

Code of Conduct Committee Decisions July – December 2003

Aventis Pharma Pty Limited Actonel (709)

Complaint

A complaint was received from Merck Sharp & Dohme (Australia) Pty Ltd alleging that Aventis Pharma Pty Limited was in breach of the Code of Conduct in relation to the promotion of Actonel. MSD claimed that the use of the abstracts and posters did not report trials specifically designed to support the claims made and therefore healthcare professionals may be misled as to the nature and strength of support for these claims.

Response

A response was received from Aventis Pharma Pty Limited denying any breach of the Code of Conduct. Aventis Pharma believed that the advertisements fulfilled all the criteria that are expected by the Guidelines to Section 1.2.2 and that MSD had based their complaint on an incorrect interpretation of the Code.

Committee Ruling

The Committee reviewed the references cited to support the claims for fast fracture protection and vertebral and non-vertebral protection in six months, which were two abstracts by S. Adami et al and S. Boonen et al and a poster presentation by N.B. Watts et al.

The Committee considered that there was inadequate information contained in these references to allow a reader to evaluate the validity of the promotional claims. The references had not been published or subjected to formal peer-review. The Committee considered that the evidence contained in the two abstracts and poster presentations were of insufficient quality to support the major claims.

The Committee concluded that the use of the two abstracts and poster presentation to support the major claims was in breach of Section 1.2.2 of the Code of Conduct.

The Committee considered that as the major claims were not supported by substantiating data of appropriate quality or detail they were misleading and therefore in breach of Section 1.3 of the Code of Conduct.

Sanction

The Committee resolved that Aventis Pharma Pty Limited 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, Aventis Pharma Pty Limited 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. The Corrective letter should include a crossed out image of the claims and graph that had been found in breach of the Code.

The Committee also resolved that Aventis Pharma Pty Limited should pay a fine of \$25,000.

Appeal

Aventis Pharma Pty Ltd lodged an appeal against the Code of Conduct Committee's decision as it considered that the decision was based on an incorrect interpretation of Section 1.2.2 of the Code.

Committee ruling

The Appeals Committee noted that the abstracts and poster had been presented by the different authors at different meetings but were based on the same retrospective analysis.

The Appeals Committee unanimously agreed that there was insufficient information provided in the abstracts and poster to allow a reader to evaluate the validity of the major claims. The appeal against finding a breach of Section 1.2.2 was not upheld.

The Appeals Committee considered that it was misleading to refer to the same data as two references with different authors. A reader may be misled into thinking that these were two independent studies. The Appeals Committee determined that the appeal against finding a breach of Section 1.3 was not upheld.

Sanction

The Appeals Committee resolved that the sanctions imposed by the Code of Conduct Committee should remain, except that the corrective letter should not include a crossed out image of the graphs. The corrective letter should state that the claims found in breach had been based on abstracts and a poster which at the time the claims were made had not been peer-reviewed for publication.

Baxter Healthcare Pty Ltd Desflurane (710)

Complaint

A complaint was received from a healthcare professional alleging that Baxter Healthcare Pty Ltd (Baxter) was in breach of the Code of Conduct in relation to the behaviour of medical representatives.

Response

A response was received from Baxter denying any breach of the Code of Conduct. Baxter maintained that there appeared to be some gaps in the communication and protocol within the hospital in relation to the trial of desflurane. As a result of this incident Baxter had heightened their sensitivity towards patient privacy issues and was satisfied that their staff had acted with the utmost professionalism at all times.

Committee Ruling

This complaint was considered by the Committee at several meetings whilst further information regarding the alleged activities subject to the complaint was sought from the hospital and Baxter Healthcare.

On the second occasion the Committee considered the complaint, it noted that no response had been received to Medicines Australia's request for more information from the hospital at which the alleged activity occurred. The Committee discussed whether it was appropriate to adjudicate on this matter without any views being expressed by the hospital. The Committee acknowledged that Baxter Healthcare Pty Ltd had promptly provided a more detailed response when specifically requested to do so by Medicines Australia. The Baxter Healthcare Pty Ltd response had provided a logical explanation of events and took on board issues relating to patient privacy.

The Committee initially was very concerned that a grave breach of patient privacy and of the doctor's autonomy may have occurred. However, having been provided with statements from the two Baxter Healthcare Pty Ltd representatives and in the absence of any contrary evidence from the hospital, the Committee considered that the evidence before it was not sufficient to find that a breach of the Code of Conduct had occurred. The Committee determined that at the time, due to the lack of conclusive evidence, it could not make a determination on this complaint. However in the course of the following two months if a response were received from the hospital it would be provided to the Code of Conduct Committee for further consideration. If no correspondence was received from the hospital by the end of this period, this matter would be considered closed as not proven on the basis that the evidence to hand is equivocal. The Committee was concerned to reassure the healthcare professional that this did not mean that the Committee had not taken his submissions in support of his complaint very seriously.

Medicines Australia subsequently received a letter from the Executive Director Medical Services at the hospital advising that an investigation had been undertaken into this complaint.

Following review of this further information, the view of the Committee was that due to the variation in the description of what actually had occurred, the complaint was not proven.

The Committee also noted that as a result of the internal discussions at the hospital, new policies and procedures have been put in place for supplier representatives visiting the hospital.

Medicines Australia wrote to Baxter Healthcare Pty Ltd advising of the outcome of this complaint. Baxter Healthcare Pty Ltd was provided with a copy of the hospital's Supplier Representative Procedure and encouraged to ensure that this procedure was immediately adopted by the company and that all representatives attending the hospital were fully briefed and agreed to comply with the hospital's policy.

Merck Sharp & Dohme (Australia) Pty Limited Zocor (713)

Complaint

A complaint was received from Pfizer Pty Ltd (Pfizer) alleging that Merck Sharp & Dohme (Australia) Pty Limited (MSD) was in breach of the Code of Conduct in relation to the promotion of Zocor. Pfizer considered that the Zocor advertisements were misleading in respect to the indications and PBS reimbursement for its product Lipitor.

