

Medicines Australia Code of Conduct Quarterly Report October - December 2009

Medicines Australia Code of Conduct

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 16 (Effective 1 January 2010).

This report covers all complaints finalised between October - December 2009. Complaints finalised during this period were in relation to materials or activities conducted under Edition 15 of the Code.

Quarterly Reports preceding this Report are available from the Medicines Australia website <http://www.medicinesaustralia.com.au/pages/page30.asp>

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How do I obtain a copy of the Code?

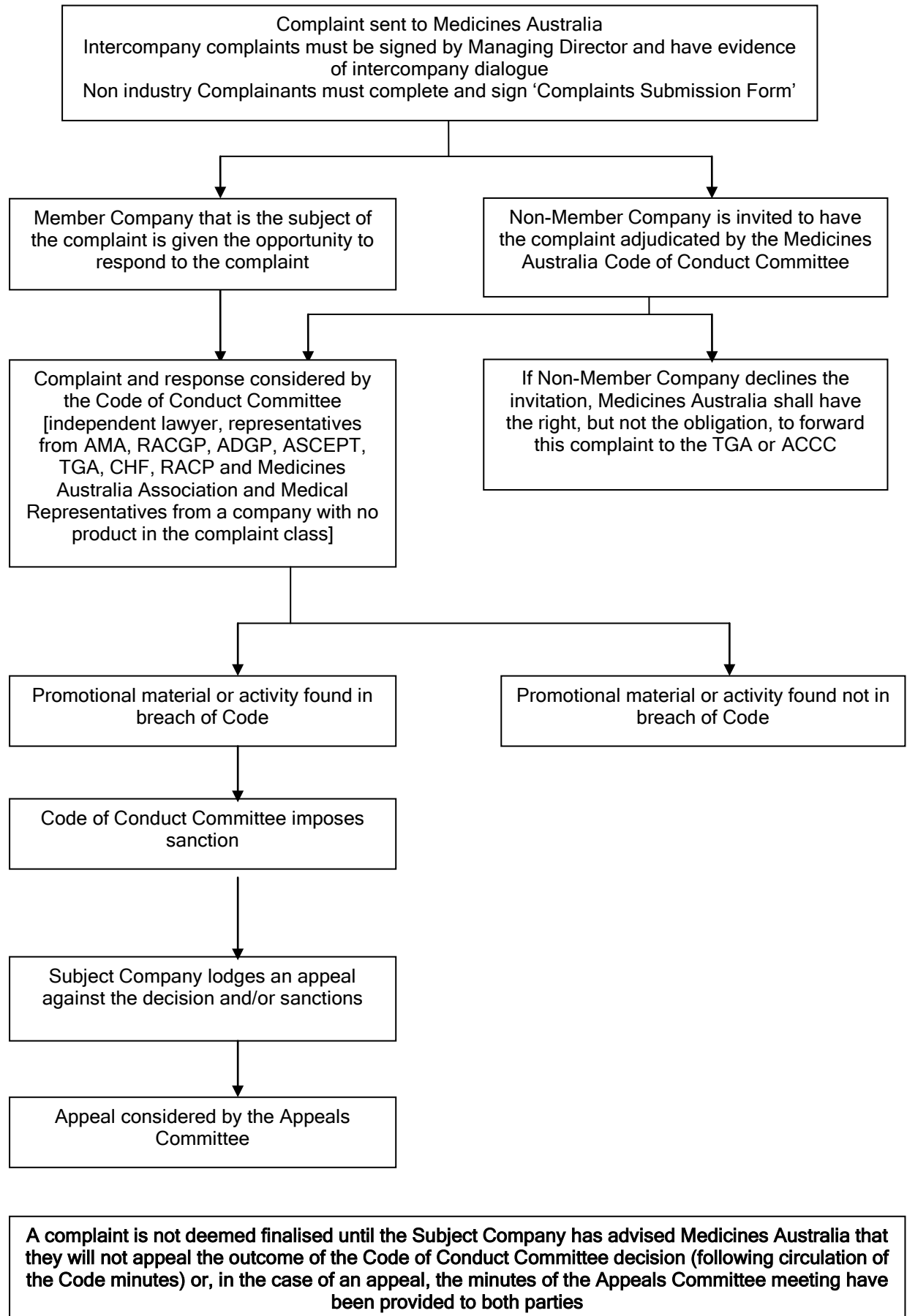
Hard copies of Edition 16 of the Code are available from Medicines Australia. An order form is available from <http://www.medicinesaustralia.com.au/pages/page251.asp>

The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://www.medicinesaustralia.com.au/pages/page251.asp>).

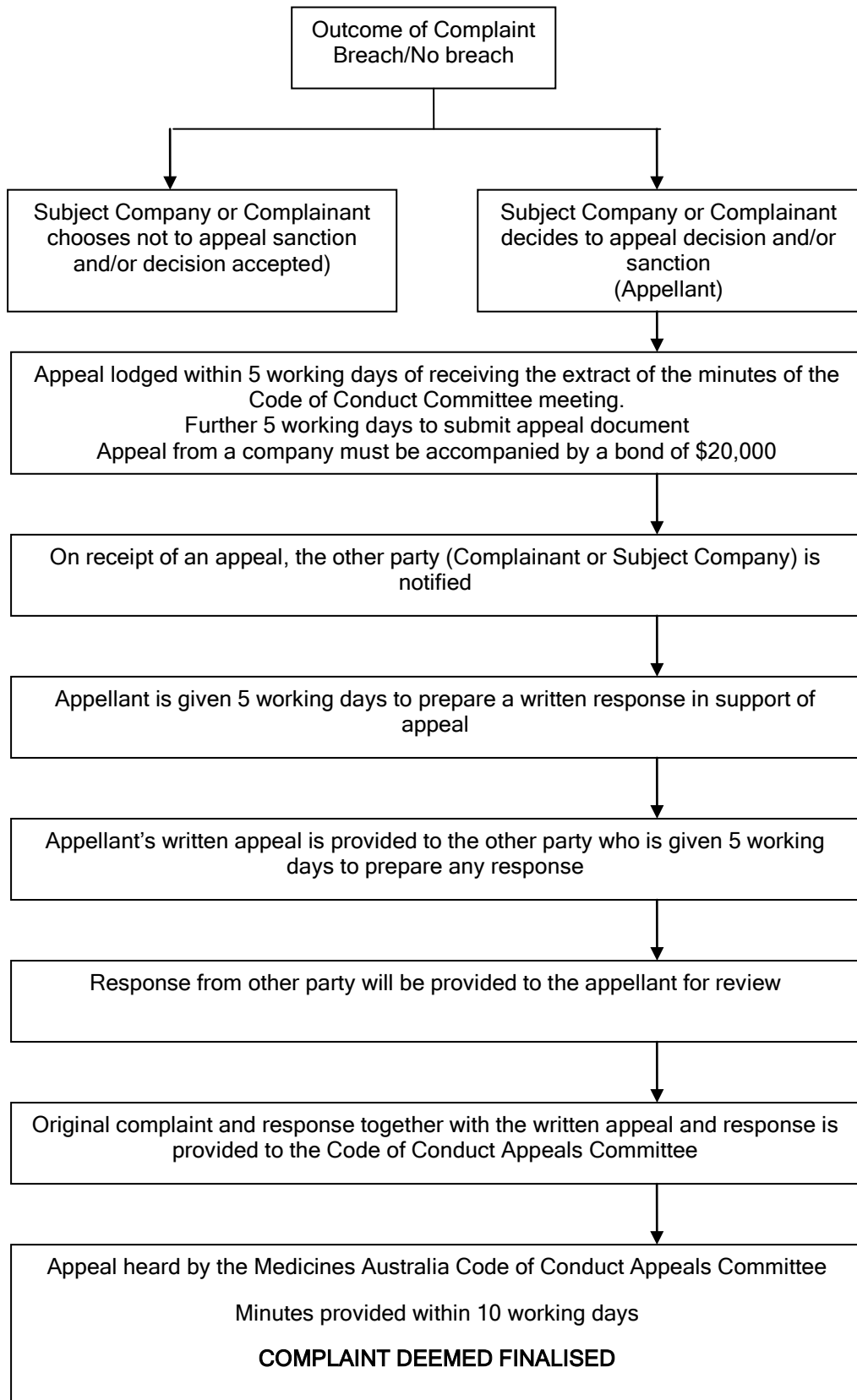
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Medicines Australia Code of Conduct Complaints Handling Process



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://www.medicinesaustralia.com.au/pages/page96.asp>

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of six 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)
 - Therapeutic Goods Administration (TGA)
 - Medicines Australia Association Representatives (maximum 3)
 - Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- 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 six 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.

Fine (applicable under Edition 15 of the Code)

<u>Breach</u>	<u>Fine</u>
Technical breach Minor breach Moderate Severe breach	Maximum of \$100,000
Severe breach where activities have ceased Breach repetitions Repeat of previous breach	Maximum of \$200,000

Guidelines for determining Code sanctions can be found at page 114 of the Code of Conduct Guidelines on the Medicines Australia website at

<http://www.medicinesaustralia.com.au/pages/page251.asp>

Table of finalised complaints October - December 2009

No.	Subject Company	Material Activity	Product	Complainant	Outcomes	Sanction
1023	Allergan	Promotional Material	Botox	MA Monitoring Committee	Breach 1.2.2, 1.3	<ul style="list-style-type: none"> • Withdraw • Corrective letter • Fine - \$100,000
1024	Pfizer	Information to the general public	N/A	Member of the general public	No breach 9.4, 9.5 & 9.10	N/A
1025	Sanofi-aventis	Promotional material	Copaxone	Merck Serono	Breach 1.1, 1.3 & 1.7	<ul style="list-style-type: none"> • Withdraw • Corrective letter • Fine - \$25,000
1027	Janssen-Cilag	Educational Event - hospitality	N/A	MA Monitoring Committee	No breach 6.2, 10.2 & 10.8	N/A
1028	MSD	Educational Event - hospitality	N/A	MA Monitoring Committee	Breach 6.2 and 10.2 No breach 10.8	<ul style="list-style-type: none"> • Fine - \$20,000
1029	Nycomed	Promotional Material	Somac	AstraZeneca	No breach 1.1, 1.2.2, 1.3, 1.5, 1.7, 4.1, 4.4, 10.5.1, 10.5.2, 10.8	N/A
1030	Servier	Promotional Material	Coversyl	Boehringer Ingelheim	Breach 1.1, 1.3, 1.7 & 1.10 No breach 4.1	<ul style="list-style-type: none"> • Withdraw • Corrective letter • Fine - \$100,000
1031	Schering Plough	Promotional material	Olmotec	Healthcare Professional	Breach 1.1, 1.10 & 3.1.4 No breach 1.9 & 10.8	<ul style="list-style-type: none"> • Withdraw • Fine - \$35,000
1032	MSD	Educational Event - hospitality	N/A	MA Monitoring Committee	Breach 6.2 & 10.2 No breach 10.8	<ul style="list-style-type: none"> • Fine- \$40,000
1033	MSD	Educational Event - hospitality	N/A	MA Monitoring Committee	Breach 6.2, 10.2 and 10.8	<ul style="list-style-type: none"> • Fine- \$10,000

