Medicines Australia Code of Conduct Quarterly Report April - June 2014

The quarterly report of determinations of the Medicines Australia Code of Conduct and Appeals Committees

The Medicines Australia Code of Conduct was introduced in 1960 and is currently operating under Edition 17 (Effective 11 January 2013).

This report covers all complaints finalised between April and June 2014. Complaints finalised during this period were in relation to materials or activities conducted under Edition 17 of the Code.

Quarterly Reports preceding this Report are available from the Medicines Australia website http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/

How to contact Medicines Australia

Address:
Level 1, 16 Napier Close
DEAKIN ACT 2600

Phone: 02 6122 8500

Fax: 02 6122 8555

Email: secretarycodecommittee@medicinesaustralia.com.au

How do I obtain a copy of the Code?

Copies of Edition 17 of the Code (effective from 11 January 2013) are available from Medicines Australia. An order form is available from http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/

The Code of Conduct and the Guidelines that accompany the Code are available from the website (http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/)

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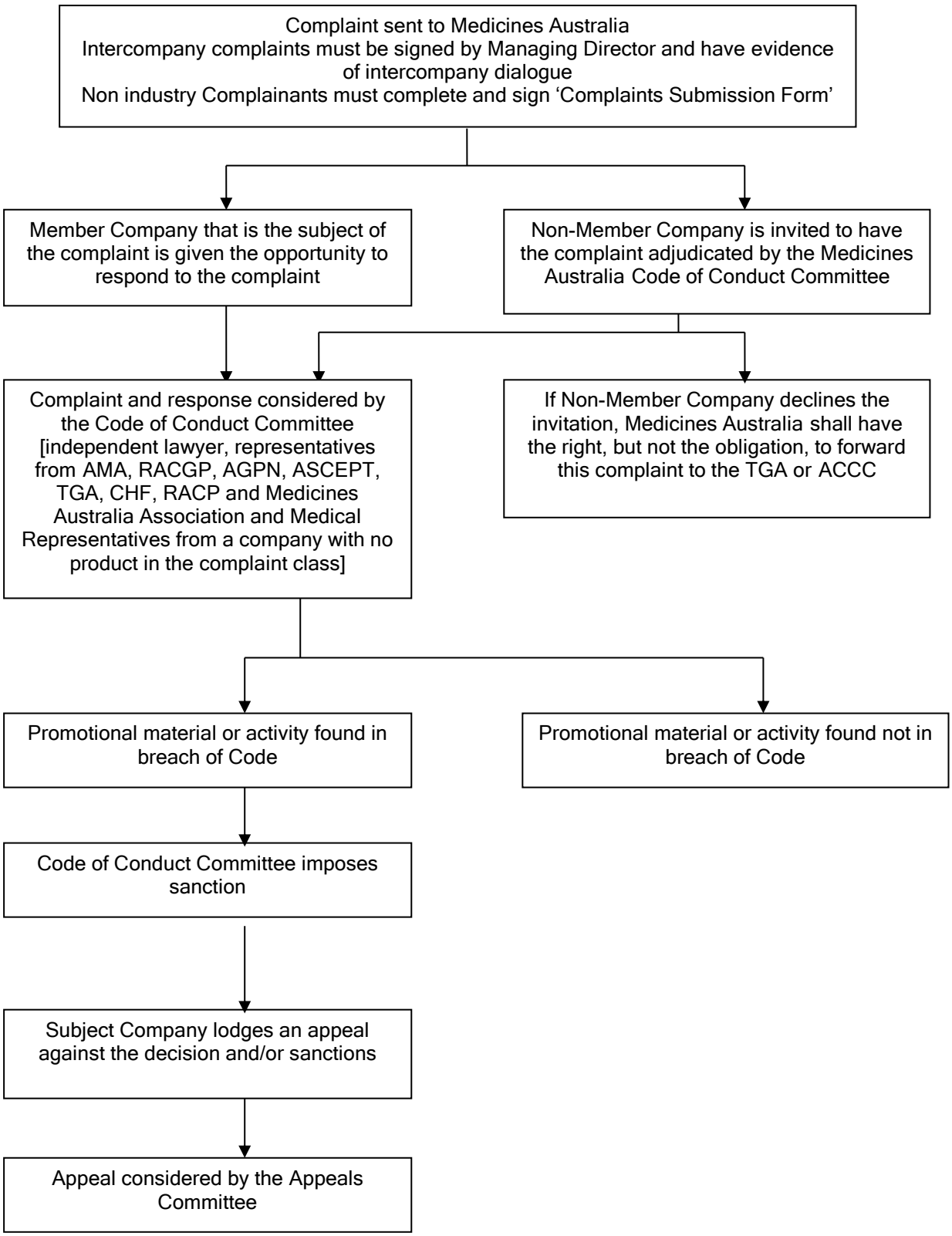
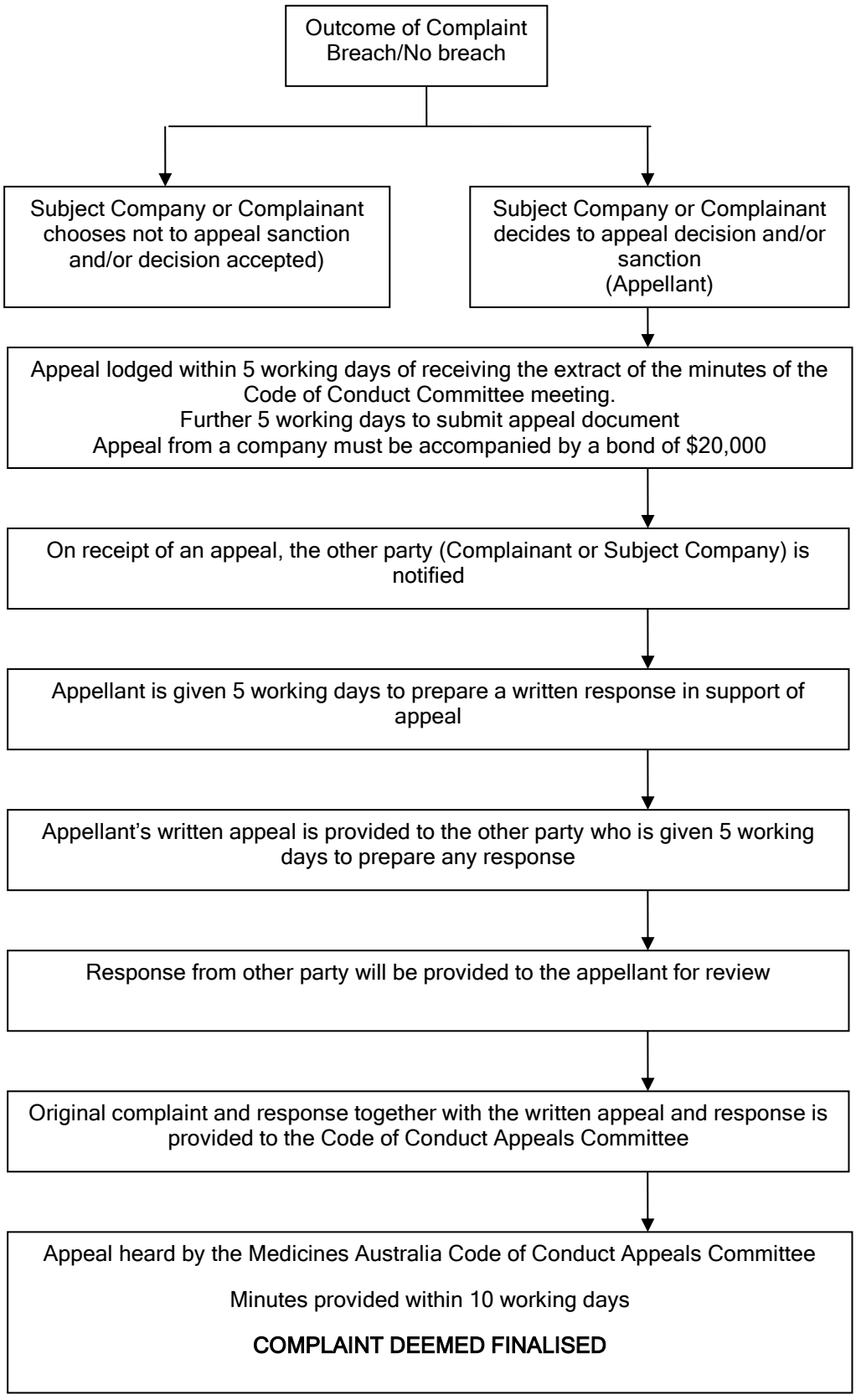
Medicines Australia Code of Conduct Complaints Handling Process