Response

A response was received from MSD denying any breach of the Code of Conduct. MSD maintained that it had been accurate in its promotion of Zocor concerning the approved indications and PBS reimbursement criteria for Zocor and the other statins, which had been achieved as a result of the findings of the Heart Protection Study.

Committee Ruling

While acknowledging the new extended TGA approved indication for Zocor, the Committee was of the opinion that it was not reflective of the practical evidence and consequences of the TGA/PBAC system. If it is accepted that hypercholesterolemia is any cholesterol level where a patient would benefit from lowering cholesterol, Lipitor is TGA indicated for patients with hypercholesterolemia and PBS reimbursed as per the PBS qualifying criteria.

The Committee unanimously found that the table in the Zocor advertisement was in breach of Sections 1.1, 1.3, 1.5 and 1.7 as the information provided by the Table regarding Lipitor's indication and availability under PBS reimbursement was not accurate, balanced or correct, was misleading and made an unfair comparison as it incorrectly implied that Lipitor may not be prescribed for patients in these categories. The table also implied that Zocor was unique in its PBS reimbursement which could not be substantiated.

Similarly, while acknowledging the new extended TGA indication for Zocor, the Committee considered that use of the term "exclusively" in relation to TGA indications and PBS reimbursement of simvastatin was not correct and was misleading. Whilst simvastatin is the only statin with the specifically worded indication, to claim exclusivity in relation to how a particular patient with cardiovascular or other risk factors and a certain cholesterol level should be treated was misleading and was not helpful to prescribers. The Committee determined that use of "exclusivity" in the advertorial was in breach of Sections 1.1, 1.3, 1.5 and 1.7 as the term was not balanced or correct, was misleading and made an unfair comparison as it implied that Lipitor may not be prescribed for patients in these categories. The Committee also considered that "exclusive" implied special merit or quality of simvastatin which could not be substantiated.

Sanction

The Code of Conduct Committee resolved that MSD 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 claims found in breach should not be used again in the same form or a manner that conveys the same or similar meaning.

In addition, MSD should be required to print a full page corrective advertisement in *Australian Doctor Weekly*. This advertisement should include reference to the misinterpretation of the PBS Guidelines and reproduce the "PBS General Statement for Lipid-Lowering Drugs Prescribed as Pharmaceutical Benefits" and the "Qualifying Criteria".

Appeal

MSD lodged an appeal against the findings of the Code of Conduct Committee.

The Appeals Committee considered that in light of the National Heart Foundation (NHF) Lipid Management Guidelines and the PBAC qualifying criteria, the Zocor advertisement was inaccurate. The Appeals Committee considered that as the heading on the reimbursement side of the table refers to total cholesterol of less than 5.5 mmol/L, the "No" statements for Lipitor were absolutely incorrect.

The Appeals Committee discussed MSD's argument that it could not have known that its Zocor advertisements were in breach of the Code due to a new interpretation of the qualifying criteria. The Committee noted that the wording for both Lipitor and Zocor in the PBS Schedule, which refers to

the criteria in the General Statement for Lipid-Lowering Drugs, is the same. The PBAC qualifying criteria provides ranges of cholesterol levels which vary according to certain risk factors and this will change over time as new studies are conducted.

The Committee noted the reference to TGA approved indications in the General Statement qualifying criteria. However, the Committee considered that the qualifying criteria could be applied equally to Lipitor and Zocor. In practice, prescriptions for Lipitor for a person with a cholesterol between 4 and 5.5 mmol/L and existing cardiovascular disease will be reimbursed and it is incorrect to claim otherwise.

The Appeals Committee unanimously considered that the advertisement and advertorial for Zocor were in breach of Sections 1.1, 1.3, 1.5 and 1.7 of the Code. The appeal was not upheld.

Sanction

The Appeals Committee agreed that the sanctions imposed by the Code of Conduct Committee should remain. However, the Appeals Committee did not consider that it was sufficient to print a single corrective advertisement in *Australian Doctor Weekly*, which would reach a much smaller cross-section of prescribers than may have been exposed to the original advertisement. In consideration of the length of time between the advertisements appearing and the finalisation of the appeal, the Committee determined that MSD should be required to issue a corrective letter, with the same content as the corrective advertisement, to all Australian doctors (specialists and general practitioners).

Pfizer Pty Ltd Lipitor (715)

Complaint

A complaint was received from Merck Sharp & Dohme (Australia) Pty Limited (MSD) alleging that Pfizer Pty Ltd (Pfizer) was in breach of the Code of Conduct in relation to the promotion of Lipitor. MSD maintained that the advertisements for Lipitor were confusing and misrepresented the correct position for Lipitor under the Schedule of Pharmaceutical Benefits.

Response

A response was received from Pfizer denying any breach of the Code of Conduct. Pfizer submitted that the assertion that the advertisements were confusing or misleading was fundamentally flawed.

Committee Ruling

The Committee considered that although the TGA indication for Lipitor is for the treatment of hypercholesterolaemia, it was an over-generalisation to claim that Lipitor is PBS reimbursed for hypercholesterolaemia alone without clarification with respect to qualifying risk criteria as described in the Schedule of Pharmaceutical Benefits. A minority of the Committee considered that the statement was not in breach of the Code as qualification of the claim was provided in the table in the advertisement. However, a majority of the Committee considered that the statement was in breach of Section 1.3 as it was misleading because not every patient with hypercholesterolaemia, such as those without qualifying risk factors, and treated with Lipitor will receive PBS reimbursement.