No.	Subject Company	Material Activity	Product	Complainant	Outcomes	Sanction
1034	Innovex (Pharmalink)	Educational Event - hospitality	N/A	MA Monitoring Committee	Breach 6.2, 6.8, 10.2, 10.3 & 10.8	• Fine- \$50,000
1035	Allergan	Promotional Material	Ganfort	Alcon	No breach 1.1, 1.2.2, 1.3, 1.7	N/A
1036	Ferring	Advertisement	Pentasa	Healthcare Professional	No breach 1.1, 1.3, 1.3.1	N/A

Botox 1023

Subject Company: Allergan Australia

Complainant: Medicines Australia Monitoring Committee

Product: Botox

Complaint

Item 1: Rejuvenation begins with Botox. The Monitoring Committee was of the view that the claim that there is a 'low frequency' of adverse events with Botox, based on the presented data from a pharmacoeconomic study, is not consistent with the commonly accepted rates of adverse events in the Australian and international regulatory environment whereby events occurring at a frequency of greater than or equal to 10% is considered to be 'common' or 'very common'. The frequency of individual adverse events with Botox treatment reported in the graph ranged from 7% to 23% with an overall rate of 15%. Monitoring Committee members were of the view that the claim 'low frequency of adverse events' was therefore misleading and in breach of Section 1.3 of the Code.

Item 4 Be proactive. The Monitoring Committee was concerned that the variation in lighting effects and photographs of the 'Regular Botox' and 'Minimal Botox' users gave a misleading impression of the likely outcomes of Botox treatment. Monitoring Committee members agreed that this aspect of Item 4 was in breach of Section 1.3 of the Code because the photographs were of sufficiently different quality to be misleading. Additionally, the Monitoring Committee considered that there was insufficient evidence to support the claimed relationship between the use of Botox and behaviour modification ('*Not only inhibiting ability to contract the target muscles but also perhaps through behaviour modification*') and therefore was in breach of Section 1.2.2 of the Code.

Sections of the Code

Materials alleged to be in breach of the following Sections of the Code:

- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims

Response

Allergan disagreed that the promotional materials subject to complaint were in breach of Sections 1.2.2 or 1.3 of the Code of Conduct. The company provided data to support its assertion that it is not misleading to state that the frequency of adverse events is low with Botox when compared with the alternative botulinum toxin product. Allergan further stated that the photographs included in the promotional piece are sufficiently technically differentiated so as to clearly define the difference in wrinkle severity between the 'regular' and 'minimal' Botox users and are not misleading and are not in breach of Section 1.3 of the Code. Allergan commented that the supplied references support the behaviour modification claim which is therefore not in breach of Section 1.2.2 of the Code.

Code of Conduct Committee determination

Item 1

'Low frequency of adverse events with Botox' and 'pre-clinical data suggest minimised migration with Botox allows greater physician control and decreased adverse events' - in a unanimous decision a breach of Section 1.3 of the Code was found

Item 4

- Variation in lighting - in a majority decision a breach of Section 1.3 of the Code was found
- Behaviour modification - in a unanimous decision a breach of Section 1.2.2 of the Code was found

Sanction

- Withdraw items found in breach and not use them again or in a manner that conveys the same or similar meaning
- Send a corrective letter to all healthcare professionals who received or were detailed with the items found in breach of the Code
- Pay a fine of \$100,000

Consideration of the complaint

Item 1

The Committee was particularly concerned with the use of the claim 'low adverse events' in the promotional item. The term 'low' is not the same as the 'lower' when

comparing two products. While the adverse events may be lower for Botox than Dysport, it is not correct to state that they are 'low' overall for Botox. There are internationally accepted terms for describing the frequency of adverse events to medicines. Members noted the Allergan response that adverse events for Botox had not been described in terms of Council for International Organisations of Medical Sciences (CIOMS) definitions and that the claim uses 'low' rather than 'uncommon'. The overall frequency of adverse events for Botox in the referenced study was 15%, and for individual types of adverse events up to 23%, which is not consistent with the description of 'low' frequency.

The Committee accepted that Botox and Dysport (also a botulinum toxin) are not identical and have a different molecular weight. The Committee particularly reviewed Allergan's explanation of how toxin spread in the mouse model related to adverse effects in humans, but did not accept that this explanation was valid. The Committee considered that the claim that *'pre-clinical data suggest that minimised migration with Botox allows greater physician control and decreased adverse events'* was misleading because it sought to link a clinical claim to animal data which could not be substantiated and was therefore misleading.

In unanimous decisions the Committee found that the claims of 'low adverse events' and *'pre-clinical data suggest that minimised migration with Botox allows greater physician control and decreased adverse events'* were in breach of Section 1.3 of the Code.

Item 4

Variation in lighting in photos

Members were of the view that it was not acceptable to make treatment comparisons using photos with different lighting (intensity and brightness) for each of the twins in the case study to compare 'regular Botox' and 'minimal Botox' use. If a comparison is to be made, the positioning of the faces and the same quality lighting must be used.

Members also commented that it is not appropriate to use a single case study comparing results in one pair of twins to

support a general claim about outcomes of Botox treatment.

In a majority decision the Committee found the photos were misleading and in breach of Section 1.3 of the Code.

Behaviour modification

The Committee was unanimous in their view that there was insufficient evidence to support the claim: *'Not only inhibiting ability to contract the target muscles but also perhaps through behaviour modification'*. The referenced paper included in its discussion section uses terms such as 'perhaps' and 'appears'. This was expressing the views of two individuals but there was no evidence contained in the study to support this conjecture. Members also commented that it is not the responsibility of the Monitoring Committee to demonstrate that the study referenced by Allergan does not constitute the body of evidence with regard to current thinking on behaviour modification, as was asserted by Allergan. A company must demonstrate to the satisfaction of the Monitoring or Code Committees that there is sufficient evidence to support a claim.

The Committee unanimously found the behaviour modification claim was in breach of Section 1.2.2 of the Code.

The Committee expressed a consensus view that there had been insufficient attention to the details of ensuring there was appropriate supporting evidence for claims in the two promotional items and recommended that Allergan's compliance and internal approval processes should be reviewed and that the concerns of the Committee should be taken seriously.

Sanctions

Having found several breaches of the Code the Committee considered appropriate sanctions. The Committee determined that there were no safety implications for patients as a result of the promotional materials, but the Committee considered that the claims were seriously misleading. The Committee therefore determined that Allergan should:

- Withdraw items found in breach and not use them again or in a manner that conveys the same or similar meaning

- Send a corrective letter to all healthcare professionals who received or were detailed with the items found in breach of the Code. The corrective letter must refer to all claims and graphics found in breach of the Code. It must be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective letter must be in a font of no less than 12 point. Medicines Australia must receive documentary evidence of the distribution of the corrective letter and the Secretary of the Code Committee must be included on the mailing list for the letter. The corrective letter must be issued within 30 calendar days of receipt of the minutes detailing the Committee's decision.
- Pay a fine of \$100,000

Television advertisement for erectile dysfunction 1024

Subject Company: Pfizer Australia

Complainant: Member of the general public

Product: N/A

Complaint

The complainant had stated that because Pfizer was advertising its logo and name to the public at the end of an advertisement it paid for about erectile dysfunction, this was in fact advertising its product for erectile dysfunction to the general public and was therefore in breach of the Code.

Sections of the Code

Pfizer had been requested by the Secretariat to respond to the complaint with regard to the following Sections of the Code:

- 9.4 Promotion to the General Public
- 9.5 Patient Education
- 9.10 Discredit to and reduction of confidence in the industry

Response

Pfizer had responded that the company takes this matter very seriously. All public broadcasts undergo a stringent internal approval process to ensure alignment with the Code, relevant legislation and Pfizer policies.

The educational broadcast subject to complaint does not mention a prescription product by name, nor does it direct patients to a particular prescription product. There are several registered and available treatments for erectile dysfunction in addition to the two Pfizer products, Viagra and Caverject. Healthcare professionals will make a decision on appropriate treatments if required.

Code of Conduct Committee determination

In a unanimous decision no breach of Sections 9.4, 9.5 or 9.10 of the Code was found.

Consideration of the complaint

The Committee noted that the television advertisement did not mention a prescription medicine by name, nor did it direct patients to a specific product. Members also noted

that there is a range of treatments available in Australia for erectile dysfunction, of which Pfizer supplies two. The Committee determined that the advertisement was not an advertisement for a particular prescription medicine and did not encourage members of the general public to seek a prescription for a particular product. The Committee unanimously determined that the advertisement was not in breach of Section 9.4 of the Code.

One Committee member noted that the advertisement stated *“You can find more information on the website or talk to your doctor”* (emphasis added). The member considered that it would be preferable to direct people to the website and their doctor, rather than as alternatives.

In reviewing the complaint the Committee noted that the complainant had stated that Viagra is available on the PBS. Viagra is not available on the PBS; however it is available on the Repatriation Pharmaceutical Benefits Scheme (RPBS); for other patients it is available as a private prescription only.

Members referred to the Section 9.5.4 of the Code which states *“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.”* The Code thus requires that the name of the company is included in any educational communication. The Committee unanimously determined that no breach of Section 9.5.4 or 9.5 had occurred.

The Committee unanimously determined that there was no breach of Section 9.10 of the Code as the information was educational in nature, did not encourage a patient to seek a prescription for a specific prescription medicine and did not bring the industry into disrepute.

Copaxone 1025

Subject Company: sanofi-aventis

Complainant: Merck Serono

Product: Copaxone

Complaint

Merck Serono stated that the claim “Works as quickly and effectively as high-dose INF- β -1a 44mcg” is a broad and unqualified comparison of Copaxone and Rebif which does not adequately reflect the evidence provided by the REGARD study to which it is referenced and which constitutes the body of evidence.

Sections of the Code

Materials alleged to be in breach of the following Sections of the Code:

- 1.1 Responsibility
- 1.3 False and misleading claims
- 1.7 Comparative statements

Response

Sanofi-aventis denied that the claim was in breach of the Code as it is an accurate representation of the primary outcome of the REGARD Study, which was time to first relapse and which is supported by the wider body of evidence.