A complaint is not deemed finalised until the Subject Company has advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Code minutes) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties

Medicines Australia Code of Conduct Appeals Committee Procedures



Committees and Secretariat

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code, and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

Committee Member Biographies

Brief biographies for all Code, Appeals and Monitoring Committee members are available on the Medicines Australia website http://medicinesaustralia.com.au/code-ofconduct/committee-membership/

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 5 trade practices lawyers

Representatives nominated by:

- Australian General Practice Network (AGPN)
- Australian Medical Association (AMA)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Consumers Health Forum of Australia (CHF)
- Royal Australasian College of Physicians (RACP)
- Royal Australian College of General Practitioners (RACGP)
- Medicines Australia Association Representatives (maximum 3)
- Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- Therapeutic Goods Administration (TGA)
- Medicines Australia member companies' employees (maximum 2)
- Observer nominated by Medicines Australia (maximum 1)

Advisors (No voting rights)

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

Appeals Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 5 trade practices lawyers

Representatives nominated by:

- The College and/or Society associated with the therapeutic class of the product subject to appeal
- The target audience to which the activity was directed eg: AMA, RACGP, AGPN
- Consumers Health Forum of Australia (CHF)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Medicines Australia Association Representatives (maximum 2)
- Medicines Australia Medical/Scientific Director (maximum 1)

Advisors (No voting rights)

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

Sanctions that can be imposed by the Code of Conduct Committee

Sanctions

If the Code of Conduct Committee finds a breach of the Code it may impose a sanction on the company found in breach. In order to determine an appropriate sanction the Committee will refer to the "Guidelines for determining Code sanctions" which are available on the Medicines Australia website. The following sanctions may be imposed:

Withdrawal of material or activity

Where promotional material or activity is found in breach of the Code the Committee will always require the company to cease use of the item or cease undertaking the activity.

Corrective letter

The Code of Conduct Committee will determine the audience for the letter based on the original distribution of the material found in breach of the Code.

Corrective advertisement

A corrective advertisement must be placed in the same publication as that found in breach of the Code.

Fines (applicable under Edition 17 of the Code)

Breach	Fine
Technical breach Minor breach	Maximum of $100,000
Moderate	Maximum of $150,000
Severe breach	Maximum of $200,000
Severe breach where activities completed Repeat of previous breach	Maximum of $250,000
Cumulative fine for multiple breaches	Maximum of $300,000
Failure to complete corrective action in 30 calendar days Failure to pay a fine in 30 calendar days	Maximum of $50,000
Abuse of the Code (in accordance with Section 25)	Maximum of $200,000

Table of finalised complaints April – June 2014

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1111	Novartis Pharmaceuticals	Leave Behind	Seebri Breezhaler	Boehringer Ingelheim	No breach	n/a
1112	Pfizer Australia	Leave Behind	Salazopyrin	Monitoring Committee	No breach	n/a

1111 – Seebri Breezhaler Leave Behind

Subject Company: Novartis Pharmaceuticals Australia

Complainant: Boehringer Ingelheim

Product: Seebri Breezhaler

Complaint
Boehringer Ingelheim alleged that the use of the claim "Add Breath Back to Mornings with Once Daily Seebri Breezhaler" used in isolation or in the context presented in the promotional material is misleading because it claims a clinical benefit for Seebri Breezhaler – improvement of COPD symptoms in the mornings – that is not supported by the body of evidence.

Sections of the Code
The promotional materials are alleged to be in breach of the following Sections of Edition 17 of the Code:

Section 1.3	False and misleading claims
Section 2.1.2	Printed promotional material

Response
Novartis denied that the claim is misleading or in breach of the Code. Novartis disputed Boehringer Ingelheim's interpretation of the product claim. Novartis state that the product claim intentionally uses the word "breath", which is evaluated by lung function as measured by spirometry. The FEV1 data for the product is fully supported by the TGA approved Product Information and the GLOW 2 study publication. In addition, the claim is qualified by a statement referring to the time of day the treatment was taken which resulted in improved FEV1, which is based on the GLOW2 study.

Code of Conduct Committee Decision
The Code of Conduct Committee determined:

- By majority decision, no breach of Section 1.3
- By majority decision, no breach of Section 2.1.2

Sanction
As the Committee did not find a breach of the Code of Conduct, no sanction was imposed.