In relation to a statement that the National Heart Foundation and Cardiac Society of Australia and New Zealand support that most patients satisfying the criteria for higher risk of CHD should be treated for hypercholesterolaemia, the Committee noted that the Lipid Management Guidelines 2001 refer to target cholesterol levels for high risk patients and not hypercholesterolaemia. The Committee found this statement to be in breach of Section 1.3 of the Code as it was misleading and not an accurate reflection of the source Guidelines.

In relation to a claim that most patients satisfying the criteria for higher risk of CHD should be treated on the basis that they have hypercholesterolaemia, the Committee considered that the use of the term hypercholesterolemia as referenced to the Lipid Management Guidelines was inaccurate and misleading as the Guidelines do not refer to "hypercholesterolemia" but rather recommend target cholesterol levels for people with certain risk factors. The Committee found that this statement was in breach of Sections 1.1 and 1.3 of the Code.

In relation to the sections of the table headed "PBS reimbursed", the Committee found no breach of Sections 1.1 or 1.3 of the Code as it specified cholesterol levels and referred to the PBS qualifying criteria.

The Committee noted that Pfizer had acknowledged that the mandatory Product Information had been omitted. The Committee found a breach of Section 3.1.1.2 of the Code.

The Committee acknowledged that there was confusion surrounding PBS reimbursement of the statin group. However, companies should take care to ensure that prescribers receive accurate and balanced information. The Committee did not consider that the matters found in breach of the Code of Conduct in the current environment in relation to statins were sufficient to find a breach of Section 10.5 of the Code.

Sanction

The Code of Conduct 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning.

Pfizer Pty Ltd Spiriva (717)

Complaint

A complaint was received from a healthcare professional alleging that Pfizer Pty Ltd (Pfizer) was in breach of the Code of Conduct in relation to the promotion of Spiriva as there was insufficient evidence to support the claims and that only two of the three references referred to in the advertisement were included in the mandatory text.

Response

A response was received from Pfizer denying any breach of the Code of Conduct and arguing that there was sufficient evidence in the literature to support the claims and that all references had been included in the mandatory text in the advertisement.

Committee Ruling

The Committee considered that there was sufficient evidence contained in the Spiriva approved Product Information and in the literature references to support the claims. No breach of Sections 1.1 or 1.3 was found.

The Committee reviewed the Spiriva advertisement from the *Medical Journal of Australia* referred to by the healthcare professional and noted that all three references were included. No breach of Section 1.2 was found as the references were fully stated.

Roche Products Pty Ltd Pegasys (718)

Complaint

A complaint was received from Schering-Plough Pty Ltd (Schering-Plough) alleging that Roche Products Pty Ltd (Roche) was in breach of the Code of Conduct in relation to the promotion of Pegasys. Schering-Plough claimed that Roche had been promoting unapproved indications for Pegasys at several scientific meetings in Australia.

Response

A response was received from Roche denying any breach of the Code of Conduct. Roche maintained that the majority of the issues had been satisfactorily addressed through inter-company dialogue and that the few matters not resolved were of a trivial nature.

Committee Ruling

A majority of the Committee considered that the package of activities undertaken in association with providing the Roche symposium at the International Symposium on Viral Hepatitis and Liver Disease (ISVHLD) was promotional. Whilst the symposium title alone did not provide a direct link to Pegasys, the use of a picture on the invitation to the symposium and on other materials supplied at the Roche trade display, and the use of the product name alongside the seminar title on the invitation provided on the ISVHLD website, were promotional activities for Pegasys, which had not been approved for use in Australia at the time of the ISVHLD meeting. A minority of the Committee considered that no breach of Section 1.3.1 should be found because it is accepted practice at

international symposia for researchers to present information on new products; at the time Pegasys was very close to being registered; and it is important for specialists to have access to information about new products. However the Committee determined by a majority that Roche Products Pty Ltd had breached Section 1.3.1 of the Code of Conduct by promoting an unapproved product.

However the Committee was concerned that the disclaimer that this product was not approved in Australia, which appeared in small print on the back page of materials provided at the trade display, was not sufficiently prominent to meet the test: "An appropriately worded label, prominently located as required by Section (6.1) of the Code." The Committee therefore found a breach of Section 6.1 of the Code.

The Committee considered that the complaint that a doctor from Roche Products Pty Ltd had said pegylated interferon alfa-2b "is an interferon pro-drug" rather than "is, or acts as, a prodrug" was unproven. No breach of Section 1.3 of the Code was found.

In relation to the statement claimed to be made by another speaker at the Roche symposium "Pegasys offers physicians the best chance of cure in difficult-to-treat patients", the Committee considered that there was no evidence that this statement had been made. No breach of Section 1.3 was found.

In relation to weight-based dosing of pegylated interferons, the Committee noted that there was currently a difference between how Pegasys and Pegatron were dosed with respect to body weight. It also noted that the FDA had reportedly requested further studies be undertaken by Roche. However, the Committee considered that the learned audience who received the presentation would be aware of the differing literature on this issue. Therefore, no breach of Section 1.3 of the Code was found.

Sanction

The Committee resolved that Roche should take immediate action for the prompt withdrawal of the materials found in breach and should permit no further appearance of them in their current form. The materials found in breach should not be used again in the same form.

Merck Sharp & Dohme (Australia) Pty Limited Zocor (719)

Complaint

A complaint was received from Bristol-Myers Squibb Pharmaceuticals (BMS) alleging that Merck Sharp & Dohme (Australia) Pty Limited (MSD) was in breach of the Code of Conduct in relation to the promotion of Zocor. BMS maintained that the advertisement did not accurately portray the registered indications of statins, in particular pravastatin.

Response

A response was received from MSD denying any breach of the Code of Conduct. MSD defended the promotional material which was to highlight the unique, broad indication that simvastatin now has, as a result of the Heart Protection Study.