Code of Conduct Committee determination

In a unanimous decision the Committee found a breach of Sections 1.1, 1.3 and 1.7 of the Code.

Sanctions

- Withdraw materials found in breach
- Send a corrective letter to all neurologists
- Pay a fine of \$25,000

Consideration of the complaint

The Committee considered the results in the Mikol et al study, which is the supporting reference for the claim “Works as quickly and effectively as high-dose INF- β -1a 44mcg”. It noted that the primary endpoint in the study was time to first relapse for which the two treatments (Betaferon beta-1a and glatiramer acetate) were comparable. A number of secondary and tertiary measures based on MRI scans were included in the study, some of which had reached statistical significance. The authors had concluded

“There was no significant difference between Betaferon beta-1a and glatiramer acetate in the primary outcome. The ability to predict clinical superiority on the basis of the results from previous studies might be limited by a trial population with low disease activity, which is an important consideration for ongoing and future trials in patients with RRMS.”

The Committee noted that the study did not accrue the number of relapse events required to detect a statistical difference in the primary endpoint. The study was statistically underpowered due to an overestimate of the expected rate of relapse events.

The Committee considered the letter from a professor of neurology to sanofi-aventis and noted that the professor’s comments were somewhat qualified through use of terms such as ‘broadly’, ‘limitations’ and ‘roughly equivalent’. The Committee noted the professor’s comments that the role of MRIs in multiple sclerosis is most relevant to diagnosis rather than in determining effectiveness of treatments.

The Committee was of the view that the claim “Works as quickly and effectively as high-dose INF- β -1a 44mcg” did not accurately reflect the conclusions of the Mikol et al study. Whilst the primary endpoint of the study, time to first relapse, was not statistically significantly different for each of the treatments, the claim of equal effectiveness is broader than can be substantiated from the study methodology or outcomes. Further, there was no evidence in the referenced study to support the claim ‘works as quickly’. The Committee concluded that the claim was misleading, had made a comparison between Copaxone and Rebif that could not be substantiated and was therefore in breach of Sections 1.1, 1.3 and 1.7 of the Code.

The Committee determined that this was a moderate breach of the Code.

Sanctions

Having found several breaches of the Code, the Committee determined that sanofi-aventis should:

- Withdraw the materials containing the claim found in breach of the Code and not use the claim again or in a manner which conveys the same or a similar meaning
- Send a corrective letter to all neurologists. The corrective letter must be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective letter must be in a font of no less than 12 point. Medicines

Australia must receive documentary evidence of the distribution of the corrective letter and the Secretary of the Code Committee must be included on the mailing list for the letter. The corrective letter must be issued within 30 calendar days of receipt of the minutes detailing the Committee's decision.

- Pay a fine of \$25,000

Janssen-Cilag Educational Event 1027

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Department Meeting - 1.5 hours	Hanauman Restaurant, Alice Springs	Psychiatrists, Registrars	2 course meal with alcohol/non-alcoholic beverages	\$230	6	\$230

Subject Company: Janssen-Cilag

Complainant: Medicines Australia Monitoring Committee

Complaint

The Monitoring Committee noted that whilst there was minimal hospitality, at a cost of \$38.33 per person, members were of the view that the sponsorship of a department planning meeting did not meet the requirement for there to be an educational purpose for meetings with healthcare professionals where hospitality is provided. The event was therefore forwarded to the Code of Conduct Committee as a formal complaint.

Sections of the Code

Event alleged to be in breach of the following Sections of the Code:

- 6.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response

Janssen-Cilag acknowledged that the information provided in the original report and to the Monitoring Committee was unclear and contained an inaccurate description of the function and apologised to the Committee.

The event was an in-service for the departmental staff which followed a departmental planning day. The in-service meeting was held at a location outside the hospital for the convenience of the staff who were also attending the planning day at that location. Janssen-Cilag did not provide any

support for the departmental planning day meeting and the staff who did not attend the in-service did not receive any hospitality from Janssen-Cilag.

The in-service agenda was prepared in response to concerns about debilitating side effects that occur among people in indigenous communities with schizophrenia who are treated with antipsychotics. The in-service was of 1.5 hours duration and included a presentation of clinical data, a demonstration of the reconstitution of Risperdal Contra and addressed questions in relation to side effects and long term issues.

The hospitality was modest at \$38.33 per head and there was meaningful education. Janssen-Cilag argued that no breach of Sections 6.2, 10.2 and 10.8 of the Code had occurred.

Code of Conduct Committee determination

In a majority decision the Committee did not find a breach of Sections 6.2, 10.2 or 10.8 of the Code.

Consideration of complaint

The Committee had a robust discussion with respect to what had occurred at this event. The Committee was concerned that companies should fully investigate any matter raised by the Monitoring Committee and provide that Committee with full, detailed and accurate information rather than only providing this information once it has been referred to the Code Committee.

Some members questioned whether there was valid education provided at the event in

question, such as the demonstration of the reconstitution of Risperdal Contra, or should the event more properly be characterised as product promotion. These members questioned the necessity of conducting what appeared to be product promotion at a location away from the workplace with hospitality provided. However other members commented that whilst in-services are usually held within the institution, on this occasion healthcare professionals from the Alice Springs area were at off-site at the planning meeting and it was convenient to hold the in-service immediately after their planning day. These members accepted that, on balance, there was an educational purpose for the meeting and the hospitality provided was very modest and proportional to the education.

In relation to the meeting agenda, which included discussion of a 2006 paper, some members commented that this did not appear to be very recent information that required communication in an educational event. Other members accepted that the study in question may be the only study in the indigenous population in the therapeutic area and its discussion in the context of side effects to antipsychotics may be valid.

In a majority decision, Members accepted that the hospitality provided was proportionate to the educational content and found no breach of Sections 6.2, 10.2 or 10.8 of the Code.

Merck Sharp & Dohme (Australia) Educational Event 1028

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Congress - European Society of Cardiology (ESC) delegate dinner	Wirtshaus im Grunta, Munich	Specialists	3 course dinner with alcoholic & non-alcoholic beverages	2,719	11	2,719

Subject Company: Merck Sharp & Dohme (MSD)

Complainant: Medicines Australia Monitoring Committee

Complaint

The Monitoring Committee had asked MSD to provide justification for the cost of the dinner held in Munich in association with the European Society of Cardiology Conference (ESC).

Sections of the Code

Event alleged to be in breach of the following Sections of the Code:

- 6.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response

MSD stated that the primary objective of the ESC was the enhancement of medical knowledge and the quality use of medicines by healthcare professionals. It is a global conference in the fields of cardiology, endocrinology and atherosclerosis, attracting approximately 25,000 physicians and scientific thought leaders. The conference provided significant high quality educational content.

MSD asserted that the hospitality provided was secondary to the educational purpose of the event and was consistent with the professional standing of delegates. The venue is popular with locals, has a casual outdoor seating area where the dinner was

held and was at the lower end of the price range of restaurants offered by the organising agency. MSD stated that the price for the standard menu during this conference was almost triple the usual price.

The hospitality in question was provided by the joint venture of MSD and Schering-Plough. MSD reported this event because it was organised through its headquarters, Merck & Co. The invoice for the dinner was sent to Merck & Co, as the restaurant was booked by the agency used by Merck & Co. Schering-Plough was later cross-charged by MSD for its portion of the dinner. Of the 18 attendees, 11 were hosted by the joint venture and 7 were hosted by Schering-Plough.

The exchange rates used in this response were the rates published by the Reserve Bank of Australia on 2 September 2008.

Code of Conduct Committee determination

In a majority decision the Committee found a breach of Sections 6.2 and 10.2 and no breach of Section 10.8 of the Code.

Sanction

- Pay a fine of \$20,000

Consideration of the complaint

The Committee accepted that venues often substantially increase their prices when a large conference is held in a city. An Australian company providing the hospitality must ensure that any agency organising the hospitality on its behalf is aware of the company's policies and requirements and

meets the standards expected under the Medicines Australia Code of Conduct, irrespective of price movements during major conferences.

Some members commented that if the exchange rate had been more favourable there may not have been any question about the cost of the dinner. However, a majority of members considered that the cost of the dinner was extravagant and could not be justified.

The Committee noted that MSD had provided the standard menu and costs for the restaurant but had not provided the actual menu for what was served at the dinner subject to the complaint, nor had the actual receipts from the venue been supplied, only the charges applied from the head office. While the standard menu and standard costs supplied by MSD was not extravagant, the majority of members were of the view that a cost of AUD \$205 per head was excessive and would not withstand

public scrutiny. Some members also questioned the cost for the provision of a hostess on the coach to take 18 delegates from their hotel to the restaurant.

In a majority decision the Committee found that the event was in breach of Sections 6.2 and 10.2 of the Code. The Committee did not find a breach of Section 10.8 of the Code.

Members commented that there is no obligation on a company to provide a dinner for conference delegates. If it is not possible to find a restaurant at a reasonable cost, the company should not take the delegates to dinner.

Sanction

Having found several breaches of the Code the Committee determined that MSD should:

- Pay a fine of \$20,000.

Somac 1029

Subject Company: Nycomed

Complainant: AstraZeneca

Complaint

AstraZeneca had alleged that, based on evidence from the GP Monitor survey, the claim of there being a unique lack of interaction between pantoprazole (Somac) and clopidogrel was being delivered by Nycomed representatives. The claim is inconsistent with the current body of evidence, the Australian approved Somac Product Information (PI) and with the current regulatory position in this area. The proportion of sales calls where the issue with clopidogrel was recalled was clearly much higher after calls from the Nycomed representatives, which AstraZeneca asserted demonstrates an active, widespread and sustained campaign.

AstraZeneca asserted that by promoting Somac as the safer proton pump inhibitor (PPI) without robust supporting clinical data, Nycomed sales representatives are misleading the medical community.

AstraZeneca asserted that the messages being promoted to doctors by Nycomed is having an impact on patient care.

Sections of the Code

Materials and conduct alleged to be in breach of the following Sections of the Code:

- 1.1 Responsibility
- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 1.5 Unqualified superlatives
- 1.7 Comparative statements
- 1.10 Distinction of promotional material
- 4.1 Company representative
- 4.4 Company representative
- 10.5.2 Medical literature/reprints
- 10.8 Discredit to and reduction of confidence in the industry

Response

Nycomed denied that a widespread national campaign has been undertaken as alleged. Nycomed sales representatives have been detailing the promotional message “Somac has a low potential for drug interactions”. The representatives have been using a

sales flier to convey this message. AstraZeneca has not expressed concern about the flier or the claims made within it. The flier is accurate and sufficiently substantiated by the literature.