Consideration of the Complaint
The Committee noted that the matter subject to complaint is whether the claim "Add breath back to mornings with Once Daily Seebri Breezhaler", as it appears in the leave behind, is a claim that the product relieves the symptom of breathlessness. The claim appeared with the qualifying statement "Treatment taken between 8am – 11am resulted in significantly improved lung function vs. placebo ($p<0.001$; FEV_1 $AUC_{0\text{-}4}h$) up to week 52".

Novartis and Boehringer Ingelheim appear to agree that the product improves lung function in the morning, as measured by forced expiratory volume in 1 second (FEV_1), if taken in the morning. However, it does not improve symptoms such as breathlessness in the morning. There had been several other matters in dispute between the two companies regarding the leave behind. During intercompany dialogue, Novartis had proposed to make some changes to the material, without prejudice, to resolve the dispute. However, the question of the claim subject to complaint had not been resolved.

The Committee reviewed the reference to support the claim, which was a study by Kerwin et al published in the *European Respiratory Journal* in 2012.

This study is referred to as the Glow 2 study. The study compared glycopyrronium bromide, the active ingredient in the Seebri Breezhaler, with placebo and open-label tiotropium. The key findings were reported in Table 2 in the study report, with various efficacy measures reported on day 1 and weeks 12, 26 and 52. The study results clearly demonstrated that for trough FEV_1, glycopyrronium bromide was superior to placebo at all time points during the study. Tiotropium also demonstrated superiority to placebo for trough FEV_1 at all the time points. The study also measured the area under the curve (AUC) for FEV_1 at various time points over a 24-hour period and glycopyrronium bromide was superior to placebo on this measure. The study also reported that glycopyrronium bromide demonstrated an improvement in dyspnoea compared with placebo as measured by the transition dyspnoea index (TDI) at weeks 12, 26 and 52 and demonstrated superiority to placebo for the St George Respiratory Questionnaire (SGRQ) total score at the same time points. In summary, the Glow 2 study provided substantiation for the superiority of the Seebri Breezhaler to placebo for a range of efficacy measurements. Figure 4 in the Glow 2 study provided a graph of FEV_1 following a dose of the comparator inhalers over the following 24 hours, which showed that the onset of action is relatively rapid. The rapid onset of bronchodilator effect was also demonstrated in the Glow 1 study, which is reported in the Product Information.

The Committee then discussed whether the claim "add breath back to mornings" with the qualifying statement was a claim for improving breathlessness, a symptom of Chronic Obstructive Pulmonary Disease (COPD), as alleged. The majority of the Committee considered that the claim with the qualifying statement immediately below it makes it clear to healthcare professionals that the claim relates to lung function as measured by FEV_1 AUC_{0-4} h and did not claim that the product improved breathlessness. The claim was not misleading because the presence of the qualifying statement removes any possibility of uncertainty about the meaning of "breath" in the claim. A minority of the Committee considered that the claim did relate to improving breathlessness, a symptom of COPD, in the morning. Whilst the GLOW 2 study did demonstrate that glycopyrronium bromide was superior to placebo on improving dyspnoea on the TDI, this was not specific to the morning period.

In a majority decision, the Code Committee concluded that the claim "Add breath back to mornings with Once Daily Seebri Breezhaler" with the associated qualifying statement was not misleading and was not in breach of Sections 1.3 or 2.1.2 of the Code of Conduct. In its decision, the Committee did not express a view on any other part of the leave behind.

Sanction

As the Committee did not find a breach of the Code of Conduct, no sanction was imposed.

1112 – Salazopyrin Leave Behind

Subject Company: Pfizer Australia Pty Ltd

Complainant: Monitoring Committee

Product: Salazopyrin

Complaint
At its 18 November 2013 meeting, the Monitoring Committee reviewed printed promotional materials for products in the Alimentary Therapeutic Class available during the period July to September 2013 in accordance with Section 2.1 of Edition 17 of the Code. The Monitoring Committee reviewed a Salazopyrin Leave Behind produced by Pfizer and queried the claim "... Confidence to maintain" which is qualified by the statement "55% reduction in risk of relapse…" The Committee questioned how 55% is sufficient to substantiate "confidence" and requested further clarification from Pfizer.