Committee Ruling

The Committee considered that the advertisement implied that no other statin could be prescribed for patients at high risk of CHD. The Committee determined that this was not accurate as these patients also fell within the indications for Pravachol and other statins and therefore resolved that the claim was in breach of Section 1.3 of the Code as it was misleading to prescribers.

Sanction

The Code of Conduct Committee resolved that MSD 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning. The Code of Conduct Committee also resolved to impose a fine of \$10,000 on MSD.

Bayer Australia Pty Ltd and GlaxoSmithKline Australia Levitra (720)

Complaint

A complaint was received from Eli Lilly Australia Pty Ltd (Eli Lilly) alleging that Bayer Australia Pty Ltd (Bayer) and GlaxoSmithKline Australia (GSK) were in breach of the Code of Conduct in relation to the promotion of Levitra. Eli Lilly contended that the claims made in relation to Levitra were not supported by sufficient evidence, were misleading and lacked qualification.

Response

A response was received from Bayer and GSK denying any breach of the Code of Conduct. Bayer and GSK maintained that there was sufficient evidence to support the claims and argued that 'consistent with the PI' does not mean 'identical to the figures in the PI'.

Committee Ruling

The Committee considered that the efficacy rates claimed in the promotional pieces did not accurately reflect the evidence documented in the Levitra approved Product Information and no qualification had been provided in the promotional material to explain the higher efficacy rates. As the claims were based on efficacy rates that were not consistent with the Product Information the Committee found a breach of Section 1.1 of the Code.

The Committee commented that while both 'completers' or 'per protocol' and 'intention to treat' are acceptable ways to analyse data, to ensure that a healthcare professional receives sufficient information on which to make a prescribing decision, a company must provide appropriate qualification or clarification in promotional material.

Members considered that the use of the efficacy rates was misleading as they referred to the 'completers only' analysis and this was not clarified in the promotional material. As the material did not specify the cohort from which this efficacy rate was determined, the promotional material was found in breach of Section 1.3.

In relation to the claim of an efficacy rate of 92% in a 'real world' population, the Committee also found that the use of the term 'real world', while used by the authors in the study, may be confusing to prescribers. Although the Committee agreed that healthcare professionals may be confused by what is meant by the terms 'broad population' and 'real world' and what is the difference between these groups, the Committee did not find that 'real world' was an unqualified superlative. No breach of Section 1.5 of the Code was found.

In relation to the complaint that the evidence to support the claims was not of sufficient quality, the Committee referred to the need for clarification when using figures from two differing types of analysis. The Committee found no breach of Section 1.2.2 in relation to the efficacy rate of 85%, as this was referenced to a study published in a peer-reviewed journal. The Committee noted that while the use of "71% in men with bi-lateral nerve-sparing prostatectomy" was based on a poster presentation, there was sufficient information available from the poster and it was supported by a study which had been published in an appropriate journal. The Committee therefore found no breach of Section 1.2.2 of the Code in relation to this claim. However, the Committee found that the evidence to support the claim of "92% in real world population", which was also referenced to a poster presentation, was not sufficient to support this major claim. A breach of Section 1.2.2 of the Code was found in relation to the claim of an efficacy rate of 92% in a real world population.

Sanction

The Code of Conduct Committee resolved that Bayer and GSK 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning.

Wyeth Australia Pty Ltd Efexor (721)

Complaint

A letter of complaint dated 5 August 2003 had been received from Pfizer Pty Ltd (Pfizer) alleging that Wyeth Australia Pty Ltd (Wyeth) was in breach of the Code of Conduct in relation to the

promotion of Efexor. Pfizer had advised that several issues had been resolved through inter-company dialogue, however the companies had been unable to agree on the extent of any corrective action.

Response

A response was received from Wyeth acknowledging that resolution to some alleged breaches had been reached but they did not agree with the corrective action proposed by Pfizer

Committee Ruling

The Committee noted that the original complaint from Pfizer referred to two matters. The first matter had been resolved following intercompany dialogue with Pfizer Pty Ltd and Wyeth's agreement to publish a corrective letter in the *Australian Journal of Pharmacy*. The Committee considered this matter closed, although it would like to see evidence that the corrective letter is published.

The Committee discussed the second matter regarding the publication of a meta-analysis comparing venlafaxine with SSRIs on an internet page on the Wyeth Depression Resource Centre, which could only be accessed by registered health care professionals through the Med-E-Serv system. The Committee agreed that while the figure summarising the meta-analysis in itself was not misleading, the claims of superior efficacy of venlafaxine compared with SSRIs based on the pooled SSRI data were misleading as the majority of the studies in the pooled data were against fluoxetine.

The Committee noted that Wyeth had conceded during intercompany dialogue that the continued use of these claims on the internet page was in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct and had agreed to amend the website. However, the nature and extent of corrective action was still subject to dispute between Pfizer and Wyeth. The Committee found a breach of Sections 1.1, 1.3 and 1.7 of the Code. No breach of Section 1.2.2 was found.

Sanction

The Code of Conduct Committee resolved that Wyeth 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning.

In addition, Wyeth should be required to send a corrective letter via Australia Post (later amended to via email) to all registrants of the Med-E-Serv website.

Merck Sharp & Dohme (Australia) Pty Limited Fosamax (722)

Complaint

A complaint was received from Aventis Pharma Pty Ltd (Aventis Pharma) alleging that Merck Sharp & Dohme (Australia) Pty Limited (MSD) was in breach of the Code of Conduct in relation to the promotion of Fosamax. Aventis Pharma contended that the claims were based on an abstract and that they were inaccurate and misleading.

Response

A response was received from MSD denying any breach of the Code of Conduct. MSD asserted that the claims were not major claims and that the abstract was not the only supporting evidence.

Committee Ruling

The Committee discussed the Fosamax promotional material and whether the claim "with evidence supporting 10 years' continuous therapy" could be considered a major claim. While some members of the Committee were of the view that it was not "the" major claim, the majority were of the view that it was "a" major claim and all agreed it was a significant claim and therefore required a high level of supporting evidence.