In the latter part of 2008 and early 2009 data began to emerge in the literature purporting an interaction between clopidogrel and PPIs. At the end of January 2009 an early release version of a paper by Juurlink et al appeared. Subsequently news articles appeared in two popular GP weekly tabloids (*Australian Doctor Weekly* and *Medical Observer*). Nycomed had provided its sales representatives with a single copy of these articles and published papers to enable them to answer questions from GPs should they arise. The published papers could be provided to GPs on request to enable them to read the full story referred to in the news articles.

Nycomed has already agreed with AstraZeneca that distribution of the materials by a single hospital representative was inappropriate and action has been taken to ensure this does not occur again.

Nycomed denied that its actions or materials were in breach of the Code.

Code of Conduct Committee determination

The claim of unique lack of interaction between pantoprazole and clopidogrel

- In a unanimous decision no breach of Sections 1.1, 1.2.2, 1.3, 1.5, 1.7 of the Code
- In a majority decision no breach of Sections 4.1 or 4.4 of the Code

The nature of the promotion that is clearly not aligned to current regulatory opinion and its potential to bring the industry into disrepute

- In a unanimous decision no breach of Sections 10.5.2 of 10.8 of the Code.

The distribution of a selective extract from the medical press and the use of a highlighted, photocopied reproduction as a promotional piece

- In a majority decision no breach of Sections 1.5, 1.7, 1.10, 4.1, 4.4, 10.5.1, 10.5.2 or 10.8 of the Code.

Consideration of the complaint

The Committee was informed that the IMS GP Monitor is available via subscription to pharmaceutical companies. A representative sample of Australian GPs (200 - 400) is paid to complete a diary of what they recall following a sales representative visit.

Members agreed that GPs receive information from a variety of sources, including sales representatives, professional journals and publications such as *Medical Observer* and *Australian Doctor Weekly*. With respect to the issues raised by AstraZeneca the Committee noted that the reference to potential interactions between PPIs and clopidogrel had been included in published articles, e-Bulletins and provided by the National Prescribing Service (NPS). In April 2009 the NPS launched an RACGP-accredited clinical audit aimed at reviewing PPI prescribing. This audit made reference to interactions with PPIs (including suspected and possible interactions) including the following statement in relation to clopidogrel “available data suggests no special precautions necessary for pantoprazole”.

Members noted that commentary from the EMEA and FDA have identified that the evidence is evolving but neither regulatory authority has confirmed that a particular PPI is superior with respect to the likelihood of drug interactions. From the evidence, all PPIs have an impact on liver enzyme metabolism and the emerging data on the differences between PPIs in interactions with clopidogrel are not yet conclusive.

The NPS publication for GPs has potentially stimulated discussion amongst the profession and, together with articles in widely read GP publications, may have contributed to GPs seeking clarification from Nycomed with respect to its product Somac.

The Committee determined that there was insufficient evidence of the proactive

marketing by Nycomed of an advantage of Somac and its potential for drug interactions. The Committee considered that the GP Monitor data was not sufficient evidence of such activities. Such data do not indicate whether the sales representative raised the issue or the GP as a result of the recent medical press articles, published studies or NPS information.

However, members were of the view that Nycomed should have given a clear directive to its sales representatives not to proactively give the journal/press articles to healthcare professionals; rather the information was to keep the representatives up to date in case of questions from a GP.

Members accepted that Nycomed sales representatives could be detailing doctors as alleged, however there was no evidence provided by AstraZeneca of widespread distribution of the *Medical Observer* or *Australian Doctor Weekly* articles. The Committee did raise some concerns about representatives being provided with articles from publications such as *Medical Observer* and *Australian Doctor Weekly*, which would not include sufficient detail for a healthcare professional to make an assessment of the veracity of the study. However, it was noted that the representatives were also given the Juurlink et al paper. Further, it was noted that there was only evidence in relation to one representative who had left copies of the articles in a hospital.

In relation to the distribution of a selective extract from the medical press and the use of a highlighted, photocopied reproduction as a promotional piece the Committee found no breach of Sections 1.5, 1.7, 1.10, 4.1, 4.4, 10.5.1, 10.5.2 or 10.8 of the Code

Having considered the information provided by AstraZeneca and Nycomed the Committee determined that there was insufficient evidence that Nycomed was promoting a unique lack of interaction between pantoprazole and clopidogrel. In a unanimous decision no breach of Sections 1.1, 1.2.2, 1.3, 1.5, 1.7 of the Code was found. In relation to the occasion where a Nycomed representative did leave the folder of medical press and scientific journal articles in a hospital, the Committee accepted that Nycomed had taken

appropriate action to ensure this did not recur. Further, there was no evidence that any promotional materials making a claim of superiority of Somac in drug interactions with clopidogrel had been provided, and the Juurlink et al article had been included in the folder. In a majority decision no breach of Sections 4.1 or 4.4 of the Code was found.

The Committee also determined that there was insufficient evidence to uphold the complaint that Nycomed was engaging in an active, widespread and sustained campaign to promote Somac outside the PI and did not find a breach of Sections 10.5.2 or 10.8 of the Code.

Coversyl 1030

Subject Company: Servier Laboratories
Australia (Servier)

Complainant: Boehringer Ingelheim

Product: Coversyl

Complaint

Boehringer Ingelheim alleged that although the promotional materials found in breach of the Code in Complaint 1006 were withdrawn by Servier, Servier has continued to breach the Code through a promotional campaign which misleads doctors in regard to the data available to support the use of angiotensin receptor blockers. Boehringer Ingelheim had identified several items of promotional material that it alleged continued to make misleading claims regarding the use of Angiotensin Converting Enzyme Inhibitors (ACEI) compared with Angiotensin Receptor Blockers (ARB). Boehringer Ingelheim further alleged that the continued use of these claims was a repeat breach of the Code.

Sections of the Code

Materials alleged to be in breach of the following Sections of the Code:

- 1.1 Responsibility
- 1.2 Level of substantiating data
- 1.3 False and misleading claims
- 1.7 Comparative statements
- 1.10 Distinction of promotional material
- 4.1 Company representatives

Response

Servier asserted that Boehringer Ingelheim had sent the complaint to Medicines Australia without following due process as required by the Code. Servier denied any breach of the Code, or any repeat breach of the Code. Servier alleged that the complaint from Boehringer Ingelheim was vexatious and was in breach of Section 12.3 of the Code.

Code of Conduct and Appeals Committee determinations

Part 1: Misleading promotion of “ACE inhibitor (Coversyl) vs ARBs”

- Unanimous decision of a breach of Sections 1.1, 1.3 and 1.7 of the Code. (Decision confirmed by the Appeals Committee)
- By a majority decision, no repeat breach of Sections 1.1, 1.3 or 1.7 was found.

Part 2: Use of indirect comparisons in detailing material to compare ACEI vs ARB trials

- Complaint not sufficiently made out. No breach was found.

Part 3: Use of Medscape article for inappropriate promotion

- In a unanimous decision a breach of Sections 1.1, 1.2 and 1.3 of the Code was found. (Decision confirmed by the Appeals Committee)
- In a majority decision a breach of Section 1.10 of the Code was found. (Decision confirmed by the Appeals Committee)
- In a unanimous decision no breach of Section 4.1 of the Code was found.
- By a majority decision, no repeat breach of Sections 1.1, 1.3 or 1.7 was found.

Sanctions

The Committee determined that this was a severe breach of the Code.

- Withdraw materials found in breach (Sanction confirmed by the Appeals Committee)
- Publish a corrective advertisement (Requirement for corrective advertisement removed by Appeals Committee)
- Send a corrective letter to all general practitioners and cardiologists (Sanction confirmed by the Appeals Committee)
- Pay a fine of \$100,000 (Sanction confirmed by the Appeals Committee)

In relation to the allegation by Servier that Boehringer Ingelheim was in breach of Section 12.3 of the Code, having found several breaches of the Code by Servier which were determined to be severe

breaches, the Committee did not find any cause to ask Boehringer Ingelheim to respond to this allegation.

Code of Conduct Committee

Consideration of the complaint

The Committee referred to the minutes for complaint Coversyl 1006 and the sanctions imposed. The Committee noted that Boehringer Ingelheim had asserted in the current complaint that Servier had not complied with the sanctions imposed in complaint 1006 and had continued to make promotional claims in relation to the comparative efficacy of ACEIs and ARBs. The current complaint was based in part on evidence provided by the market survey data from GP Monitor and in part on items of promotional material.

The Committee noted the allegation from Servier that Boehringer Ingelheim had lodged the complaint prior to finalisation of the minutes of an intercompany meeting and had not followed due process as set out in the Code. The Committee was satisfied that Servier had had the opportunity to fully respond to the allegations of breach of the Code.

Part 1: Misleading promotion of “ACE inhibitor (Coversyl) vs ARBs”

The Committee understood that this part of the complaint related to evidence submitted from the market research service “GP Monitor” regarding promotional claims made by Servier representatives and a Dear Doctor letter issued by Servier on 25 June 2009 (Attachment 3 in the BI complaint) which referenced a meta-analysis by Al Khalaf MM et al 2009. Overall the complaint concerned the manner in which Servier was promoting to healthcare professionals that ARBs were not as effective as ACEIs in reducing the risk of cardiovascular events.

These claims were being made to healthcare professionals in a number of different formats. The Committee was of the view that the ‘Dear Doctor’ letter and Servier item ‘Differential effects of ACE inhibitors and ARBs on cardiovascular events’ (Attachment 7 in the BI complaint) should be considered as part of this complaint.

Members noted the limitations of the evidence submitted from GP Monitor about what Servier representatives have said to doctors. The Committee understood that GP Monitor is a *post hoc* record by participating GPs of what was said during a particular representative visit. It further noted that none of the GP Monitor reports stated that a Servier representative had made the alleged comments or statements. However, the Committee did not completely disregard the evidence from GP Monitor. The Committee members were of the view that the ‘Dear Doctor’ letter from Servier of 25 June 2009 and Servier item ‘Differential effects of ACE inhibitors and ARBs on cardiovascular events’ provided evidence that Servier was providing promotional material that was not balanced, did not reflect the body of evidence and had the potential to mislead prescribers. The Committee considered that the Dear Doctor letter did not accurately reflect the full body of evidence. It considered that there was a body of evidence, including the Law et al meta-analysis published in the *British Medical Journal* in 2009, that both ACEIs and ARBs have some protective effects for cardiovascular events. The reference to the El Kalaf MM et al meta-analysis in the Dear Doctor letter was selective and did not reflect the body of evidence. The Committee unanimously determined that Servier was in breach of Sections 1.1, 1.3 and 1.7 of the Code.

By a majority decision, no repeat breach of Sections 1.1, 1.3 or 1.7 was found. The Committee accepted that Servier had not continued to use exactly the same claim as had been found in breach in complaint 1006.

