advertising material entitled:

“Something your patients will notice
Something they won’t”

Field Force Activities

Complaint

A complaint was received from Solvay Pharmaceuticals (Solvay) alleging that promotional material for Adalat Oros by Bayer Australia Limited (Bayer) was in breach of Sections 1.1 and 1.3 of the Code of Conduct. Solvay alleged that the claims made by the Bayer field force and in the advertising material was unsupported, unbalanced, unfair, false and misleading.

Response

A response was received from Bayer denying any breach of the Code of Conduct. Bayer maintained that the Adalat Oros 20mg dose was approved by the Therapeutic Goods Administration (TGA) and that Bayer had the right to promote this dosage along with the 30mg and 60mg doses which were also approved by the TGA and all three strengths of Adalat Oros were reimbursed by the Pharmaceutical Benefits Scheme (PBS).

Committee ruling

The Committee was concerned that the statement “New once a day Adalat Oros 20mg provides effective 24 hour BP control with a side effect profile similar to placebo” implies that a patient can be started on a 20mg dose when this is not an approved initiation dose according to the current Product Information (PI) or the clinical data that refer to an initiating dose of 30mg. The Committee considered that this statement was in breach of Sections 1.1 and 1.3 of the Code.

The Committee was not convinced that evidence had been provided to it to support the promotional claim "... with a placebo like effect profile" and a breach of Sections 1.1 and 1.3 of the Code was found.

The Committee was concerned that the focus of the whole promotional campaign to promote the 20mg form as a new approved dose was based on claims that were false and could not be substantiated and breaches of Sections 1.1 and 1.3 of the Code were found.

Sanction

The Committee resolved that Bayer 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 or in a manner that conveys the same or similar meaning.

It was also resolved that Bayer should print a corrective advertisement to correct the misleading and incorrect claims made in the promotional item and prepare a directive to its medical representatives, sales and marketing staff, advising of the breaches of the Code and the corrective messages regarding the approved initiation dose for Adalat Oros.

Bayer was also ordered to pay a fine of \$15,000.

Appeal

An appeal was lodged by Bayer who maintained that there was no suggestion or indication in the advertisement that patients should be initiated on Adalat Oros 20mg. Bayer also asserted that there was sufficient evidence available to support the claims made in the promotional material.

Committee ruling

The Committee discussed the appeal before it and agreed with the Code of Conduct Committee that the promotional material was misleading as it promoted the use of a form of a product that was not in accord with its current Product Information. The finding of breaches of Section 1.1 and 1.3 of the Code was upheld. In addition, the Appeals Committee resolved to uphold the finding of a breach of Section 1.1 and 1.3 of the Code in relation to the claim of placebo like effects profile as no sufficient unequivocal evidence existed to support such a major claim. In relation to the breaches of Section 1.1 and 1.3 of the Code as a result of activities by Bayer medical representatives, the Committee agreed with the findings of the Code of Conduct Committee as no new arguments had been provided to convince it that this decision had been incorrect.

Sanction

The Committee resolved that the sanctions imposed by the Code of Conduct Committee should remain.

14. Allergan Australia Pty Ltd Lumigan (682)

Data on file

Complaint

A complaint was received from Alcon Laboratories (Australia) Pty Ltd (Alcon) alleging that Allergan Pty Ltd (Allergan) was in breach of Section 1.2 of the Code of Conduct as the company had not supplied requested data held on file within the specified timeframe.

Response

A response was received from Allergan denying any breach of the Code of Conduct. Allergan advised that the original request from Alcon did not stipulate that the request for data was in relation to a Code of Conduct complaint and the company did not perceive this request as pertaining to a breach for which the 10 working days would apply. Allergan also asserted that appropriate intercompany dialogue in relation to what was required by the company had not been adequately undertaken.

Committee ruling

The Committee resolved that as the information requested by Alcon had been supplied, the spirit of the Code had been complied with, albeit on one interpretation, a little late. In the circumstances the Committee was not prepared to record against Allergan that it had committed a breach of the Code on the grounds that their fault, if any, was de minimus and that the complaint had occupied the whole Committee, when in the circumstances it need not have been made. No breach of Section 1.2 of the Code was found.

15. Baxter Healthcare Pty Ltd NeisVac-C (683)

Promotional material entitled:

“Important Meningococcal Notice”

“NeisVac-C. A new meningococcal C conjugate vaccine that delivers superior immunogenicity”

Complaint

A complaint was received from CSL Limited (CSL) alleging that Baxter Healthcare Pty Ltd (Baxter) was in breach of Sections 1.3 and 1.7 of the Code of Conduct. As a Medicines Australia-non member company Baxter Healthcare had been invited to address these issues under the Code of Conduct.

Response

A response was received from Baxter Healthcare denying any breach of the Code of Conduct. Baxter maintained that the evidence to support the claims was taken directly from the findings of the best available evidence to date on the subject.

Committee ruling

The Committee, which included members of the medical profession, agreed that the use of the term “immunogenicity” may not be well understood by the average prescriber and that it was likely that an inference of efficacy would be made, particularly as no qualification had been made in relation to this term. In addition, the Committee was concerned that the claim was a generalisation and that a reader may infer that the results from the referenced study could be expected in all clinical settings when this may not be the case.

As the Committee considered that a prescriber may be misled by this claim as the term “immunogenicity” had not been clearly defined and was a generalisation that could not be fully supported, the Committee resolved that it breached Section 1.3 of the Code. The Committee also considered a breach of Section 1.7 of the Code had occurred as this claim was a disparaging and incorrect comparison to other vaccines.

The Committee noted that without appropriate qualification the use of the word “delivers” was misleading and hence in breach of Section 1.3 of the Code. The Committee also found a breach of Section 1.7 of the Code as the claim was a disparaging and misleading comparison.

Sanction

The Committee resolved that Baxter 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 or in a manner that conveys the same or similar meaning. Baxter was also required to print a corrective advertisement correcting the misleading claim made in the promotional item.

16. Alcon Laboratories (Australia) Pty Ltd Travatan (684)

Promotional material entitled:

“POWER ▼ CONTROL”

Complaint

A complaint was received from Pharmacia Australia Pty Ltd (Pharmacia) alleging that Alcon Laboratories (Australia) Pty Ltd (Alcon) was in breach of Sections 1.3, 1.5 and 1.7 of the Code of Conduct. Pharmacia alleged that Alcon had not abided by sanctions imposed by the Code of Conduct Committee at a previous meeting and that the matter should be considered as urgent and heard as a repeat breach of the Code.

Response

A response was received from Alcon denying any breach of the Code of Conduct. In their response Alcon requested that the complaint be referred back to Pharmacia as they had not undertaken intercompany dialogue and the matter was not urgent as alleged by Pharmacia as it had taken them more than two months to lodge this complaint.

Committee ruling

The Committee agreed that it should examine the use of the claim “the most powerful prostaglandin” to determine whether it was still in breach of Section 1.5 of the Code and therefore its continued use a repeat breach. In relation to the other claims the Committee resolved that following intercompany dialogue and the provision of any supporting evidence, should Pharmacia still have concerns regarding these claims they could be brought to the Committee for consideration.

The Committee considered that the level of substantiating data was insufficient to support such a strong claim as ‘most powerful’ and that the qualification “based on clinical and pre clinical data” had not altered the overall thrust of the claim or provided sufficient qualification to prevent a finding of a breach of Section 1.5 of the Code. The Committee reiterated its concern about the use of terms such as ‘powerful’, which is unclear and has the potential to be confused with potency and efficacy if not adequately qualified.