The Committee reviewed the abstract and formed the view that it provided insufficient information to support the major claim. However the Committee did acknowledge that it was very commendable to follow up patients for a 10 year period and that with peer-reviewed, published evidence available this may be sufficient to assess the veracity of the claim. A breach of Section 1.2.2 of the Code was found.

The Committee discussed the placement of the two claims “reduces fracture risk fast” and “with evidence supporting 10 years continuous therapy” and noted that the proximity of the two claims varied in each promotional piece.

The Committee did not agree with Aventis Pharma that the statements were false or misleading, but considered that the data was insufficient to decide whether there was adequate evidence to support the claims. The Committee noted that it was incorrect to assert that there was no data on fracture risk reduction in the abstract. Further, the claims relating to the 10 year data were specifically identified as relating to changes in spine bone mineral density rather than fracture risk reduction. No breach of Section 1.3 of the Code was found.

Sanction

The Code of Conduct Committee resolved that MSD 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning.

Servier Laboratories Australia Pty Ltd Coversyl (723)

Complaint

A complaint was received from Aventis Pharma Pty Ltd (Aventis Pharma) alleging that Servier Laboratories Australia Pty Ltd (Servier) was in breach of the Code of Conduct in relation to the promotion of Coversyl. Aventis Pharma contended that a Servier trade display included misleading statements for Coversyl and Natrilix which were also outside the approved indications.

Response

A response was received from Servier claiming the use of the material was inadvertent and apologised for the error.

Committee Ruling

The Committee noted that Servier had conceded that it had breached the Code by use of promotional material previously found in breach of the Code at a trade display at the Cardiac Society of Australia and New Zealand meeting, but the use of the material at the trade display was inadvertent and unintentional. In their response Servier also described the steps it had taken to remove the promotional material from distribution since it had been found in breach.

The Committee considered that Aventis Pharma should have discussed the use of the trade display materials at the meeting with the Servier staff present. This immediate discussion would have enhanced compliance with the Code rather than waiting until the meeting had finished, which allowed specialists to view the materials which had been found in breach of the Code, and then submitting a complaint to the Code of Conduct Committee. In their response Servier indicated that if they had been advised of the breach, they would have been prepared to remove the display material.

The Committee found a breach of Section 1.3.1 as the claims relating to reduction in stroke and major vascular events emphasise stroke rather than the approved indication which is hypertension for Coversyl and hypertension in patients not adequately controlled with either indapamide hemihydrate or perindopril erbumine monotherapy for Coversyl Plus. As these claims had previously been found in breach of 1.3.1, this constituted a repeat breach.

Sanction

While acknowledging Servier’s expression of contrition, the Committee was concerned that the display of materials containing claims previously found in breach of the Code must be treated as a serious breach.

The Code of Conduct Committee resolved that Servier 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning.

In addition, Servier should be required to send a corrective letter to all healthcare professionals (Australian residents only) who had attended the Cardiac Society of Australia and New Zealand meeting in Adelaide during the period 10-13 August 2003. The corrective letter should identify that the claims had been found in breach of the Code and their continued use at the Cardiac Society meeting was a repeat breach.

The Committee also imposed a fine of \$30,000.

Appeal

An appeal was lodged by Servier against the sanction imposed by the Code of Conduct Committee.

Appeals Committee ruling

Servier unreservedly apologised for the unintentional breach of the Code of Conduct. Servier acknowledged that an error in removing all materials previously found in breach had occurred and has instituted changes to procedures that will make sure it doesn't happen again. The appearance of the poster was a genuine mistake. Servier requested that the fine imposed by the Code of Conduct Committee should be reduced or removed along with the requirement to issue a corrective letter.

The Committee noted that Servier had admitted that a breach had occurred. Regardless of what might have happened had intercompany dialogue taken place, the company should not have allowed the repeat breach to occur.

Sanction

The Appeals Committee unanimously agreed that some sanction should be imposed for the repeat of a previous breach. In relation to the corrective letter, the Appeals Committee considered what should be the content of such a letter, if imposed. Members were mindful of the specialist cardiologist audience to whom the letter would be addressed. The Appeals Committee concluded that the usual corrective letter approach was not appropriate in this case.

However, accepting Servier's explanation of how the repeat breach had occurred, the Code of Conduct is a standard that must be maintained. The Appeals Committee considered that in the circumstances the fine of \$30,000 was appropriate.

Eli Lilly Australia Pty Ltd Cialis (724)

Complaint

A complaint was received from GlaxoSmithKline Australia (GSK) and Bayer Australia Pty Ltd (Bayer) alleging that Eli Lilly Australia Pty Ltd (Eli Lilly) was in breach of the Code of Conduct in relation to the promotion of Cialis. GSK and Bayer were of the view that the workbook and website contained incorrect, misleading and out of date information.

Response

A response was received from Eli Lilly denying any breach of the Code of Conduct. They maintained that the workbook was correct at the time of publication and were of the view that the website complied with the Code.

Committee Ruling

Workbook

While accepting the Eli Lilly argument that the workbook was produced prior to vardenafil being approved for the Australian market, the Committee considered that it was important that a company maintain current, accurate and correct information in all educational materials. It was therefore imperative that Eli Lilly update the workbook to reflect current data and the vardenafil Australian approved Product Information. A breach of Sections 1.1 and 1.3 was found as the workbook was not accurate, correct and or consistent with the vardenafil approved Product Information and could therefore mislead a prescriber. Through the use of the outdated and inaccurate data this had the potential to be disparaging to a competitor product and was therefore in breach of Section 1.7 of the Code.

Website

The Committee agreed that the statements on the Cialis website did not have to be identical to the Consumer Medicine Information but should be accurate, current and balanced and that a link to the CMI would be useful.