Part 2: Use of indirect comparisons in detailing material to compare ACEI vs ARB trials

The Committee noted that Servier had stated that the material alleged to be in continued use had been withdrawn. The Committee determined that Boehringer Ingelheim had not provided sufficient evidence that that was still being used.

The Committee did not find any breach of Sections 1.1 or 1.3 of the Code with respect to this part of the complaint.

Part 3: Use of Medscape article for inappropriate promotion

The Committee noted that Medscape was a professional news service and the author of the summary article titled “ARBs unable to TRANSCEND placebo in high-risk patients” was a journalist. The Committee considered that the Medscape article did not have equivalent scientific rigour to a peer-reviewed clinical publication and was simply a collation of differing opinions put together by a journalist.

Whilst accepting that Servier had not published the Medscape article, Servier had used the item in a promotional manner, based on the heading relating to ARBs. The Committee considered that this item falls short of the high quality of evidence expected under the Code for materials distributed by a company to healthcare professionals. While noting that the Medscape article was not identified as an item of Servier promotional material, it had been distributed to healthcare professionals by Servier representatives in a promotional manner.

Members were of the view that opinions expressed in the Medscape item were not consistent with the body of evidence for ARBs and was therefore misleading due to the manner in which it was used by Servier.

In a majority decision the Committee found that the item was promotional as defined by the Code, particularly in the manner in which it was used by Servier, and this was in breach of Sections 1.1, 1.2, 1.3 and 1.10 of the Code.

The Committee unanimously found no breach of Section 4.1 of the Code as the representatives had distributed the material which had been approved by the company.

In a majority decision the Committee determined that the distribution of the Medscape article was not technically a repeat breach under the Code and therefore did not find a repeat breach of Sections 1.1, 1.3, or 1.7. However, some members expressed the view that while Servier was using different materials, there was sufficient evidence provided by Boehringer Ingelheim that Servier had continued to distribute

misleading promotional material concerning the comparative effects of ARBs and ACEIs. The Committee found the ongoing, misleading promotion by Servier as reviewed in this complaint to be unacceptable and that this was a severe breach of the Code because it had the potential to have a major impact on prescribing.

Sanctions

Having found several breaches of the Code and determining that this constituted a severe breach of the Code, the Committee determined that Servier should:

- Withdraw the materials found in breach of the Code and not use them again, or in a manner which conveys the same or a similar meaning.
- Publish a corrective advertisement in *Medical Observer* and *Australian Doctor Weekly*.
- Send a corrective letter to all general practitioners and cardiologists. The corrective letter must be approved in writing by the Chairman of the Code of Conduct Committee. The text of the corrective letter must be in a font of no less than 12 point. Medicines Australia must receive documentary evidence of the distribution of the corrective letter and the Secretary of the Code Committee must be included on the mailing list for the letter. The corrective letter must be issued within 30 calendar days of receipt of the minutes detailing the Committee's decision.
- Pay a fine of \$100,000.

Appeals Committee

Appeal

Servier appealed the decision of the Code of Conduct Committee on the grounds that the Committee had erred by:

- Failing to dismiss the complaint insofar as it related to the Dear Doctor letter and ‘Rahman’ promotional piece because the complaints made in relation to these materials were not brought to the Committee by following the intercompany dialogue procedure set out in the Code.
- Its determination that the Al-Khalaf meta-analysis did not adequately reflect the current body of evidence concerning

the efficacy of Angiotensin Receptor Blockers (ARBs) in reducing cardiovascular events in non-heart failure patients. Of the two randomised controlled trials (RCT) provided by Boehringer Ingelheim, one is in post-myocardial infarction heart failure and therefore irrelevant to the Al Khalaf meta-analysis, which only considered and made conclusions on non-heart failure trials. The other RCT (ONTARGET) is one of three large outcome trials testing telmisartan in high-risk patients but the only one that returned a positive outcome on the primary endpoint. Boehringer Ingelheim chose to include this study only. It therefore does not reflect the body of evidence available regarding telmisartan or the entire ARB class.

- Finding the circulation and distribution of the Dear Doctor letter and ‘Rahman’ promotional piece had breached Sections 1.1, 1.3 and 1.7 of the Code.
- Finding that the Medscape article was a promotional item or distributed in a promotional manner, and that this item was in breach of Sections 1.1, 1.2, 1.3 and 1.10 of the Code.
- Requiring Servier to send a corrective letter to general practitioners and cardiologists who did not receive the Dear Doctor letter and requiring Servier to place corrective advertising, where no advertising of the material subject to complaint had taken place.

Response to appeal

Boehringer Ingelheim responded to the appeal by stating that Servier had provided little or no new evidence from that presented to the Code Committee in support of their position.

With respect to the procedural irregularities alleged by Servier, Boehringer Ingelheim agreed with the Code Committee that Servier had sufficient opportunity to respond to the concerns regarding the misleading promotion of “ACE Inhibitor (Coversyl) versus ARBs” and the use of the MedScape article.

With respect to the Dear Doctor letter and the ‘Rahman’ promotional piece, Boehringer Ingelheim considered that these items were further evidence for the concerns it had

raised with Servier regarding the campaign promoting the benefits of ACE Inhibitors versus ARBs. Further the Dear Doctor letter had been raised by Boehringer Ingelheim in correspondence with Servier and in the intercompany meeting.

Boehringer Ingelheim was of the view that the decisions of the Code Committee should be upheld.

Consideration of the appeal

Prior to the appeal being heard by the Committee the Chairman highlighted a number of procedural issues raised in the appeal.

The Appeals Committee noted the Code definition of ‘repeat of previous breach’ which means the same or similar breach is repeated in the promotion of a particular product, whereas the definition ‘breach repetition’ refers to the same breach in the promotion of any of a company’s products. Appendix 1 to the Code, at page 198, uses the expression ‘repeat breach’ which is not specifically defined in the Glossary, but is understood to mean a ‘repeat of a previous breach’. In the case of a ‘repeat breach’ the complainant may direct a complaint to Medicines Australia without a renewal of inter-company dialogue.

Matters for consideration by the Appeals Committee include:

- Was the complaint in relation to a repeat breach? If so, there was no need to follow the intercompany dialogue procedure, and the Code Committee was entitled to consider the complaint.
- Do all elements of the complaint relate to the same claim and are they further evidence of the same alleged breach or further instances of it? It should be borne in mind that the decision in January 2009 was that the subject company should “*not use the information again, or in a manner which convey the same of similar meaning.*”
- If the complaint was not about a repeat breach (in the same sense of ‘repeat of a previous breach’) then were the proper procedures followed in relation to inter-company dialogue as set out at page 196 of Appendix 1 of the Code? The requirement for consensus minutes of the intercompany meeting was not adhered

to, but the Appeals Committee may wish to consider whether every effort was made on the part of both the complainant and the subject company to resolve this matter by intercompany dialogue. If the subject company did not use every effort to resolve the matter, the conclusion may be open that the Code Committee was entitled to consider the complaint in any event.

- Were the Dear Doctor letter and 'Rahman' promotional pieces raised in intercompany dialogue? The complainant asserts that they were whereas the subject company asserts they were not.

The following outlines the appeal presentation by Servier:

The complaint shouldn't have been heard in its entirety. The Code Committee erred in four key areas and Servier seeks that the decisions are overturned.

There are clear requirements for intercompany dialogue in the Code of Conduct. The complaint concerned four different materials; for two of these - the Dear Doctor letter and the promotional item providing the opinion of Dr Rahman (the 'Rahman' piece) - intercompany dialogue was not followed in its entirety. With respect to the Dear Doctor letter, there had been an exchange of correspondence with Boehringer but the intercompany dialogue process described in the Code was not followed. In relation to the Rahman piece Boehringer did not identify what aspects it alleged were in breach of the Code despite two written requests from Servier for this information.

The corrective action imposed by the Code Committee exceeds Medicines Australia's Guidelines for determining sanctions. The Guidelines state that corrective advertising would be required in journals where an advertisement originally appeared. None of the materials subject to complaint were advertisements in Australian Doctor or Medical Observer. Further the Dear Doctor letter was sent to some 5000 doctors, whereas the sanction requires a corrective letter to be sent to all GPs and cardiologists.

Regarding the MedScape article, it was written by an experienced author who is a medical journalist and who has written more than 40 articles in the cardiovascular field since 2004. The article did not include any promotion of perindopril. It is a resource for use by Servier representatives. Section 1.10 is not relevant to the material because it is not promotional material. It should be treated as medical literature or a reprint. The content of the MedScape article MedScape reprint was fair, balanced and accurate with quotes from authors of the peer-reviewed, published studies TRANSEND and ONTARGET. The concluding sentence of the article did not favour either ARBs or ACEIs.

Servier argued that the Al Khalaf et al meta-analysis, which is quoted in the Dear Doctor letter and Rahman promotional piece, is consistent with the body of evidence.

Servier invited a Professor of Clinical Pharmacology and Therapeutics to discuss the evidence with respect to ACE Inhibitors and ARBs. Prior to commencing his presentation the Professor stated that he had received grants from, and conducted trials in association with manufacturers of both ACEI and ARB products. He had also received travel grants from both Boehringer and Servier in the past.

The Al Khalaf et al paper is a meta-analysis which separately analysed heart failure and non-heart failure trials. The authors concluded that in patients who do not have heart failure ARBs are not equivalent to ACEIs because ARBs do not confer protection against myocardial infarction (MI) in these patients. The Professor proceeded to outline the conclusions from a number of studies and meta-analyses. From this evidence he stated that there is clearly evidence to support that ACEIs confer a benefit through reduction of MI in heart failure patients over and above any reduction in blood pressure, whereas with ARBs it is difficult to demonstrate a benefit in reducing MI risk. The Professor stated that the Al Khalaf et al meta-analysis was consistent with the body of evidence.

The Professor referred to recent opinions from the European Medicines Agency (EMA) and US Food and Drug Administration (FDA), which contrast with each other. The European “Committee for Medicinal Products for Human Use (CHMP)” has issued a positive opinion on the use of telmisartan (an ARB) use in high risk CV patients. The reasons for this decision have not been disclosed. This contrasts with the FDA Cardio-Renal Advisory Committee of July 29 2009 in consideration of an application from the sponsor for marketing approval based on the ONTARGET study for “reducing risk of CV death, MI, stroke or CHF hospitalisation inpatients ≥ 55 years at high risk of developing major cardiovascular events”. The FDA Advisory Committee concluded that:

- ONTARGET does not demonstrate superiority of telmisartan/ramipril vs ramipril (ACEI) monotherapy
- Telmisartan does not meet requirements for non-inferiority vs ramipril
- Neither TRANSEND or PRoFESS studies demonstrates telmisartan superiority over placebo

The Professor concluded that the Al Khalaf et al meta-analysis is consistent with the body of evidence that it is difficult to demonstrate a benefit of ARBs in reducing MI risk in patients without heart failure and there is a demonstrable MI risk reduction with ACEI over and above reduction in blood pressure.