By a unanimous decision the Committee agreed that the claim was in breach of Section 1.5 of the Code as it was a claim that had some special merit, quality or property that could not be substantiated. Having considered that this claim was a breach of Section 1.5 of the Code and that it had been previously found in breach, the Committee resolved that its continued use constituted a repeat breach as defined by the Code of Conduct.

Sanction

The Committee resolved that Alcon 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 or in a manner that conveys the same or similar meaning.

It was also resolved that Alcon should pay a fine of \$60,000.

17. Mayne Pharma Pty Ltd Pamisol (687)

Mailer entitled:

“Pamisol – the solution”

Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Mayne Pharma Pty Ltd (Mayne Pharma) was in breach of Sections 1.3, 1.10, 3.5.1, 3.5.3 and 10.2.2 of the Code of Conduct. The complaint received by the TGA

from an undisclosed healthcare professional and submitted to Medicines Australia alleged that the material was delivered in an envelope disguised as medical results. As a non-Medicines Australia member, Mayne Pharma had been invited to address the concerns raised in this complaint under the Code of Conduct.

Response

A response was received from Mayne Pharma acknowledging that the envelope in which the promotional material was mailed may have been misleading but this was an oversight and unintentional. The company advised that as part of their standard operating procedure all envelopes would be reviewed to ensure compliance with the Code.

Committee ruling

As the envelope only contained promotional material and not patient X-rays, the Committee considered that this method of delivery of promotional material was inappropriate and had the capacity to bring discredit to the industry.

Although agreeing that the delivery of this promotional material was misleading, the Committee resolved not to find a breach of Section 1.3 as this section refers specifically to product claims rather than, in this instance, a misleading statement regarding the contents of the envelope. In addition, the Committee could not agree with the complainant that the inclusion of the image of the X-ray hand and the words “the solution” could imply to a healthcare professional that the product being promoted is related to X-rays and/or X-ray developing solutions or that this would be misleading in terms of the indications for use of Pamisol. The Committee unanimously agreed to find no breach of Section 1.3 of the Code.

The Committee unanimously agreed that the envelope containing the inference that it contained patient X-ray material was a clear breach of Section 1.10 of the Code that requires promotional material to be clearly identified as such and a breach of Section 3.5.1 of the Code as this activity could be described as a mailing as defined by the Code of Conduct.

The Committee considered that a breach of Section 3.5.3 of the Code which requires envelopes should not be used for dispatch of promotional material if they bear words implying that the contents are non promotional had occurred.

The Committee discussed this aspect of the complaint and could not agree with the complainant that the activity fell within the definition of medical educational material as alleged and therefore resolved that no breach of Section 10.2.2 of the Code should be found.

Sanction

The Committee resolved that Mayne Pharma Pty Ltd should take immediate action to ensure that such an activity is not repeated and that the envelope subject to this complaint was withdrawn and not used again.

18. Baxter Healthcare Pty Ltd NeisVac-C (689)

Promotional material entitled:

“NeisVac-C. A new meningococcal C conjugate vaccine that delivers superior immunogenicity”

“Don’t delay order your meningococcal C conjugate vaccine now”

“IMPORTANT MENINGOCOCCAL NOTICE”

Complaint

A complaint was received from Wyeth Australia Pty Ltd (Wyeth) alleging that Baxter Healthcare Pty Ltd (Baxter) was in breach of Sections 1.2, 1.3, 1.5 and 1.7 of the Code of Conduct. Wyeth alleged that the claims used in the promotional material could not be supported by the references quoted and that Baxter failed, following reasonable request, to provide data referenced in their promotional material. As a non-Medicines Australia member company, Baxter Healthcare had been invited to address the concerns raised in this complaint under the Code of Conduct.

Response

Baxter Healthcare accepted this invitation and maintained that the claim was capable of substantiation and that in respect to the provision of substantiating data they were reticent in supplying this data to a competing meningococcal manufacturer and not doctors, as it was a commercial-in-confidence document.

Committee ruling

In relation to the claim “superior immunogenicity” and the inference that would be taken by the audience to which it was addressed the Committee considered that the term immunogenicity may not be fully understood by a number of healthcare professionals to which this material was directed and as the claim inferred a positive clinical outcome that had not been demonstrated, the claim regarding superior immunogenicity was potentially misleading. Whilst accepting that it may not have been Baxter’s intention to create this inference the lack of qualification and clarification regarding the difference between superior immunogenicity and efficacy has created the possibility for readers to be misled.

By a majority decision, the Committee agreed that the results from the studies were strong surrogate measures but could not be used for a clinical effect which would include other measures such as side effects, tolerability and intolerance and had the potential to mislead a prescriber and was therefore in breach of Section 1.3 of the Code.

The Committee did not consider that the claim was an unqualified superlative as data existed to support a claim of superior immunogenicity. In relation to Section 1.7 of the Code the Committee could not agree that the claim was a breach of this section as the comparison itself was appropriate however the lack of clarification was misleading and therefore in breach of Section 1.3 of the Code. No breaches of Sections 1.5 or 1.7 of the Code were found.

In relation to the complaint that Baxter Healthcare did not provide supporting data to Wyeth Australia when requested, the Committee noted that the Code required the disclosure of this data and that if Baxter Healthcare was not prepared to release it then this reference should not have been used. The Committee resolved to find a breach of Section 1.2 of the Code for the non-provision of this data.

Sanction

The Committee resolved that Baxter Healthcare 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 or in a manner that conveys the same or similar meaning.

19. Baxter Healthcare Pty Ltd NeisVac-C (690)

Letter to healthcare professionals entitled:

“IMPORTANT UPDATE: NeisVac-C Meningococcal Group C Polysaccharide Conjugate Vaccine

NeisVac-C Meningococcal Conjugate Vaccine Clinical Data Sheet

Complaint

A complaint was received from CSL Limited (CSL) alleging that Baxter Healthcare Pty Ltd (Baxter) was in breach of Sections 1.3, 1.5 and 1.7 of the Code of Conduct. CSL also alleged that Baxter had been recalcitrant in responding to requests to supply the referenced material used to support the claims. As a non-Medicines Australia member company, Baxter had been invited to address the concerns raised in this complaint under the Code of Conduct. The Committee subsequently directed Medicines Australia to request Baxter to provide the supporting data to CSL and held over the decision relating to this complaint until the next Code meeting.

Response

Baxter accepted this invitation and denied any breach of the Code of Conduct. Baxter had provided the Public Health Laboratory Service (PHLS) Report to Medicines Australia in confidence solely for the purpose of evaluating this complaint.

Committee ruling

The Committee agreed that in order to appropriately evaluate failure rates with different products, the number of doses administered and the population sub-groups that had received each vaccine must be disclosed. The Committee noted that the three meningococcal vaccines had been introduced at different times and had been allocated to different age groups. As this information had not been disclosed in the clinical data sheet, the Committee considered that the statement was misleading and was not a fair comparison between NeisVac C and other meningococcal vaccines. The Committee therefore found that the statement was in breach of Sections 1.3 and 1.7 of the Code.

The Committee then considered the use of the word “safe” in the statement “... it should be safe and effective if used as a second or third dose in infants who have already commenced immunisation with Meningitec.” The Committee considered that as “safe” had been used without qualification this was in breach of Section 1.5 of the Code.

Sanction

The Committee resolved that Baxter 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 or in a manner that conveys the same or similar meaning.

The Committee also resolved that Baxter should pay a fine of \$5,000.