The Committee noted that Eli Lilly had agreed to amend the website. The Committee determined that these changes should be made immediately.

In relation to the statement that “For most men, clinical effects occur within 16-30 minutes after taking Cialis, and the medication is clinically effective for up to 36 hours after dosing” the Committee considered that that this was not an accurate reflection of the data in the approved PI. Members considered that as this statement was pivotal to the Eli Lilly promotional claims, it should be more explicit about the number of men who experience efficacy for 36 hours. It was noted that the PI stated that for 60% of men the effect lasted for 36 hours. Therefore it was not efficacious in a significant number of men at 36 hours. The Committee was of the view that “most men” was not sufficient to qualify the percentage of men where Cialis was effective at 36 hours. Further, the 60% effectiveness at 36 hours post-dose was only for the 20mg dose, which should also be clearly stated on the website information.

While acknowledging that the information was only available to patients who had been prescribed Cialis the Committee did not find a breach of Section 9.4 of the Code. However members were of the view that the information provided was not sufficiently educational as it did not accurately reflect the approved Product Information for Cialis and was therefore in breach of Section 9.5 of the Code.

Dosing, duration of action and efficacy claims

The Committee was of the view that the statement “A simple 20mg tablet can be taken with or without food or alcohol” was misleading as it was not an accurate reflection of the approved PI for Cialis. Members agreed that the reference to alcohol should be removed and that Eli Lilly should ensure that reference to the particular dose should be made clear. It was further noted that Eli Lilly had agreed to amend this statement to read “Cialis can be taken with or without food”.

As previously stated in relation to consideration of the Cialis website, the Committee considered that the statements “Works for up to 36 hours ...” and “... Gives your patients 36 hours to choose the moment” were misleading were not an accurate reflection of the data in the approved PI. Members of the Committee agreed that the statement should be amended and adequately qualified in terms of the dose with which effectiveness at 36 hours was experienced and the percentage of patients who experienced this efficacy to ensure that prescribers and consumers will not be misled.

The Committee was of the view that the statement “Cialis works in 16-30 minutes and is effective in 81% of patients with ED” was misleading as it was not qualified to a particular dose as identified in the approved PI.

As the claims relating to dose, duration of action and efficacy results were found to be misleading and not fully consistent with the approved PI the Committee found that these claims were in breach of Sections 1.1 and 1.3 of the Code.

Market research and data on file

While Eli Lilly had agreed not to use the Hackett reference again, the Committee considered that Eli Lilly should provide the data on file to Bayer & GSK. Whilst the claim is referenced to a secondary source which refers to the data on file, Eli Lilly should have referenced the claim to the primary data, being the data on file. A breach of Section 1.2.1 of the Code was found.

The Committee noted that on receipt of the data from Eli Lilly, Bayer & GSK could assess whether it was of sufficient quality to support the claim. No breach of Section 1.2.2 of the Code was found.

Sanction

The Code of Conduct 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning until there is appropriate supporting data other than an abstract.

The Committee determined that Eli Lilly should be required to send a letter to all health care professionals who had attended an Eli Lilly CPD meeting and received the Workbook advising them of the changes and providing updated materials.

The changes to the Cialis website proposed by Eli Lilly should be instituted immediately. In addition, further qualification of the duration of effectiveness for up to 36 hours in relation to the dose and percentage of men that experienced extended effectiveness should also be instituted immediately.

Appeal

Eli Lilly lodged an appeal against the findings of the Code of Conduct Committee.

Committee ruling

It was noted by the Committee that “most” was not a medical term with a precise definition and hence it could have many interpretations. It was the view of the Committee that the term implied greater than a simple majority and probably a range greater than two-thirds with one Committee member suggesting a range greater than 75%. The Committee also suggested that these estimates would be impacted by what it was referring to particularly if it was in relation to a safety issue that would require an even higher percentage to satisfy an interpretation of “most”. This discussion prompted the comment from the Committee that in preference the use of a less interpretable term in promotional material would be advisable.

The Committee did not consider that 60% was sufficient to support a likely inference of what quantified “most” and agreed with the Code of Conduct Committee’s decision that without qualification this claim could be misleading and not supported by the evidence available at the time.

The Appeals Committee agreed with the Code of Conduct Committee that the question was not about the efficacy of the product but rather the impression as to how many men in which a positive response would be achieved. The Committee acknowledged that in some men Cialis was efficacious at 36 hours but without proper qualification it was possible to infer that a greater percentage of men would achieve a positive results than the data available indicated.

On the basis of this discussion the Committee resolved to uphold the Code of Conduct Committee’s decision to find breaches of Sections 1.1, 1.3 and 9.4 of the Code of Conduct.

Sanction

The Appeals Committee agreed that the sanctions imposed by the Code of Conduct Committee were appropriate and should remain.

Lundbeck Australia Pty Ltd Ebixa (725)

Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Lundbeck Australia Pty Ltd (Lundbeck) was in breach of the Code of Conduct in relation to a press release for Ebixa. The TGA was concerned that the press release to the lay media was promotional and included anecdotal testimonials concerning the advantages to patients.

Response

A response was received from Lundbeck denying any breach of the Code of Conduct. Lundbeck denied that the press release was intended to promote the use of Ebixa amongst patients but was designed to be informative only. Lundbeck made reference to the provision of the Code which allowed a press release to the lay media.

Committee Ruling

One Committee member expressed the view that many press releases to the general public cause much angst to doctors and consumers, who frequently come into a doctor’s surgery asking for the ‘new’ drug that will help their condition.

The Committee considered that the use of statements such as ‘New Hope’ and ‘bringing new hope to patients’ and ‘a significant advance in the treatment of this condition’ were promotion of a prescription medicine to the general public. The Committee found that the press release was in breach of Section 9.2 of the Code.