Servier concluded its presentation reiterating the view that the decisions of the Code Committee should be overturned or, as a minimum, the sanctions should be amended.

The following summarises the presentation in response to the appeal made by Boehringer Ingelheim:

The Professor’s presentation illustrated that this is a very complex area and the scientific community has not yet reached a conclusion on the relative benefits of ARBs and ACEIs.

Boehringer noted that in complaint 1006 from January 2009 Servier was found in breach for misleading comparison of EUROPA and TRANSCEND studies and misleading comparison of Coversyl (an

ACEI) trials vs ARBs. Servier did not appeal this decision.

Boehringer discussed the procedural issues raised by Servier. It was noted that the Code Committee had been satisfied Servier had had the opportunity to fully respond to the allegations of breaches of the Code. With regard to the provision of consensus minutes, a full recording of the intercompany meeting was provided to Servier and the minutes were amended on request from Servier and a revised version was forwarded to Medicines Australia for inclusion with the complaint prior to the Code Committee considering the complaint.

Boehringer outlined the sequence of contacts between the companies leading up to the complaint and argued that:

- Boehringer from its earliest contact with Servier had raised concerns about a co-ordinated campaign, demonstrated by specific promotional pieces.
- Numerous verbatim comments had been recorded in GP Monitor from various states around Australia, indicating misleading promotion by Servier that only ACE Inhibitors have proven benefits in reducing CV events.
- Boehringer had also received reports that healthcare professionals had been detailed with materials highlighting misleading comparisons and claims concerning ARBs and ACEIs.
- Boehringer was particularly concerned at Servier’s reluctance to enter into intercompany dialogue following earlier contact in regard to the same issues, and believe this is not within the spirit of the Code.
- As soon as further supporting evidence of the misrepresentation of the body of evidence became available, Boehringer had advised Servier.
- The Dear Doctor letter from the Servier representative simply reinforced Boehringer concerns that had been raised initially with Servier. Refusing to discuss the letter at the intercompany meeting was an attempt to further delay addressing this important matter.
- All supporting materials were tabled at the intercompany meeting

- Boehringer reiterated that the materials supported its original concerns regarding misleading promotion of ACEIs in comparison to ARBs

Servier had referred to complaint 908 in which the subject company had raised a number of procedural issues in relation to the complaint where the Code Committee had determined that one aspect of the complaint was not properly brought before the Committee because it had not been the subject of proper intercompany dialogue. Boehringer considered that these issues were not relevant to the current complaint 1030.

Boehringer considered that the misleading promotion of ACEIs vs ARBs was not a new issue. Servier had previously used indirect comparisons to compare Coversyl and ARBs in complaint 1006.

Servier has made a sweeping generalisation from a complex therapeutic issue, where multiple studies exist, through the selective use of a single meta-analysis to support one view. Since the finding of a breach of the Code in complaint 1006, Servier has chosen to use a selective meta-analysis by Al Khalaf et al to support claims that ARBs do not reduce CV morbidity and mortality.

Boehringer pointed to study limitations reported in the Al Khalaf meta-analysis: *“Our approach may, indeed, recognise some limitations because it includes very heterogeneous conditions and patients with different susceptibilities to MI. Most trials titrated doses to balance tolerability and achievement of desired effect; hence there was a wide range of dosages used even within the trials. Other limitations of our study include potential variation in the definition of MI between trials. Results are based on relatively small number of events, resulting in ORs that could be affected by small changes in the classification of events.*

Furthermore, we pooled the results of trials that were not all originally intended to explore cardiovascular outcomes. In some cases, the basis used to make a diagnosis of MI was not clearly defined. We were unable to obtain data on MI events from all studies identified in our literature search. Perhaps most notably, data on MI from VALIANT,

which included 14,703 patients, were not available for our analysis.”

Boehringer also noted that perindopril (Coversyl) is not identified by Al Khalaf et al as being included in any study included in the meta-analysis. This is a limitation for the study being used as the basis for the claims for the comparative benefit of Coversyl.

Boehringer outlined other relevant meta-analyses, including by Reboldi et al (2008) and Law et al (2009), which came to conclusions contrary to those of Al Khalaf et al:

- Law et al - concluded *“With the exception of the extra protective effect of β blockers given shortly after a myocardial infarction and the minor additional effect of calcium channel blockers in preventing stroke, all the classes of blood pressure lowering drugs have a similar effect in reducing CHD events and stroke for a given reduction in blood pressure so excluding material pleiotropic effects.”*
- Reboldi et al - concluded that ARBs are as effective as ACEIs on the risk of myocardial infarction, cardiovascular mortality and total mortality.
- Volpe et al (2009) - concluded *“This meta-analysis indicates that the risk of MI is comparable with use of ARBs and other antihypertensive drugs in a wide range of clinical conditions.”* Servier promotional materials had stated *“A meta-analysis of heart failure trials studying the effects of ARBs, published in 2009, concluded that there is no evidence to suggest that ARBs provide protection against MI.”*

Boehringer referred to the FDA Advisory Committee decision raised by Servier. It noted that the expanded indication recommended for approval by the FDA included the reduction in risk of myocardial infarction, stroke or death from cardiovascular disease. Boehringer further noted that these differing opinions from regulatory authorities indicate that this is not a clear cut issue.

Boehringer referred to the National Heart Foundation *Guide to management of hypertension 2008* which states *“ACE inhibitors and angiotensin II receptor antagonists have been shown to be equally*

efficacious in prevention of combined end points of cardiovascular disease death, myocardial infarction, stroke and heart failure admissions in patients at high risk due to past cardiovascular events”.

Boehringer stated that the varying evidence and divergent opinions concerning the relative benefits of ACEIs and ARBs in protection against cardiovascular disease demonstrate that there is continuing debate in the medical and scientific community. Boehringer considers that the single meta-analysis by Al Khalaf does not reflect the body of evidence. Other meta-analyses show different results.

Regarding the Code Committee’s statement that there was no evidence that a Servier representative had made the alleged comments or statements, Boehringer stated that every call recorded by GPs entering data into GP Monitor includes a record of the product presented and the company promoting that product. The company name for the representative is entered on the recording sheet. The records submitted as part of this complaint clearly state the verbatim comments were as a result of discussion with Coversyl representatives from Servier. Boehringer remains concerned that misleading information is being conveyed by Servier representatives.

Regarding the MedScape Article, Boehringer considers that it was used in a promotional manner. Further the article doesn’t satisfy the expected standard of high quality evidence; it is not peer-reviewed whereas there is peer-reviewed evidence available. Boehringer agrees comments by the Code Committee in its decision with respect to the use of the item in a promotional manner. Boehringer contends that the distribution of the materials subject to complaint support its original contention that Servier was engaged in a widespread campaign distributing misinformation.

In response to a question from the Chairman regarding the requirement for a corrective letter to be sent to a wider audience than the doctors who received the Dear Doctor letter, Boehringer responded that there has been substantial activity by Servier representatives for some time using materials identified in this complaint in

addition to the Dear Doctor letter. Boehringer stated that more doctors have been exposed to the misleading information than the Dear Doctor letter recipients.

In the discussion that followed Boehringer’s presentation, Servier representatives stated that they had taken a literal interpretation of the intercompany dialogue process, with the expectation that with each new piece of promotional or other material raised there should be a letter from the complainant describing the aspects considered to be contrary to the Code and then a ten day period for intercompany dialogue to occur. Boehringer did not agree with this approach, because it considered that the different pieces of promotional material were further examples of the conduct it had originally complained about.

In response to a question about whether the complaint was a repeat breach, which would have obviated the requirement for intercompany dialogue, Servier denied it was a repeat breach. Boehringer stated that it did consider that this was a repeat breach, but nevertheless it decided to engage in intercompany dialogue with Servier. It was concerned with Servier’s approach which it regarded as trying to split the complaint into three separate complaints.

The Servier and Boehringer Ingelheim representatives left the meeting following these presentations.

GP Monitor evidence

Appeals Committee Members reviewed the recording sheet for GP Monitor which included the requirement for the general practitioner to write the name of the company and product in addition to completing other sections on their recollections of the representative visit. The issues raised by Boehringer with respect to the activities of Servier representatives are reinforced by the GP entries into GP Monitor.

MedScape heartwire article

Appeals Committee Members considered that the MedScape article was an opinion piece prepared by a journalist who is not a clinician expert in cardiovascular disease. It provides a collection of extracts from published studies and editorials. It is a

professional news service of WebMD and is not a peer reviewed publication. It was published in August 2008 and therefore does not take into account subsequent published articles. Although the article was originally published independently, its use by the Servier sales force was in a promotional context (particularly noting the title of the article relating to the efficacy of ARBs in cardiovascular disease). The Committee concluded that it agreed with the Code Committee's decision.

Dear Doctor Letter

While noting the discrepancies between Servier and Boehringer in relation to intercompany dialogue processes, the Committee was of the view that the concerns raised by Boehringer in relation to the activities of Servier representatives was the same as that raised in relation to the Dear Doctor letter. Although the letter was not identified at the time of the original complaint, it was evidence for the promotional claims being made by Servier regarding the effectiveness of ARBs in comparison with Coversyl in cardiovascular protection. The Appeals Committee considered that Servier should have been on notice that Boehringer's concerns were about these claims wherever they were being made. The subsequent identification of the Dear Doctor letter (and the Rahman article) was further evidence that the same or similar claims were being made. The Appeals Committee also agreed that Servier had had adequate opportunity to respond to these concerns in the intercompany dialogue and to the Code Committee.

The Committee accepted that the Al Khalaf et al meta-analysis was published in the peer-reviewed scientific literature. However, it was not convinced that the Al Khalaf et al meta-analysis represented the definitive position of the expert medical community or was fully representative of the body of evidence. The Committee accepted that there was evolving evidence of the relative efficacy of ARBs and ACEIs in offering protection in cardiovascular disease including in different sub-populations. This is also reflected by the apparently differing views of the EMEA and FDA. Members considered that this is a complex area and data relevant to the effectiveness of ACEIs and ARBs was not presented in a balanced

manner. Healthcare professionals should be provided with literature in a more balanced manner which discusses all evidence.

The Appeals Committee considered that the Dear Doctor letter was not balanced through its reference to the Al Khalaf et al meta-analysis as the supporting evidence for the claim concerning comparative efficacy of ARBs and ACEIs, which did not fully represent the body of evidence, and was therefore misleading. The Committee agreed with the decisions of the Code Committee.