20. Sanofi-Synthelabo Australia Pty Limited Stilnox (691)

Advertising feature entitled:

“Managing Sleep”

Complaint

A complaint was received from an academic alleging that an educational feature sponsored by Sanofi-Synthelabo Australia Pty Limited (Sanofi-Synthelabo) was in breach of Section 9.4 of the Code of Conduct. It was alleged that the feature in the Qantas magazine was advertising a prescription product directly to the general public.

Response

A response was received from Sanofi-Synthelabo maintaining that the advertorial was not intended as a direct promotion but rather a discussion around the topic of sleep. Sanofi-Synthelabo acknowledged that they were in breach of the Code and the brand should not have been mentioned but that this was inadvertent and not a deliberate attempt to breach the Code. Sanofi-Synthelabo gave an assurance that the piece would never be used again and that they would strengthen their internal approval processes to ensure that a similar mistake could not happen again.

Committee ruling

Whilst acknowledging it was not Sanofi-Synthelabo’s intention to deliberately attempt to breach the Code of Conduct, the publication of this advertising feature in the lay media was a serious breach of the Code of Conduct as it promoted the use of prescription only product to members of the general public. By unanimous agreement the Committee found this advertising feature a breach of Section 9.4 of the Code.

Sanction

The Committee resolved that Sanofi-Synthelabo should permit no further appearance of this advertisement in any lay media and pay a fine of \$50,000 which the Committee noted was the maximum for this type of breach.

21. CSL Limited Tramal (692)

Promotional material entitled:

“Victory over cancer pain is measured in little pleasures”

Complaint

A complaint was received from Mundipharma Pty Ltd (Mundipharma) alleging that CSL Limited (CSL) was in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct. Mundipharma alleged that the studies were insufficient to substantiate such strong claims and that the claims were misleading and disparaging to Mundipharma products.

Response

A response was received from CSL denying any breach of the Code of Conduct. CSL maintained that the referenced studies could withstand scrutiny and that the analgesic ladder adapted from World Health Organisation (WHO) was not intended to replicate the WHO ladder but to show the situations in which Tramal may be considered for treatment of pain.

Committee ruling

The Committee was concerned that although the study may support a claim of “global quality of life” the evidence was not sufficient to support a major claim “Tramal – superior quality of life vs morphine”. The Committee considered that this study was not rigorous enough to support such a major claim and the inference of positive clinical effect. It was also concerned that CSL had selectively used the results from this study and whilst CSL acknowledged that it did not include all aspects of the study, the Committee considered it was inappropriate to only include the favourable aspects of a study.

The Committee found that as there was insufficient unequivocal evidence to support a major claim that inferred a positive clinical outcome this was misleading and therefore in breach of Section 1.3 of the Code. The Committee also found that the claim was in breach of Section 1.7 of the Code as it was not a fair comparison in all aspects of the term ‘quality of life’. No breach of Section 1.1 of the Code was found as it was considered that evidence had been provided to support the graph but the inference from the major heading was misleading and therefore in breach of Section 1.3 of the Code.

The Committee agreed that the adapted version of the WHO ladder had the potential to mislead or confuse healthcare professionals and therefore was in breach of Sections 1.3 and 1.7 of the Code. The Committee also found the CSL version of the ladder to be unbalanced and inaccurate and therefore in breach of Section 1.1 of the Code.

The Committee found a breach of Sections 1.1 and 1.3 of the Code in relation to the claim “Victory over cancer pain is measured in little pleasures: a restful night’s sleep, enough energy for a family visit and effective control of cancer pain with less of the side effects” as there was insufficient evidence to support the claim and it was considered to be misleading. A breach of Section 1.7 of the Code was also found as it was considered that the comparison to other products was not fair and was disparaging.

Sanction

The Committee resolved that CSL 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 or in a manner that conveys the same or similar meaning. It was also resolved that CSL should print a half page corrective advertisement to correct the misleading claims.

Appeal

CSL Ltd lodged an appeal in relation to the findings of the Code of Conduct Committee. This appeal was subsequently withdrawn and the corrective action as determined by the Code of Conduct Committee undertaken by the company.

22. Roche Products Pty Ltd Roche and the Healthy Weight Taskforce (693)

Healthy Weight Taskforce Website

Complaint

A complaint was received from Abbott Australasia Pty Ltd (Abbott) alleging that Roche Products Pty Ltd (Roche) was in breach of Sections 3.1.4, 3.7, 9.3, 9.4 and 9.5 of the Code of Conduct. Abbott alleged that the material provided by the Healthy Weight Taskforce (HWT) was misleading and unbalanced and that there was no acknowledgement of Roche sponsorship on the website or in any correspondence to the media.

Response

A response was received from Roche denying any breach of the Code of Conduct. Roche maintained that the HWT was an independent network of GPs, pharmacists and dieticians who were committed to improving the health and well being of all Australians. Roche acknowledged that they sponsored the group but that all activities undertaken by the HWT were independent of any pharmaceutical or weight loss company.

Committee ruling

The Committee considered that the activities of the HWT and the media interest it sought and generated was a breach of Section 9.3 of the Code as selective and unbalanced information regarding the options available to the treatment of obesity had been provided to members of the general public.

The Committee agreed that through the HWT Roche was promoting a prescription-only product to the general public and that the material provided was not balanced in that it inferred a more positive view of Xenical over other treatment options. A breach of Sections 3.9 and 9.4 of the Code was found.

The Committee did not consider the material to be balanced public education given its unfair comparisons between Xenical and other treatment options. The Committee was particularly concerned regarding the unbalanced description of "prescription medications". A breach of Sections 3.9 and 9.5 of the Code was found.

The Committee was of the view that the material produced by the HWT could be considered as a company commissioned article and considered that acknowledgement of the Roche sponsorship should also have been made on the HWT website. A breach of Section 3.1.4 of the Code was found.

Sanction

The Committee resolved that Roche should a fine of \$75,000 being the maximum fine for a severe breach where an activity has ceased.

Appeal

An appeal was lodged by Roche against the findings of the Code of Conduct Committee. Roche maintained the individuals in the HWT were well respected and had significant experience in either weight management or public education campaigns and had been selected as representatives of primary care medicine who were at the forefront of community health. Roche acknowledged that they had provided advice to the group but had not encouraged them to provide information that was favourable to the Roche product Xenical.

Committee ruling

The Appeals Committee concluded that Roche was in breach of Section 3.9 of the Code as the sponsorship of the HWT website by Roche should have been clearly evident on the site, which the company had acknowledged.

In relation to Section 9.4 of the Code, the Committee considered that Roche did not exhibit appropriate responsibility for the activities of the HWT, which included promotion of prescription medicines to the general public. The appeal in relation to Section 9.4 was not upheld.

In relation to Section 3.1.4 of the Code, the Appeals Committee considered the definition of a “company commissioned article” and accepted that within the broad sponsorship provided to the Taskforce materials produced by them were not specifically commissioned by Roche Products Pty Limited. The Roche appeal was upheld and no breach of Section 3.1.4 of the Code was found.

In relation to Sections 9.3 and 9.5 of the Code, the Appeals Committee acknowledged the arguments presented regarding whether the HWT website and evaluation tool were balanced. The Committee concluded that the case for finding breaches of Sections 9.3 and 9.5 was not sufficiently made out. The Roche appeal in relation to these Sections was upheld.

In reaching its conclusions, the Appeals Committee expressed considerable concern about activities involving promotion of prescription medicines to the general public. It also noted that any involvement in groups such as the HWT should be acknowledged to enhance transparency.