Members of the Committee also noted that Section 9.2 of the Code requires information such as the product's precautions, adverse reactions, warnings, contraindications and interactions must be included in a media statement to the general public. The Committee considered that the Ebixa press release did not provide balanced educational information to a member of the general public. Reference to the PBS listings or restrictions was also omitted from the press release.

In relation to the use of testimonials in a press release, the Committee was of the view that it would be acceptable for a press release to quote a healthcare professional's expert opinion. While acknowledging the value of a consumer's comment, the Committee considered that it would be more appropriate to use a patient support group eg the Alzheimer's Association rather than an individual carer's testimonial where the comments can be construed as promotion to the general public. Members considered that a comment from a patient support group would more likely be of an educative rather than promotional nature.

Sanction

The Committee resolved that Lundbeck should pay a fine of \$15,000.

Roche Products Pty Ltd Roaccutane (726)

Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Roche Products Pty Ltd (Roche) was in breach of the Code of Conduct in relation to a communication directed to members of the general public discussing the treatment of cystic acne. The TGA was concerned that the advertorial in a lay magazine may be perceived as advertising of a prescription medicine to the general public.

Response

A response had been received from Roche denying any breach of the Code of Conduct. Roche believed that the advertorial was compliant with the Code with its purpose being to provide education with respect to acne management.

Committee Ruling

Members of the Committee were of the view that the advertorial was sufficiently general in its content that it could not be linked to a specific prescription medicine. Healthcare professional members of the Committee expressed the view that acne and the resulting psychosocial effects were a serious concern within the medical community and that it was important to communicate information on the many possible treatments of acne and encourage members of the general public to see their doctor to discuss their specific condition. Members noted that people suffering from cystic acne could potentially encounter mental health issues as a result of their increasing lack of confidence, withdrawal from their social environment and potential depression. The Committee expressed the view that there was a real consumer benefit in raising issues surrounding acne and acne treatment and advising members of the general public to 'see your doctor', yet were cognisant that this must be done in a manner which did not promote any specific prescription medicine.

The Committee noted the market research provided by Roche which stated that "The Roche logo is largely overlooked, and few, if any, consumers associate this with Roaccutane" and "... the majority of consumers are unaware of the manufacturer of the product. They also do not appear overly interested in who the manufacturer may be". The Committee was also aware that a number of treatment options are available for cystic acne and that the advertorial did not identify any one treatment but referred members of the general public to their doctor to discuss proper diagnosis and consideration of referral to a specialist for possible treatments.

Some members of the Committee commented that the requirement of the Code (Section 9.5.4) that "The educational material must include the name and the city, town or locality of the registered office of the supplier of the material, but their location should not be given prominence" could be viewed as offering a company the opportunity to *de facto* promote their particular prescription medicine. Members of the Committee requested that Medicines Australia further investigate the issues surrounding this requirement and refer the matter to the relevant Working Group or the Code Review Panel for comment, advice and potential amendment to the Code if considered appropriate.

The Code of Conduct Committee made a recommendation that rather than requiring inclusion of the company name, the material could state “A health education message sponsored by a member of the pharmaceutical industry. The sponsor is registered with Medicines Australia.” The Committee was of the view that this action may alleviate some of the concerns in relation to the publication of educational material sponsored or provided by a pharmaceutical company.

The Committee noted that the advertorial encouraged readers to see their doctor to discuss their specific concerns. Members also commented that the Roche product could not be prescribed by general practitioners and could only be prescribed by a dermatologist following a referral from a general practitioner. Further, Roaccutane can only be prescribed following a discussion with the patient on issues such as the length of treatment and possible side effects including possible birth defects. The Committee commented that the risks and benefits of Roaccutane therapy are always discussed by the healthcare professional with patients. Indeed, patients are often required to sign a consent form prior to the initiation of therapy.

Several members of the Committee raised some concerns in relation to the section in the Advertorial on “What sort of side effects can I expect from my acne treatment”. While this material was couched in general terms and was not specifically referring to cases of severe cystic acne where Roaccutane may be prescribed, members questioned whether it treated the potential side effects of acne treatment too lightly. There was however an opposing view that if the company had discussed the very serious side effects of Roaccutane there would have been a link to a specific prescription medicine which may have breached the Code. Members reiterated the view that there is extensive counselling when a patient is prescribed Roaccutane, especially to women of child-bearing age.

Members raised some concerns with the before and after photos included in the advertorial. While acknowledging the benefits of including the statement “This person is not related to the story featured above”, members were of the view that it risked raising unfounded hopes of successful treatment. Members agreed that if a patient came into a general practitioner’s surgery with the advertorial and asked for the treatment that would “make me look like the person in the photo”; the onus would be on the prescriber to consider all the issues for that particular patient. If the doctor considered the patient required a specialist-only treatment there would be sufficient opportunity for both the general practitioner and the specialist to provide detailed information on all treatment options and potential side effects. While acknowledging that it may be the photo that triggers a person’s interest in reading the advertorial and that severe cystic acne is a serious problem for some young people, companies should carefully consider using any pictorial representation to ensure that it is representative of sufferers of the condition and does not cause confusion or undue alarm. The Committee commented that if a company was in any doubt as to whether a photo or photos could cause concern or alarm it was preferable that they not be included.

In relation to the specific sections of the Code of Conduct, the Committee resolved the following:

Section 9.3

The Committee considered that no breach of this section had occurred as the material in question did not concern a particular prescription medicine.

Section 9.4 – Promotion to the General Public

Having considered that the advertorial was written in such a way so as not to identify any specific treatment option for acne, noting that several treatments options were available and noting that it was unlikely that a member of the general public would associate the company’s name with a specific prescription medicine, the Committee found there was no breach of Section 9.4.