Rahman article

The Appeals Committee noted Servier's assertion that Boehringer had not lodged a formal complaint specifically in relation to the Rahman piece and that the intercompany dialogue process had not been followed. Members were of the view that the Rahman item was a Servier promotional piece, which specifically conveyed the opinion of a healthcare professional on the issue of the differential efficacy of ACE Inhibitors and ARBs on prevention of cardiovascular events. Members considered that this item was within the scope of the concerns raised by Boehringer regarding Servier's promotion of ACE Inhibitors versus ARBs. The Appeals Committee considered that it was appropriate for the Code Committee to consider the Rahman article because it contained the same message with respect to the benefits of ACE Inhibitors over ARBs.

The Committee considered that the Rahman article conveyed the message that ARBs were less effective than ACEIs in preventing myocardial infarction and death, with reference to the Al Khalaf et al meta-analysis. For the same reasons as found regarding the Dear Doctor letter, the Committee considered that the Rahman article was not balanced, did not fully represent the body of evidence, and was therefore misleading.

The Appeals Committee concluded that it agreed with the Code Committee that the complaint concerned the manner in which Servier was promoting to healthcare professionals that ARBs were not as effective as ACEIs in reducing the risk of cardiovascular events and that these claims

were not able to be adequately substantiated. These claims were evident in a number of different items and representative conduct, supported in part by the GP Monitor information.

In a unanimous decision the Appeals Committee did not uphold the Servier appeal.

Sanctions

Having not upheld the appeal the Appeals Committee reviewed the sanctions imposed by the Code of Conduct Committee. The Committee discussed at length the requirement for a corrective letter and

corrective advertisement. In a majority decision the Committee determined that the requirement for a corrective letter to be sent to all general practitioners and cardiologists imposed by the Code Committee should remain.

In a unanimous decision the Committee determined that the requirement for a corrective advertisement should be removed.

In a unanimous decision the Committee determined that the requirement for Servier to pay a fine of \$100,000 should remain.

Olmetec 1031

Subject Company: Schering-Plough

Complainant: Healthcare Professional

Complaint

The complainant stated that he was concerned about the wording of the publication 'Hypertension News' which is ostensibly an advertisement only. The complainant did not like the whole flavour of the item, espousing the esteemed qualifications of the 'interviewee' and then linking his prescribing preference for the advertised product specifically. He questioned why the 'interviewee' did not endorse a class of drug rather than one member of the class. Thirdly, he sought clarification on the relationship between the 'interviewee' and Schering-Plough and what payment was made to him or was it pro-bono because there is no disclosure on the item.

Sections of the Code

The Secretariat had asked Schering-Plough to respond to the complaint with respect to the following Sections of the Code:

- 1.1 Responsibility
- 1.9 Medical ethics
- 1.10 Distinction or promotional material
- 3.1.4 Company commissioned article
- 10.8 Discredit to and reduction of confidence in the industry

Response

Schering-Plough responded that *Hypertension News* is a two page promotional piece compiled to provide information to healthcare professionals about Olmetec and Olmetec Plus, using actual case studies presented by cardiologists who have prescribed the products.

The case study includes a patient profile, treatment and outcome, with general questions relating to hypertension and the products posed to the cardiologist. The cardiologist's response is reviewed by Schering-Plough medical to ensure consistency with the Product Information.

Five *Hypertension News* pieces have been developed, of which three have been

distributed in the field. It is intended that two such newsletters be distributed every three months, using a different cardiologist in each newsletter in order to obtain a range of clinical management strategies used with the products.

The newsletter is personally distributed by Schering-Plough sales representatives who promote the products. The sales representatives explain to the healthcare professional that the purpose of the newsletter is to provide information relation to the treatment practices of the cardiologist in the context of using the products. The newsletter is not distributed by mail to a wider audience who may not have been detailed on the products.

Schering-Plough had the approval of the cardiologist to have his name and photograph in the newsletter. Schering-Plough paid the cardiologist for his time in preparing the case study, answering the questions raised in the newsletter and reviewing the final version of the newsletter.

Schering-Plough denied that the newsletter breached any section of the Code.

Code of Conduct Committee determination

- In a unanimous decision the Committee found a breach of Sections 1.1, 1.10 and 3.1.4 of the Code and no breach of Sections 1.9 and 10.8 of the Code.

Sanctions

- Withdraw the item found in breach and not use it again or in a manner that conveys the same or similar meaning
- Pay a fine of \$35,000

Consideration of the complaint

It was noted that the name of the company was included on the back page of the newsletter. However, it was also noted that the newsletter states "Proudly sponsored by Schering-Plough" which may give the impression that it is an independent publication sponsored by the company. Members were of the view that the presentation of 'independent opinion', which included unreferenced claims about Olmetec and Olmetec Plus, in a company

promotional item should not be used as an opportunity to avoid the requirements of Section 1 of the Code.

In reference to the title of the newsletter, 'Hypertension News', members were of the view that this was not balanced and was potentially misleading because the newsletter did not provide 'news' about hypertension or a discussion of a range of treatment options but was solely a promotional item for Olmetec and Olmetec Plus.

Members noted that the Code does not require a company to disclose whether a healthcare professional was paid for contributing their opinion on a topic. However a company promotional item, in this case the newsletter, should clearly identify on the front page that it is a company promotional item and not leave a reader in any doubt. Where it is clear to a reader that an item is promotional material, a healthcare professional may then weigh up the value and potential bias of the information provided therein.

In a unanimous decision the Committee found a breach of Sections 1.1, 1.10 and 3.1.4 of the Code because it was not sufficiently clear to a reader reviewing the front page that the newsletter was company promotional material. The information is not balanced because it purports to be providing news of a general nature but in fact only promotes the interests of the company with respect to their products. As the healthcare professional whose opinions were contained in the newsletter had provided his consent for information under his name to appear in the newsletter the Committee agreed that there was no breach of Section 1.9 of the Code.

The Committee also determined that there was no breach of Section 10.8 of the Code.

Sanctions

Having found several breaches of the Code the Committee determined that Schering-Plough should:

- Withdraw the item found in breach of the Code and not use it again or in a manner that conveys the same or similar meaning
- Pay a fine of \$35,000.

Merck Sharp & Dohme (Australia) Educational Event 1032

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Congress - European Association for the Study of Diabetes (EASD) delegate dinner	Entoca, Rome	Specialists	3 course dinner with alcoholic & non-alcoholic beverages	1,098	6	1,098

Subject Company: Merck Sharp & Dohme (MSD)

Complainant: Medicines Australia Monitoring Committee

Complaint

The Monitoring Committee had asked MSD to provide justification for the cost of the dinner held in association with the European Association for the Study of Diabetes (EASD).

Sections of the Code

Event alleged to be in breach of the following Sections of the Code:

- 6.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response

MSD stated that the primary objective of the (EASD) was the enhancement of medical knowledge and the quality use of medicines by healthcare professionals. The conference, which brought together 18,000 delegates, provided significant high quality educational content.

MSD asserted that the hospitality provided was secondary to the educational purpose of the event and was consistent with the professional standing of the delegates. It was chosen for its central location and pricing which was within the company's guidelines. Unfortunately due to the small number of attendees on the evening the

fixed price menu was not offered to the attendees. Instead, the attendees were required to order from the á la carte menu.

The exchange rates used in this response were the rates published by the Reserve Bank of Australia on 8 September 2008.

The hospitality in question was provided by the joint venture of MSD and Schering-Plough. MSD reported this event because it was organised through its headquarters, Merck & Co. The cost of the dinner including beverages was AUD\$233 per head (excluding VAT). With the exception of one bottle of wine (which was ordered without the knowledge or consent of the joint venture or its staff), this event would have been within company guidelines as the price would have been reduced by \$45 per person. Staff from the organising agency signed off and settled the bill on the evening without the concurrence of the joint venture staff.

As a result of this incident MSD has changed its internal processes and it no longer permits agencies to sign off bills on its behalf or on behalf of the joint venture. This process will also be communicated to Schering-Plough.

Code of Conduct Committee determination

In a unanimous decision the Committee found a breach of Sections 6.2 and 10.2 and no breach of Section 10.8 of the Code.

Sanction

- Pay a fine of \$40,000

Consideration of the complaint

Members were of the view that the onus is always on a company to exert control over its event. It was noted that MSD had subsequently changed its policy to not permit an agency to sign off on bills. The Committee considered that a company must make it clear to its agents and the venue that nothing should be debited to the company account without the permission of the company personnel present at the event.

The Committee considered that the food consumed at the dinner was not extravagant, however the inclusion of one very expensive bottle of wine (€160) was extravagant and would not withstand public scrutiny. MSD had conceded that the level

of expenditure went beyond its own guidelines. Some members expressed concern that a healthcare professional would take advantage of the company and order such an expensive bottle of wine without the permission of the company.

The Committee was particularly concerned that MSD or its agents had not exerted sufficient control over the hospitality provided at the event and in a unanimous found a breach of Sections 6.2 and 10.2 of the Code. In unanimous decision the Committee did not find a breach of Section 10.8 of the Code.

Sanction

Having found several breaches of the Code the Committee determined that MSD should:

- Pay a fine of \$40,000.

Merck Sharp & Dohme (Australia) Educational Event 1033

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
HIV - GP Clinic Journal Club.	GP Clinic, WA	HIV General Physicians	Light refreshments	213	2	213

Subject Company: Merck Sharp & Dohme (MSD)

Complainant: Medicines Australia Monitoring Committee

Complaint

The Monitoring Committee had requested an explanation for the cost of hospitality for a journal club meeting. MSD had advised the Monitoring Committee that the event was a representative detail meeting held over dinner. The Monitoring Committee referred the event to the Code Committee because it was concerned that that representative detailing was conducted over dinner and that the balance between education and hospitality at this event was not consistent with the Code.

Sections of the Code

Event alleged to be in breach of the following Sections of the Code:

- 6.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response

MSD had stated that the event was a detail meeting attended by two MSD representatives and two doctors working in a HIV medicine GP practice. MSD referred to the Explanatory Note to Section 4.11 of the Code which states that the provision of a meal (to healthcare professionals by company representatives) which complies with the requirements of Section 10 of the Code is not a breach of this section.

MSD asserted that the hospitality provided at the restaurant was modest, consistent with the professional standing of the

delegates and secondary in nature to detailed discussions between the attendees regarding the improvement of services to patients.