Sanction

The Committee determined that the sanction should be at the maximum for a moderate breach and resolved that the fine should be amended to \$50,000.

23. Pfizer Pty Ltd Viagra (694)

Sales representative behaviour

Promotional poster entitled:

“This pharmacy sells Viagra at a starting price of ...”

Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Pfizer Pty Ltd (Pfizer) was in breach of Sections 3.1.1, 3.3.1.2 and 9.4 of the Code of Conduct. The TGA advised that the complaint had been submitted by the Pharmacy Guild on behalf of an unnamed person. The TGA alleged that the advertisement was promoting a prescription product to the general public.

Response

A response was received from Pfizer acknowledging a breach of the Code of Conduct and explaining the circumstances in which it had occurred. In their response Pfizer advised that they had undertaken to retrieve the posters from public viewing and that the manager had visited all pharmacies in the area to ensure that there were no posters still in the possession of the pharmacies.

Committee ruling

The Committee noted that Pfizer had taken immediate action to investigate the incident on receipt of the complaint from Medicines Australia. While acknowledging that Pfizer did not endorse the activities of the sales representative and the responsible manager, the Committee considered the action was a serious breach of the Code of Conduct. Although the request for the material was instigated by a pharmacist with the purported objective of advising international travellers that Viagra was available from the pharmacy for a competitive price, the behaviour of the sales representative and in particular the action of the manager in acceding to this request and then attempting to provide the material to other pharmacies was irresponsible and had the potential to bring the industry into disrepute.

While noting that only two posters had been used, the Committee was of the view that they could not be construed as information directed to international visitors that Viagra was available at a competitive Australian price. The manner in which they had been designed was for the promotion of a prescription medicine to the general public. The Committee found a breach of Sections 9.4, 3.1.1 and 3.3.1.2 of the Code.

Sanction

The Committee resolved that Pfizer should pay a fine of \$10,000. The level of this fine should not be interpreted to indicate that the Committee did not consider this to be a very serious breach of the Code of Conduct. The Committee considered that while Pfizer management had not initiated this material, they had a duty to instil a corporate culture that values the Code and to ensure an understanding of the Code and relevant legislation by all employees.

24. Novo Nordisk Pharmaceuticals Pty Ltd Vagifem (695)

Website

www.whylovehurts.com.au

General Public Awareness Campaign

Complaint

A complaint was received from the Consumers' Health Forum (CHF) alleging that Novo Nordisk Pharmaceuticals Pty Ltd (Novo Nordisk) was in breach of Section 9.4 and 9.5 of the Code of Conduct. The CHF alleged that Novo Nordisk was using hairdressers to promote a prescription medicine and that information on a website sponsored by Novo Nordisk could encourage a consumer to seek a particular prescription medicine. As a non-Medicines Australia member, Novo Nordisk Pty Ltd was invited to address the concerns raised in this complaint under the Code of Conduct.

Response

Novo Nordisk accepted this invitation and a response was received denying any breach of the Code of Conduct. Novo Nordisk maintained that the hairdressers were not promoting a prescription medicine as they did not know the name of the product and were given a script which only raised the awareness of atrophic vaginitis. Novo Nordisk also asserted that the hairdresser's cape with the name of the website printed in reverse so that a consumer could read it in the mirror was an attempt to provide women with educational material on atrophic vaginitis.

Committee ruling

The Committee noted that there was no mention in the suggested conversation sheet provided to hairdressers that the activity was sponsored by a pharmaceutical company. Members were of the view that incentives should not be involved in providing educational information to the general public.

The Committee was of the view that much of the material in the fact sheets and on the website was educational and would be of value to members of the general public. However to be balanced and provide a range of information the material should have made mention of the full range of treatments available. Members of the Committee commented that if a patient had followed through with a visit to the doctor, it would be a positive opportunity for the patient to discuss this and any other matter and if a prescription medicine was required the healthcare professional would prescribe appropriately. Some members of the Committee noted that if a woman left the surgery with a prescription she would not know whether it was the "no mess no fuss" product as no product name was mentioned in the material on the website.

By a majority the Committee agreed that the statements repeatedly referring to the "no mess, no fuss treatment" provided a tenuous but sufficient link to a specific prescription medicine and were therefore in breach of Sections 9.4 and 9.5.2 of the Code.

In relation to the website www.whylovehurts.com being promoted on the hairdresser's capes, the Committee was of the view that the name of the company should have been displayed and was therefore in breach of Section 9.5.4 of the Code.

Sanction

The Committee resolved that Novo Nordisk 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 and ensure that the current website and fact sheets are amended to take account of the concerns of the Committee.

The Committee also resolved that Novo Nordisk should pay a fine of \$20,000.

Appeal

An appeal was lodged by Novo Nordisk against the findings of the Code of Conduct Committee. Novo Nordisk maintained that the material on the website was of an educational nature and that there was no attempt to promote a specific prescription medicine to members of the general public.

Committee ruling

The Committee accepted that it might be argued that the capes, conversation sheet and Facts Sheets together could be regarded as educational material that should include the name and locality of the sponsor. However, the Code of Conduct Committee had specifically referred to the capes as being in breach of Section 9.5.4 of the Code. The Appeals Committee concluded that the hairdressers capes were not educational material and therefore the Novo Nordisk appeal should be upheld.

The Committee accepted that the majority of the information on the website was educational. However, the references to low dose, no mess, no fuss topical oestrogen therapy and in particular the reference to 17 beta oestradiol were sufficient to allow a consumer to seek a prescription for a specific prescription medicine. The Committee concluded that the www.whylovehurts.com website was in breach of Sections 9.4 and 9.5.2 of the Code. The Novo Nordisk appeal was not upheld.

Sanction

The Appeals Committee resolved that as the appeal against the most substantial part of the Code of Conduct Committee's decisions had not been upheld, the fine should remain at \$20,000.

25. Aventis Pasteur Pty Ltd

Vaxigrip (696)

Winter Survival Pack

Complaint

A complaint was received from CSL Limited (CSL) alleging that Aventis Pasteur Pty Ltd (Aventis Pasteur) was in breach of Sections 3.8, 9.4 and 10.1 of the Code of Conduct. CSL alleged that the practice of providing healthcare professionals with packets of confectionery and other consumables for distribution to patients was encouraging a patient to seek a prescription for a specific prescription medicine and that as a gift or offering to healthcare professionals it was inappropriate under the provisions of the Code.

Response

A response was received from Aventis Pasteur denying any breach of the Code of Conduct. Aventis Pasteur maintained that the Vaxigrip Immunisation Program was developed to assist doctors in raising awareness of the seriousness of influenza and reducing fears that accompany vaccination. The "Winter Survival Kit" was a token value "reward" for getting vaccinated and that the practice of offering lollipops or stickers etc was practised by other companies including the complainant.

Committee ruling

Members of the Committee noted that most healthcare professionals would purchase a bulk quantity of a vaccine from one supplier and that this differed from normal prescribing when they could choose any product on the day. In the case of the

Vaxigrip materials subject to this complaint, the doctors would have already received a selection of promotional materials from companies and made their decision to use this particular product.

The Committee did not view the practice of providing to healthcare professionals packets of confectionery and other consumables for distribution to patients as an incentive to a member of the general public to seek vaccination with a specific product and was only handed to patients after they had received their vaccination. With respect to the distribution of the confectionery and other consumables included in the pack as an incentive to be vaccinated, the Committee did not find a breach of the Code.