Section 9.5 – Patient Education

Although some concern was expressed regarding 9.5.6 and 9.5.7 in relation to the discussion of side effects and the inclusion of the before and after photographs, the Committee considered that the advertorial satisfied the requirements of this section and should not be found in breach.

Novartis Pharmaceuticals Pty Ltd Famvir (730)

Complaint

A complaint was received from GlaxoSmithKline Australia (GSK) alleging that Novartis Pharmaceuticals Pty Ltd (Novartis) was in breach of the Code of Conduct in relation to promotional material for Famvir. GSK was concerned that Novartis was misleading doctors regarding the ability of Famvir to reduce the transmission of genital herpes to partners of patients with the condition.

Response

A response was received from Novartis denying any breach of the Code of Conduct and claiming that the complaint had not been formulated with the necessary precision. Novartis indicated that the detail aid had been discontinued.

Committee Ruling

Claim: “[suppressive therapy] reduces the stress of potentially infecting their [the patients’] partner”

The Committee was of the view that the Stanberry article “*Prevention of Genital Herpes Transmission Tomorrow*”, which was the supporting reference for the claim, did not include any reference to reducing stress or evidence that suppressive treatment with Famvir will decrease transmission. There was insufficient evidence to support the claim and therefore it was misleading. The Committee found the claim in breach of Section 1.3 of the Code.

Table summarising the “Effect of Antiviral Therapy on Asymptomatic Viral Shedding”

The Committee was of the view that the table summarised the relevant data on asymptomatic viral shedding and no inferences regarding transmission were made from this table. Members considered that the table was a careful presentation and found no breach of Section 1.3 of the Code.

Article published in the Australasian Journal of General Practice

The Committee noted that Novartis had acknowledged that as this was a company commissioned article it should have been identified as such and included the name of the company.

Members found that the statements referred to by GSK in their complaint were factual statements and made no inferences regarding reduction of transmission by Famvir. The Committee found no breach of Sections 1.3 or 1.7 of the Code.

Sanction

The Code of Conduct Committee resolved that Novartis 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 claims found in breach should not be used again in the same form or in a manner that conveys the same or similar meaning.

The Committee also resolved that Novartis should pay a fine of \$10,000.

Baxter Healthcare Pty Ltd Desflurane (733)

Complaint

A complaint was received from a healthcare professional alleging that Baxter Healthcare Pty Ltd (Baxter) representatives were in breach of the Code of Conduct in relation to an incident in the operating theatre at a hospital.

This complaint was a further complaint from the healthcare professional in relation to the alleged activities considered in complaint Desflurane (710).

Response

A response dated was received from Baxter outlining their position in relation to this complaint.

Committee ruling

Baxter Healthcare’s response to the complaint outlined the processes for gaining access to the hospital and the operating theatres for the trial of Desflurane. It was noted that the Trial Coordinator for new products, the Senior Anaesthetic Technician and the Director of Anaesthetics had been involved in these negotiations. It was further noted that a Coordinator for the trial had been

appointed and the Baxter representatives had ensured that, to the best of their knowledge at the time, they complied with all hospital requirements. It was noted that the Baxter response indicated that their representatives only entered the operating theatre at the direction of the Trial Coordinator and that in relation to the patient being exposed to them on entering the theatre they stated that the patient was covered.

The Committee also understood the complainant's frustration that as a professional he has authority in the operating theatre and should have the right to refuse permission for any non-medical personnel to be in the operating theatre regardless of any agreement between the hospital and an external organisation.

The Committee noted that there were differing perspectives on what occurred during these incidents at the hospital. Members commented that no supporting evidence from other hospital staff present in the theatre at the time of the incidents had been provided. The Committee acknowledged that it was not possible to find a breach of the Code unless on the balance of probabilities there had been a breach by the subject company.

The Committee noted that Baxter had followed all hospital procedures and protocols for the trial in place at the time; they had not been told that they needed the approval of each anaesthetist or surgeon. Therefore it appeared that there had been no deliberate attempt on behalf of the Baxter representatives to bring the industry into disrepute. In his letter to Medicines Australia, the hospital Executive Director, Medical Services had indicated that new protocols for supplier representatives had been implemented. Baxter had been advised of this policy and encouraged to provide education on the policy to their representatives. The Committee determined that the complaint that Baxter had breached Section 9.8 of the Code of Conduct was not made out as Baxter had not been told that they needed approval from individual healthcare professionals.

In relation to the alleged breach of patient privacy, it was noted that the patient had requested confidentiality prior to the operation. Again there were differing perspectives from Baxter, hospital staff and the complainant as to whether the patient had been exposed to the representatives when they entered the theatre. The Committee agreed that in future Baxter should ensure that the hospital has obtained patient consent for them to be in attendance.

The Committee discussed the incident when the Baxter representative was asked to leave the theatre and noted that the representative had done so when requested. The Committee also discussed the matter of a representative giving advice to a healthcare professional when in the operating theatre and were of the view that this was inappropriate, irrespective of whether the healthcare professional was using the product for an unapproved indication. This raised some issues in relation to patient safety if a healthcare professional was distracted from their duties. Again the Committee reaffirmed their position that irrespective of hospital policy, if an individual healthcare professional asks a representative to leave the operating theatre they must do as directed.

In summary, the Committee accepted the healthcare professional's concerns that he has the right to refuse access to any non-medical personnel to the operating theatre and that at all times the rights of the patient must be respected. However the majority of the Committee was of the view that Baxter appeared to have followed all the protocols and agreements established with the hospital but the problem had occurred because systems for obtaining permission to attend the operating theatre or for appropriate patient consent were not in place. There had been no intention to breach the Code or bring the industry into disrepute. The Committee considered that on the evidence before it a breach of Section 9.8 of the Code was not proven. The Committee indicated that the requirement for individual permission from anaesthetists could have been more clearly articulated by the hospital which has introduced new protocols to ensure that this unfortunate incident will not be repeated.