Pfizer had responded to the Monitoring Committee that remission will be achieved in the majority of patients; that the remission rate is significant and is supported by scientifically accepted evidence; and that the remission rate is greater than that achieved with corticosteroids. Pfizer's response did not resolve the Monitoring Committee's concerns. The Committee did not agree that a 55% reduction in risk of remission would give "confidence" that remission would be achieved and maintained. It therefore referred this matter as a complaint to the Code of Conduct Committee

Sections of the Code
The promotional material is alleged to be in breach of the following Sections of Edition 17 of the Code:

Section 1.1	Responsibility
Section 1.2.2	Level of substantiating data
Section 1.3	False and misleading claims

Response
Pfizer responded to the Monitoring Committee's complaint, stating that the claim was fully supported and unambiguous; was not in breach of the Code; and that the intended audience for the Salazopyrin leave behind would not be expected to misinterpret the promotional claims. Pfizer would have considered modifications to the leave behind if Pfizer had been made aware in the first letter from the Monitoring Committee that the Committee considered the claim gave a false and misleading impression of the efficacy of Salazopyrin. Pfizer also noted that the material had been only sparingly used, as this product is not promoted widely, and advised that the use of this leave behind ceased earlier this year.

Consideration of the Complaint
The Chairman outlined the key elements of the complaint that the Committee needed to consider. The complaint relates to the claim of "confidence" in the headline "Power • Confidence • Flexibility". The claim appears across an image of a young female rhythmic gymnast. Below the image there were four points, each with a qualifying statement. The second point stated "With the Confidence to Maintain (in 3-4 weeks)" with the qualifying statement "55% reduction in risk of relapse (over 6-12 months) compared to placebo". Pfizer had responded to the complaint arguing that more than half of patients

taking Salazopyrin (sulfasalazine) will maintain remission, which is significant and greater than that achieved with standard therapy or corticosteroids.

The Committee noted that sulfasalazine is a medicine that has been used to treat ulcerative colitis for some sixty years. Ulcerative colitis is a remitting and relapsing condition that is very difficult to treat and maintain patients in remission. Members considered that a 55% reduction in risk of relapse was significant, in light of the nature of the condition, and is similar to or better than other medicines used in this condition. A majority of the Committee considered that the qualifying statement "55% reduction in risk of relapse (over 6-12 months) compared to placebo" adequately qualified the claim of "confidence". Further, doctors who treat patients with ulcerative colitis would not see "confidence" as a guarantee of a successful outcome. The Committee noted that both European and Australian therapeutic guidelines recommend sulfasalazine for maintenance of remission in ulcerative colitis.

A minority of the Committee were not wholly persuaded that the use of the term "confidence" did not overstate the likely benefit of Salazopyrin. These members thought that a 55% reduction in risk of relapse was not sufficient to engender "confidence". Other members of the Committee, who did not think that the claim was misleading, reiterated that their acceptance of the claim of "confidence" would not extend to treatments for other medical conditions which achieved 55% effectiveness. However, for this condition a physician would not expect a higher success in achieving or maintaining remission.

The Committee discussed the location of the qualifying statement. Section 1.3 of the Code requires a qualifying statement to be located directly below or adjacent to the relevant claim. The Committee noted that this matter had not been raised by the Monitoring Committee and Pfizer had not been given the opportunity to give its perspective. The Committee concluded that the actual claims for Salazopyrin appeared as four points below the image and the headline "Consider Salazopyrin for the acute and maintenance treatment of Ulcerative Colitis". Each claim was qualified and the qualifying statement appeared immediately below the relevant claim. The Committee accepted that the location of the qualifying statements was consistent with Section 1.3.

By majority, the Committee found that the claim of "confidence" was not misleading and could be adequately substantiated. By majority decisions no breach of Sections 1.1, 1.3, and 1.2.1 was found.

The Committee considered Pfizer's concern that the Monitoring Committee's first communication to the company had been simply a request for clarification as to whether a 55% reduction is sufficient to substantiate a claim of "confidence". In its first request for clarification, the Committee had not communicated that its concern was of a serious nature and that the Committee considered that the claim was or might be in breach of the Code, nor specified any specific section of the Code. The Committee agreed that the process between the Monitoring Committee and member companies should be conducted in a similar manner to intercompany dialogue, where any areas of concern and the reasons for alleging a potential breach

of the Code are specified. This did not appear to have occurred in relation to this complaint. Ms Monk undertook to request the Monitoring Committee to provide further explanation of its concerns to companies and to identify the relevant sections of the Code if the Committee considers that there is a potential breach.

Sanction

As the Committee did not find a breach of the Code of Conduct, no sanction was imposed.