However the Committee expressed concern with respect to the patient pamphlet included in the “Winter Survival Pack”. Although the pamphlet was received after the patient had received their flu vaccination, some of the statements and the inclusion of a picture of the “Winter Survival Pack” which is associated with Vaxigrip could be viewed as the promotion of a specific product to the general public. Members reiterated their view that as the healthcare professional would have previously purchased a supply of Vaxigrip, the intent of having the practice name stamped on the pamphlet and inviting consumers to book an appointment at this particular practice was promoting the use of Vaxigrip, although the name of the product was not mentioned in the material. The Committee found a breach of Section 9.4 of the Code.

The Committee was of the view that the “Winter Survival Packs” did not constitute a gift. Members considered that the pack was of such a trivial nature that it could not be considered an inducement to prescribe a particular product. No breach of Section 3.8 of the Code was found nor did they constitute an inappropriate material benefit to the healthcare professional. No breach of Section 10.1 of the Code was found.

Sanction

The Committee resolved that Aventis Pasteur should take immediate action for the prompt withdrawal of the patient pamphlet found in breach and should permit no further appearance of it in its present form or in a manner that conveys the same or similar meaning.

26. Wyeth Australia Pty Ltd Efexor (697)

Promotional material entitled:

“Expect more dogs in parks Expect more 1st time”

“This week’s appointments”

Complaint

A complaint was received from Pfizer Pty Ltd (Pfizer) alleging that Wyeth Australia Pty Ltd (Wyeth) was in breach of Sections 1.2, 1.3 and 1.7 of the Code of Conduct. Pfizer acknowledged that considerable efforts to achieve a resolution through extensive correspondence and face to face meetings had occurred and a number of issues had been resolved. However, Pfizer alleged that by citing the meta-analyses to support a strong claim of superior efficacy in the promotional material was misleading and unbalanced.

Response

A response was received from Wyeth denying any breach of the Code of Conduct. Wyeth maintained that the promotional materials submitted by Pfizer were no longer in use or had been replaced following the discussions between the two companies. Wyeth asserted that the claims in the promotional material were an accurate representation of the available evidence and were not misleading.

Committee ruling

The Committee considered that on pharmacokinetic grounds the pooling of immediate release trials and extended release trials was justifiable. The treatment of psychiatric illness relies on steady state levels of a drug, which are achieved after some weeks of antidepressant therapy. Therefore there should not be any difference in efficacy between the immediate release and extended release formulations of Efexor. Further, Wyeth had conducted efficacy studies for the two formulations and these data had been evaluated by the Therapeutic Goods Administration (TGA) and accepted as the basis for extending the indications of Efexor XR. Therefore the Committee concluded that no breach of Sections 1.1, 1.3 or 1.7 of the Code should be found in relation to this aspect of the complaint.

The Committee noted that most of the studies included in the meta-analyses used fluoxetine as the comparator; only one trial used sertraline as the comparator. The Committee considered that the claim that venlafaxine has superior efficacy to the SSRIs as a class was not contrary to the body of evidence and was consistent with the conclusions of the meta-analysis. However, the claim was not sufficiently qualified in the promotional material subject to the complaint in relation to providing details about the trials included in the supporting meta-analyses. In particular, the Committee recommended that the plot of pooled remission rates for individual agents should have been included in full rather than the abbreviated figure. The Committee concluded that the claims of superior efficacy included in the promotional materials were in breach of Sections 1.1, 1.3 and 1.7 of the Code as they were not sufficiently qualified.

Sanction

The Committee resolved that Wyeth should permit no further appearance of the material found in breach in its present form or in a manner that conveys the same or similar meaning.

27. Wyeth Australia Pty Ltd Efexor (698)

Promotional material entitled:

“Expect more dogs in parks Expect more 1st time”

“This week’s appointments”

Complaint

A complaint was received from Lundbeck Australia Pty Ltd (Lundbeck) alleging that Wyeth Australia Pty Ltd (Wyeth) was in breach of Sections 1.3 and 1.7 of the Code of Conduct. Lundbeck alleged that in the claim of blanket superiority in favour of venlafaxine over the SSRIs, Wyeth did not acknowledge that the meta analysis in the cited studies did not include citalopram and there have been no head-to-head studies comparing the two products.

Response

A response was received from Wyeth denying any breach of the Code of Conduct. Wyeth maintained that the materials presented by Lundbeck were no longer in use or had been substantially modified.

Committee ruling

The Committee was concerned that any generalisation from the meta-analysis to the SSRI class should be approached cautiously and be appropriately qualified. The Committee concluded that the generalisation expressed by the claims that Efexor works for more depressed patients than SSRIs (as a class) were misleading and therefore in breach of Sections 1.3 and 1.7 of the Code.

The Code of Conduct Committee noted that the claim that there is more chance of remission with Efexor is referenced to the Smith et al meta-analysis. Similarly to the Committee’s concerns in relation to efficacy claims based on this meta-analysis, the Committee considered that as the claims regarding remission rates were not sufficiently qualified with respect to which SSRIs were included, or not included, in the meta-analysis they were misleading and therefore in breach of Sections 1.3 and 1.7 of the Code.

Sanction

The Committee resolved that Wyeth should permit no further appearance of the material found in breach in its present form or in a manner that conveys the same or similar meaning.

In deciding not to impose a fine in relation to the finding of breaches of the Code, the Committee recognised the earnest effort by Wyeth and Lundbeck in endeavouring to resolve the complaint through intercompany dialogue and modification of the promotional material subject to the complaint.

28. Pfizer Pty Ltd Viagra (700)

Advertisement entitled:

“One in three men have erection problems. Until last week he was one of them”

Complaint

A complaint was received from an academic alleging that Pfizer Pty Ltd (Pfizer) was in breach of the Code of Conduct. The complainant alleged that the claims in the promotional material misrepresented the cited study. As the complainant had not identified any particular section of the Code of Conduct Pfizer was requested to respond to Section 9.5 of the Code.

Response

A response was received from Pfizer denying any breach of the Code of Conduct. Pfizer maintained that the purpose of the campaign was to encourage men who suffered from a distressing problem (erectile dysfunction) in silence to come forward and seek professional help.

Committee ruling

Given that the prevalence of erectile dysfunction reached one in three only within certain age groups in this study, whereas in the advertisement to the general public there had been no qualification of the age group that experienced this prevalence, the Committee considered that the advertisement was misleading. In addition, the Committee considered that a false impression of the prevalence of erectile dysfunction could be generated by the claim “one in three men have erection problems” as this prevalence was reported only amongst men who had visited their doctor, which might not reflect the prevalence in the general population, as had been implied in the advertisement.

The Committee considered that as this advertisement was directed at the general public, there was a greater responsibility on the sponsor company to ensure that all statements are accurate and fully disclose any qualifications associated with any claims compared with advertisements directed to healthcare professionals. The Committee unanimously determined that the advertisement by Pfizer was in a breach of Section 9.5 of the Code.

Sanction

The Committee resolved that Pfizer 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 Committee further resolved to impose a fine of \$10,000 reflecting their concern that promotion to the general public must be accurate and not be misleading.

29. CSL Limited

CSL Website (701)

CSL Website

Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that CSL Limited (CSL) was in breach of Sections 3.9 and 9.4 of the Code of Conduct. The TGA alleged that the CSL website went beyond providing Consumer Medicines Information (CMI) and Product Information (PI) and that it promoted the positive attributes of the medicines and that this was viewed as the promotion of a prescription medicine to the general public. To ensure full consideration of the complaint, Medicines Australia also requested CSL to also respond in terms of Sections 9.5 and 9.6 of the Code of Conduct.

Response

A response was received from CSL denying any breach of the Code of Conduct. CSL maintained that the information they provided on the website was factual disease information followed by a brief statement of the action of the product against the disease and a link to the CMI. CSL also noted that they had indicated their willingness to enter into further dialogue with the TGA which the complainant had not pursued.

Committee ruling

The Committee reviewed the original version of the website, as submitted by the TGA in their complaint, whilst noting the amendments to the website that had been instituted by CSL following receipt of the TGA complaint.

The Committee discussed the overall presentation of the CSL website, which comprised pages headed with a product name and included information about different diseases with links to related documents including the CMI for particular CSL products.

The Committee considered that the testimonials included on the influenza website, www.flu.com.au that were accessible to the general public were promotional and therefore not consistent with the Code of Conduct. The Committee also considered that the banner statement “preventing flu in the workplace” and similar statements referring to “preventing” influenza within the website were not able to be substantiated, because no vaccine was one hundred percent effective in preventing infection, and were promotional.

The Committee unanimously determined that the influenza website included elements that promoted a particular prescription medicine to the general public and therefore was in breach of Sections 3.9 and 9.4 of the Code.

The Committee considered that the perceived intention of the Menjugate page on the website was different to the influenza website. No breach of the Code of Conduct in relation to the Menjugate section was found.

The ADT vaccine page on the website included links to the ADT vaccine CMI and a poster “Time to target tetanus”. A number of members considered that immunity to tetanus was a significant public health issue and encouraging tetanus vaccination was a community service. Other members considered that the poster, which included a picture of a birthday cake, was more than informational and encouraged the general public to obtain a prescription for a particular medicine. By a majority decision, the Committee concluded that the ADT vaccine section of the CSL website was in breach of Sections 3.9 and Section 9.4 of the Code as it promoted a particular prescription medicine to the general public.

The H-B-Vax II page of the website included links to the product CMI and a patient leaflet on hepatitis B infection. The Committee considered that the content of the patient leaflet was acceptable, however, its availability via a product-specific website for H-B-Vax II linked the brochure to a specific prescription medicine which was, by a strict interpretation of the Code, in breach of Section 9.4 of the Code as it promoted the product to the general public.

The Q-Vax page of the website included links to the product CMI, a patient leaflet, a poster and a list of South Australian clinics for immunisation. By a majority decision, the Committee concluded that the availability of an otherwise acceptable patient leaflet and poster via a product-specific website was, by a strict interpretation of the Code, in breach of Section 9.4 of the Code.

Sanction

The Committee resolved that CSL should take immediate action for the prompt withdrawal of the material found in breach of the Code and should permit no further appearance of it in the same or similar form.

30. Aventis Pharma Pty Limited Clexane (702)

Brochure entitled:

“The Flow”

Complaint

A complaint was received from a healthcare professional alleging that Aventis Pharma Pty Limited (Aventis Pharma) was in breach of the Code of Conduct. The healthcare professional alleged that a statement in the leading paragraph in an advertising brochure for Clexane was erroneous and misleading.

Response

A response was received from Aventis Pharma acknowledging that an error had occurred in the promotional material, as identified by the healthcare professional. Aventis advised that on being made aware of the error the company immediately ensured that no remaining copies were distributed and that Aventis would issue an “Erratum notice” in the next Flow newsletter.

Committee ruling

The Committee accepted that Aventis Pharma had admitted that an error had occurred whereby an incorrect statement about the incidence of deep vein thrombosis or pulmonary embolism in surgical patients appeared in the Flow newsletter. It also noted that Aventis Pharma proposed to issue an “erratum notice” in the next edition of the newsletter. The Committee determined that the article in the Flow newsletter was in breach of Sections 1.1 and 1.3 of the Code.

Sanction

The Committee resolved that Aventis Pharma should take immediate action for the prompt withdrawal of the material found in breach of the Code and should permit no further appearance of it in the same or similar form. Further, Aventis Pharma should publish an “erratum notice” in the next newsletter, as it had proposed to do. As Aventis Pharma had undertaken to take this corrective action, no further sanction was imposed by the Committee.

31. Sanofi-Synthelabo Australia Pty Limited Plavix/Karvezide (703)

Competition Prize

“Palm Pilot”

Complaint

A complaint was received from a healthcare professional alleging that Sanofi-Synthelabo Australia Pty Limited (Sanofi-Synthelabo) was in breach of the Code of Conduct requirements relating to competitions. The healthcare professional alleged that the value of the prizes offered in the Plavix and Karvezide competitions were above that stated in the Code. As the healthcare professional did not refer to a specific section of the Code Sanofi-Synthelabo was requested to respond to Section 3.7 of the Code.

Response

A response was received from Sanofi-Synthelabo denying any breach of the Code of Conduct. Sanofi-Synthelabo maintained that under Edition 13 of the Code there were no specific monetary values attached to competition prizes but rather a statement that the value of prizes should be assessed on an individual basis. Sanofi-Synthelabo was of the view that the palm pilots with medical software would offer a portable and convenient means for accessing pharmaceutical medical information.

Committee ruling

The Code of Conduct Committee noted that the competition, which offered prizes of a Palm Pilot loaded with MIMS, had commenced in November 2002 prior to the commencement of Edition 14 of the Code of Conduct and the publication of the Guidelines and therefore agreed to hear the complaint under the provisions of Edition 13 of the Code.

Committee members considered that the Palm Pilot with MIMS software would be directly relevant to the practice of medicine and would be a valuable clinical tool for doctors, although the value of the individual prizes was quite high. The Committee considered that the prize would have been acceptable under Edition 13 of the Code of Conduct.

The Committee considered the value of the individual prize of a Palm Pilot and MIMS software in relation to Edition 14 of the Code and the Guidelines. The Committee noted that Section 3.7.1 (iii) allowed that an item of educational material, such as a medical textbook, could be offered as a prize where its value may exceed the suggested \$500 limit. The Committee considered that the medical and educational value of a prize should be taken into account when considering its monetary value, as well as the difficulty and relevance of the competition questions.

The Committee was not convinced that in this case the questions were based entirely on medical knowledge or the acquisition of medical knowledge. However, as no complaint was before the Committee in relation to the questions, no breach of this section was found.

The Committee determined that the prize in the Plavix/Karvezide competition was not in breach of Section 3.7.1 of Edition 13 or Edition 14 of the Code under the period of grace. However, the Committee noted that it was extremely difficult to adjudicate such cases and each must be determined on its merits. If the monetary value of the prize had been higher or the Committee had not agreed that the item provided considerable medical and educational value to medical practitioners, the competition may have been found in breach of Edition 14 of the Code of Conduct. The Committee considered that the perceived value of the prize was close to the limit of what might withstand public and professional scrutiny.

32. Boehringer Ingelheim Pty Ltd

Mobic (704)

Competition Prize

“Palm Pilot”

Complaint

A complaint was received from a healthcare professional alleging that Boehringer Ingelheim Pty Limited (Boehringer Ingelheim) was in breach of the Code of Conduct. The healthcare professional alleged that the value of the prizes offered in the Mobic competition was above that stated in the Code. As the healthcare professional did not refer to a specific section of the Code Boehringer Ingelheim was requested to respond to Section 3.7 of the Code.

Response

A response was received from Boehringer Ingelheim denying any breach of the Code of Conduct. In their response Boehringer Ingelheim stated that while the State legislations require the sponsor to record the recommended retail value of a prize the actual purchase price of the palm pilot was considerably less. Boehringer Ingelheim acknowledged that the value was slightly over that suggested in the Edition 14 Guidelines, however this competition had been initiated in 2002 prior to the introduction of Edition 14 and also that there was a three month grace period in 2003 for activities commenced in 2002 to be finalised.

Committee ruling

The Code of Conduct Committee noted that the competition, which offered prizes of a Palm Pilot loaded with MIMS and Medical Director prescribing software, had been initiated by Boehringer Ingelheim in late 2002 - the prizes were purchased in December 2002 - prior to the commencement of Edition 14 of the Code of Conduct and the publication of the Guidelines to Edition 14 of the Code.

Committee Members considered that a Palm Pilot loaded with MIMS and Medical Director software would be directly relevant to the practice of medicine and would be a valuable clinical tool for doctors, although the value of the individual prizes was quite high. In consideration of the fact that the Guidelines to Edition 14 of the Code, which suggest that the value of a competition prize should not exceed \$500, did not exist when the competition was planned and initiated the Committee considered that the prize would have been acceptable under Edition 13 of the Code of Conduct.

The Committee considered the value of the individual prize of a Palm Pilot loaded with MIMS and Medical Director Software in relation to Edition 14 of the Code and the Guidelines. The Committee noted that Section 3.7.1 (iii) allowed that an item of educational material, such as a medical textbook, could be offered as a prize where its value may exceed the suggested \$500 limit. The Committee considered that the medical and educational value of a prize should be taken into account when considering its monetary value, as well as the difficulty and relevance of the competition questions.

The Committee determined that the prize in the Mobic competition was not in breach of Section 3.7.1 of Edition 13 or Edition 14 of the Code. However, it commented that it was extremely difficult to adjudicate such cases. If the monetary value of the prize had been higher or the Committee had not agreed that the item provided considerable medical and educational value to medical practitioners, the competition may have been found in breach of Edition 14 of the Code of Conduct. The Committee considered that the perceived value of the prize was close to the limit of what might withstand public and professional scrutiny.

33. Merck Sharp & Dohme (Australia) Pty Ltd Fosamax (705)

Promotional material entitled:

“Fosamax Fast fracture risk reduction – with evidence supporting 10 years continuous therapy”

“Fosamax Unsurpassed vertebral/non vertebral fracture protection”

Complaint

A complaint was received from Aventis Pharma Pty Limited (Aventis Pharma) alleging that Merck Sharp & Dohme (Australia) Pty Ltd (Merck Sharp & Dohme) was in breach of Sections 1.3 and 1.7 of the Code of Conduct. Aventis Pharma alleged that the meta-analyses of therapies for post menopausal osteoporosis conducted by the Osteoporosis Research Advisory Group were used in a manner that was comparative and misleading.

Response

A response was received from Merck Sharp & Dohme denying any breach of the Code of Conduct. Merck Sharp & Dohme maintained that the publication presented the results of seven systematic reviews of osteoporosis therapies and that it was not within the provisions of the Code for Aventis Pharma to seek to have Merck Sharp & Dohme prohibited from using this material.

Committee ruling

The Committee discussed the ORAG meta-analysis and determined that it would be excessive to restrict the use of a meta-analysis in a comparative way in promotional material. Meta-analyses can be regarded as high level evidence and should be able to be used to support promotional claims as long as the meta-analysis is of good quality. The ORAG meta-analysis was considered to be of very good quality. No breach of the Code of Conduct was found.

The Committee determined that there was no evidence that the data for alendronate (Fosamax) had been surpassed. The Committee found that the heading statement “Fosamax. Unsurpassed vertebral/non-vertebral fracture protection” in the context of the accompanying graph was factual and not comparative. No breach of the Code was found.

To enable a reader to make a fair evaluation of the presented data, sufficient detail must be included in the graph, such as the p-values, confidence intervals and number of subjects, as well as any qualifications regarding how to interpret the data. The Committee concluded that the graphs presenting the ORAG data were misleading by omission and distortion and therefore in breach of Sections 1.3 and 1.7 of the Code.

Sanction

The Committee resolved that Merck Sharp & Dohme should take immediate action for the prompt withdrawal of the promotional material found in breach of the Code and should permit no further appearance of it in the same or similar form.

It was also resolved that Merck Sharp & Dohme should send a corrective letter to all recipients of the promotional material found in breach of the Code or who had been detailed using this material and pay a fine of \$25,000.

34. AstraZeneca Pty Ltd Arimidex (706)

Promotional material entitled:

“Pick an aromatase inhibitor that’s effective and well tolerated”

“Don’t compromise when picking an aromatase inhibitor”

Complaint

A complaint was received from Novartis Pharmaceuticals Australia Pty Ltd (Novartis) alleging that AstraZeneca Pty Ltd (AstraZeneca) was in breach of Sections 1.3 and 1.7 of the Code of Conduct. Novartis alleged that there had been a history of promotional material that Novartis believed breached the Code and which AstraZeneca had agreed to amend. Novartis was of the view that the latest promotional materials were also in breach and that AstraZeneca should endeavour to put in place a more stringent review process to ensure that a fair and competitive environment is guaranteed.

Response

A response was received from AstraZeneca denying any breach of the Code of Conduct. AstraZeneca sought clarification on which pieces of promotional material Novartis was claiming to be in breach of the Code as they were of the view that all materials had been amended to reflect the concerns of Novartis.

Committee ruling

The Committee noted that AstraZeneca had conceded that it had failed to include an indication of the relevant comparators in certain statements in the promotional material. The Committee considered that the heading “Arimidex for a better benefit/risk ratio” and the subsequent dot points on the promotional item should have been referenced to comparators. A breach of Section 1.7 of the Code was found.

The Committee accepted that the statement “Arimidex - First-line treatment of hormone receptor-positive advanced breast cancer in postmenopausal women”, was acceptable to indicate the treatment setting in which the promotional claims were made. No breach of Section 1.7 of the Code was found.

The Committee considered that the generalisation that Arimidex is better tolerated or has a better benefit/risk ratio was too strong in view of the fact that only one adverse event category, thromboembolic disease, was statistically significant when Arimidex was compared with tamoxifen.

On the basis of the omission of a qualifying statement regarding the lack of clinical significance of parameters listed in the table, the inappropriate generalisation from the presented data and the lack of reference to the relevant comparator the Committee found a breach of Section 1.7 of the Code.

The Committee commented that the statement “pick an agent with fewer side effects” was a hollow statement that did not contribute to improved understanding of the place of Arimidex in the treatment of breast cancer.

Sanction

The Committee resolved that AstraZeneca should take immediate action for the prompt withdrawal of the promotional material found in breach of the Code and should permit no further appearance of it in the same or similar form.

In addition, the Committee resolved that a fine of \$7,500 should be imposed on AstraZeneca.

35. Schering-Plough Pty Ltd Elocon (708) Inflated Detail Aid

Complaint

A complaint was received from CSL Limited (CSL) alleging that Schering-Plough Pty Ltd (Schering-Plough) was in breach of Sections 3.5.6, 4.4, 9.4 and 10.5 of the Code of Conduct. CSL alleged that the use of a gimmicky, ‘fun’ blow up representation of a prescription medicine for presenting written scientific and clinical information about the product, devalued the content of that information and the responsible use of medicines.

Response

A response was received from Schering-Plough denying any breach of the Code of Conduct. Schering-Plough maintained that the CSL complaint was not in relation to the content of the information on the detail aid and that the assertion that the use of the inflatable item per se would diminish a medical representative’s ability to remain professional when detailing the product to a healthcare professional was rejected by Schering-Plough.

Committee ruling

A majority of the Committee considered that the inflatable Elocon tube was inappropriately gimmicky, would not withstand public and professional scrutiny and would bring discredit to, and decrease confidence in, the pharmaceutical industry. Members expected that promotional material should be presented to doctors in a professional manner, which the Elocon inflatable tube did not do. By majority, the Committee determined that the Elocon tube was in breach of Section 10.5 of the Code. A minority of the Committee thought that the Elocon tube was trivial, useless and silly, but not sufficiently so to find a breach of the Code of Conduct.

The Committee determined that as it had been proposed that the Elocon tube would be covered from view of the general public, no breaches of Sections 9.4 or 3.5.6 of the Code were found.

Sanction

The Committee resolved that Schering-Plough should take immediate action for the prompt withdrawal of the promotional material found in breach of the Code and should permit no further appearance of it in the same or similar form.

36. AstraZeneca Pty Ltd Nexium (711)

Promotional material entitled:

“More effective acid control than other PPIs ”

Complaint

A complaint was received from Wyeth Australia Pty Ltd (Wyeth) alleging that AstraZeneca Pty Ltd (AstraZeneca) was in breach of Sections 1.2.2 and 1.3 of the Code of Conduct. Wyeth alleged that the use of data in abstract form was insufficient evidence on which to support a major claim and that other claims were misleading.

Response

A response was received from AstraZeneca denying any breach of the Code of Conduct. AstraZeneca maintained that it had agreed to modify the claim considered to be misleading and that other claims were supported by the highest level of available evidence.

Committee ruling

The Committee noted that of the seven secondary outcome measures, four of these showed statistically significant difference in favour of esomeprazole. In addition, the primary outcome measure in the study supported the claim of faster symptom resolution with esomeprazole.

The Committee acknowledged that the claim “faster symptom resolution than omeprazole and lansoprazole” was factually correct and consistent with the evidence, but considered that the promotional claim would be enhanced by the inclusion of further clarification of the actual difference in time to symptom resolution so that a reader could make a judgement with respect to the likely clinical significance of the difference. The Committee determined by a majority that the claim was not in breach of Section 1.3 of the Code.

The Committee considered that data presented in the abstracts were consistent with other published peer-reviewed papers and no contradictory evidence had been identified to refute their conclusions. The Committee determined by a majority that the use of abstracts to support the claim was not in breach of Section 1.2.2 of the Code.

For the reasons stated above in relation to the use of abstracts to support the promotional claim “Intra-gastric acid control compared to other PPIs”, the Committee determined that the graph was not in breach of Section 1.2.2 of the Code.

MONITORING REPORT

1 JULY 2002 – 30 JUNE 2003

The Monitoring Committee reviewed two therapeutic categories (Central Nervous System and Musculoskeletal) and company websites available to the general public during the 12 months from 1 July 2002 to 30 June 2003.

The review of printed promotional material in the Central Nervous System category (226 pieces, 27 products and 14 companies) covered three meetings. The first meeting reviewed 73 pieces of material resulting in the Committee requesting further information on 22% of the materials to satisfy itself regarding compliance with the Code. The second meeting reviewed 47 pieces of material resulting in the Committee requesting further information on 15% of the materials to satisfy itself regarding compliance with the Code. The final meeting reviewed 106 pieces resulting in the Committee requesting further information on 15% of the materials to satisfy itself regarding compliance with the Code. On receipt of the further information from the companies no material was submitted to the Code of Conduct Committee as a potential breach of the Code of Conduct.

The meeting to review all advertisements in the Musculoskeletal category covered 42 advertisements (4 products and 3 companies) resulting in the Committee requesting further information on 38% of the materials to satisfy itself regarding compliance with the Code. On receipt of the further information from the companies no material was submitted to the Code of Conduct Committee as a potential breach of the Code of Conduct.

Over a series of three meetings the Committee reviewed 22 company websites available to the general public. The Committee found only one company website which raised significant concerns. Recommendations relating to the use of the Medicines Australia recommended statements prior to linking to other websites, information on what is a Consumer Medicines Information and greater acknowledgement of the sponsorship of websites were made in relation to six company websites although the Committee did not find the material available on the websites was in anyway misleading or inaccurate. The Committee also made recommendations to three companies in relation to the use of some words that may be considered to be promotional. Overall the Committee commented that the information available on the company websites was of educational value to the general public.

Monitoring Committee

Permanent Members

- Retired/consulting industry representative with Code of Conduct experience(Chair)
- Representative of the Royal Australian College of General Practitioners (RACGP)
- Representative of the Australian Medical Association (AMA)
- One member of the Medicines Australia Secretariat

Rotating Members

- One expert in a particular therapeutic class, generally a representative of the relevant College or Society
- One member of a relevant patient support group
- Medicines Australia member company Medical/Scientific Director (with no conflict of interest in the class of the complaint/s being heard)
- Medicines Australia member company Marketing Director (with no conflict of interest in the class of the complaint/s being heard)



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 Product Information.

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.

3. Promotional Material*

3.1 Journal Advertising

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 2 mm as measured by the font's Product Information 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.

3.1.1 Full advertisement*

3.1.4 Company Commissioned articles*

3.3.1 Printed promotional material

3.3.1.2 All Member printed promotional material must include the following information:

- (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
- (d) Full or abridged disclosure Product Information

3.3.4 Medical literature/reprints

3.5.1 Mailings must comply will all relevant provisions of Section 1 of this Code.

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

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

3.7 Competitions

3.8 Gifts/Offers

No items shall be offered or given to healthcare professionals, their families or employees unless they are consistent with the principles contained within Sections 3.3.3 (Brand Name Reminders), 3.7 (Competitions), 10.1 (Entertainment) or 10.2 (Medical Educational Material) of this Code.

3.9 The Use of the Internet for Pharmaceutical Information

APMA supports the right of its Members to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and healthcare professionals. However, the promotion of products covered by the Code of Conduct to the general public via the Internet would breach Section 9.4 of the Code.

The following provisions are applicable to information generated for use via Australian Internet sites.

9. Communications with the General Public

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.

9.5.2 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.

9.5.7 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

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 hosProduct Informationality 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 reciProduct Informationents might reasonably be expected to incur for themselves under similar circumstances.

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

10.2.2 Material supplied with medical education may include promotional claims and/or statements, but must comply with Sections 1 and 3 of the Code of Conduct.

This material should be clearly identified as promotional material.

PROVISIONS OF THE CODE

EDITION 14



1.2 Substantiating Data

1.2.2 Level of Substantiating Data

Any information used to support a medical or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim.

Such substantiating information must not rely solely on data on file.

1.3 False or Misleading Claims

All information, claims and graphical representations provided to healthcare professionals and members of the general public must be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

Claims must be referenced where there is a possibility that a reader may be misled if the source of the reference is not disclosed.

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 properly reflects the body of evidence and 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.

3.5 Mailings*

3.5.6 Exposed mailings including postcards, envelopes or wrappers must not carry matter which might be regarded as promotion to the general public or which could be considered unsuitable for public view.

4. Medical Representatives

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

9.4 Promotion to the General Public

Prescription products may only be promoted to healthcare professionals. Any information provided to members of the general public must be educational. Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited.

10.5 Discredit to, and Reduction of, Confidence in, the Industry

Activities engaged in by Companies with healthcare professionals or materials provided to healthcare professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry. A breach of this requirement is a Severe Breach of the Code of Conduct.