Code of Conduct and Appeals Committees determinations

In a unanimous decision the Committee found a breach of Sections 6.2 and 10.2 of the Code (Decision confirmed by the Appeals Committee)

In a majority decision the Committee found a breach of Section 10.8 of the Code. (Decision overturned by the Appeals Committee)

Sanction

- Pay a fine of \$50,000 (Fine reduced to \$10,000 by the Appeals Committee)

Code of Conduct Committee

Consideration of the complaint

The Committee noted that a number of errors had occurred in the reporting of this event. Firstly it had been as a journal club and secondly the cost of hospitality was incorrect. The actual cost of hospitality was \$53.30 per head. Members also noted that MSD had advised that it was providing additional training to representatives on educational event reporting requirements.

Members considered MSD's response that the reported meeting was a two way conversation to exchange information that could not have been conducted in a standard sales call and that the dinner timeslot was selected as this was the only time the two doctors could get together.

While the venue may be popular, casual and inexpensive, the Committee considered that if the issues stated by MSD were covered in this meeting, it had been inappropriately conducted in a public restaurant rather than in a private room. The Committee considered that the restaurant in question was an inappropriate venue for conducting a sales call or educational event.

Members were of the view that there was a lack of educational purpose in the meeting and therefore was in breach of the Code for the type of hospitality provided; if the meeting was actually a sales call, it was inappropriate with regard to the venue and that hospitality in association with a sales call should be minimal and no alcohol should be provided. The Committee was of the view that this event could not withstand public scrutiny and was wholly inconsistent with the standard that was expected of the industry.

In a unanimous decision the Committee found a breach of Sections 6.2 and 10.2 of the Code. In a majority decision the event brought the industry into disrepute and was in breach of Section 10.8 of the Code.

Sanction

Having found several breaches, including a breach of 10.8 of the Code, the Committee determined that MSD should:

- Pay a fine of \$50,000.

Appeals Committee

Appeal

MSD lodged an appeal stating that the educational merit of the meeting had not been adequately clarified to the Code committee. The primary purpose of the meeting was to discuss with HIV experts how MSD could help support the education of Western Australian physicians and health care workers in this highly specialised area of medicine. The majority of the meeting was devoted to discussion about data presented at a recent international conference and how important information from very recent scientific meetings could be communicated to interested physicians in a timely manner.

Consideration of the appeal

The following outlines the appeal presentation from MSD:

- MSD acknowledged that the initial reporting of the event was inaccurate. This was due to the representative, who was new to the company, being unfamiliar with the reporting procedures.
- To prevent any further errors MSD has implemented the following actions:
 - Educational event reporting training
 - Revisions to documents used for reporting
- Education of doctors in HIV medicine is critical. HIV medicine is a complex area. People with HIV have multiple disease conditions, require multiple medicines, and there are many drug-drug interactions. The successful management of patients with HIV requires HCPs to be well informed of recent advances and how the various treatment regimens should be used in clinical practice.
- International and local scientific meetings are important for the latest information on treatment regimens
- Physicians consider specialist pharma representatives *“an invaluable tool in the practice of evidence based medicine”*.
- The purpose of the meeting subject to complaint was to discuss the latest information from clinical trials and how this relates to clinical practice. The educational needs of WA HIV specialists were discussed. The content and purpose of the meeting was educational.
- The venue afforded privacy to the representatives and physicians for the discussion. The group was seated in a part of the restaurant away from other patrons.
- The physicians use the venue independent of industry involvement and considered it to be conducive to education.
- In a letter from the physicians who attended the meeting they noted that the time when they can see company representatives together is limited to cross over times at the surgery. The most convenient time to them is after the work day when both are present in the practice. Consulting finishes at 7.00pm

and it is therefore common for the physicians to suggest a representative visit after this time.

- Having both physicians together enabled greater input and a broader clinical discussion.
- The cost of the hospitality was modest and appropriate to the professional standing of the attendees.
- Based on the further clarification provided of the educational event, MSD requested that the Appeals Committee uphold this appeal and dismiss the findings of the Code of Conduct Committee.

In response to a question from the Committee regarding the manner in which MSD had requested the doctors' letter to the Committee, MSD advised that it had requested that the MSD representative obtain advice regarding the privacy afforded by the venue and the educational value of the meeting.

In response to a question from the Committee seeking clarification about why the description of the meeting had changed from the original report to being characterised as a detail meeting and now an educational meeting, MSD explained that the representative who reported the event was new to the company. She had originally mis-recorded the event as a journal club and later characterised the event as a detail meeting. However, there was no detailing in the meeting. The discussion included the educational requirements of WA HIV physicians, which had been described in the response to the Code Committee. As a result of the meeting two educational meetings had been arranged in WA with over 30 attendees, demonstrating that the interest in education was not limited to the two doctors who attended the event in question.

The MSD representatives left the meeting following this presentation.

Members were concerned that there had been three different descriptions provided for the purpose of this meeting. While accepting that a new representative may have initially incorrectly reported the event as a journal club, MSD should have ensured that full and correct responses were provided to the

Monitoring and Code Committees. It seemed to the Appeals Committee that there was a shifting of position each time a Committee sought further information about the event.

The Committee noted that MSD had stated that papers from a recent international conference and recent clinical studies were discussed at the meeting and how MSD could assist to make the educational content from an upcoming HIV conference in Brisbane available to interested WA physicians who are unable to attend the conference. However, MSD had not provided any documentary evidence to the Code Committee or Appeals Committee that would support MSD's explanation, such as the papers discussed with the physicians or the program that was developed as a result of this meeting. Some members commented that if there was a planning meeting on what education would be most valuable for all HIV physicians in WA there would be consultation with a wider group than with two individual physicians.

The Committee discussed the balance between the hospitality provided, which was relatively modest at \$53.00 per head, and the educational content or purpose. It was noted that the Code requires hospitality to be secondary to the educational purpose. The Committee was not persuaded that the educational content of the meeting was sufficient to satisfy the test that the hospitality was secondary to the education. Members considered that the meeting was more characteristic of a detailing meeting because it lacked any evidence of formality such as an agenda or other documentation to indicate the educational purpose. Whilst the cost of the meal was modest, the Committee considered it was not consistent with the Code to provide a meal and alcoholic beverages to health professionals in a restaurant for a meeting with sales representatives with minimal education provided.

The Committee took into consideration the letter from the two doctors who had attended the meeting. Members were not persuaded that the character of the meeting was other than a normal representative visit. The Committee was unanimous in its view that the appeal in relation to Sections 6.2 and 10.2 should not be upheld as MSD had

not provided any evidence to support its contention that the educational content of the meeting was proportionate to the hospitality provided.

The Committee considered that the meeting, whilst in breach of the Code, would not bring the industry into disrepute and upheld the appeal with respect to Section 10.8 of the Code.

Sanctions

Having upheld one aspect of the appeal the Appeals Committee reviewed the sanctions imposed by the Code of Conduct Committee. Having overturned the finding of a breach of 10.8 of the Code, which is regarded as a serious breach of the Code the Appeals Committee determined that the fine should be reduced to \$10,000.

Innovex Educational Event 1034

Description of function including duration of educational content delivered	Venue	Professional status of attendees	Hospitality provided	Total cost of hospitality	Number of attendees	Total cost of function
Pletal Launch Meeting with an International Specialist presenting a Symposium on Intermittent Claudication. Scientific Presentation on the Diagnosis and Treatment of Patients with Peripheral Arterial Disease. Peripheral Arterial Disease Case Studies. Peripheral Arterial Disease and Diabetes epidemiology and current management guidelines. New Advances in the treatment of Intermittent Claudication. 7.5 hours of educational content.	The Sheraton on the Park, Sydney, NSW	Cardiologists, Endocrinologists, Vascular Surgeons & Physicians, General Practitioners	Friday: Meal with alcohol/non alcoholic drinks provided. Accommodation for Regional and interstate delegates. Saturday: Meals with non alcoholic drinks provided.	\$31,534.55	76	\$98,170.58 (includes Honorarium, AV, room hire, international speaker and local speaker travel & accommodation)

Subject Company: Innovex (known as Pharmalink)

Complainant: Medicines Australia Monitoring Committee

Complaint

The Monitoring Committee had asked Innovex to provide justification for the cost of the dinner associated with the educational event.

Sections of the Code

Event alleged to be in breach of the following Sections of the Code:

- 6.2 Hospitality
- 10.2 Hospitality
- 10.8 Discredit to and reduction of confidence in the industry

Response

Pharmalink had stated that the intention of the launch meeting was to conduct it in a clinically and ethically responsible manner, in a venue which has been used by the industry many times over the years. The speakers had a completely free hand in the development and delivery of their respective presentations. The format and the

environment of the meeting had a significant clinical focus and was facilitated by a clinician and not one of the Pharmalink team.

Pharmalink asserted that the hospitality was modest and appropriate to the needs of the attendees. The selection of the venue was not to impress doctors but to provide a functional location, which was readily accessible by local, regional and interstate delegates.

Pharmalink denied that the educational event had breached the Code.

Code of Conduct Committee determination

In a unanimous decision the Committee found a breach of Sections 6.2, 6.8, 10.2, 10.3 and 10.8 of the Code.

Sanction

- Pay a fine of \$50,000

Consideration of the complaint

The Committee noted that there was a difference between the reported duration of education (7.5 hours) and the actual hours of education (4 hours) excluding meal

breaks. The educational component is the actual hours of education, not simply the duration of the event. Members acknowledged that while there may have been discussion over dinner, this is not regarded as part of the formal educational component.

Members did not question the ethics or veracity of the presenters or education. However members questioned whether the event needed to be held over two days given the educational component was only 4 hours over the two days. The event could have been held from late morning to late afternoon on the Saturday, which would not have required accommodation for many of the delegates. For example ACT delegates could have flown to Sydney on the morning of the event. The Guidelines that accompany the Code provide guidance in relation to the appropriate balance between hours of education and provision of hospitality, accommodation and travel. The general guidance is that a minimum of 6 hours education is required to justify the provision

of overnight accommodation, depending on the origin of the attendees.

The Committee was of the view that the dinner which cost \$168 per delegate was extravagant and would not withstand public scrutiny. The Committee referred to previous decisions in relation to the balance between hospitality and educational content for events held in Australia and unanimously agreed that the event was in breach of Sections 6.2 and 10.2 of the Code.

Having found that the provision of overnight accommodation for all interstate and regional delegates and that the cost of hospitality was disproportionate to the education provided the Committee also found a breach of Section 10.8 of the Code.

Sanction

Having found several breaches, including a breach of Section 10.8 of the Code, the Committee determined that Pharmalink should:

- Pay a fine of \$50,000.

Ganfort 1035

Subject Company: Allergan Australia Pty Ltd (Allergan)

Complainant: Alcon Australia (Alcon)

Product: Ganfort

Complaint

Alcon alleged that the Allergan promotional piece '*When Monotherapy is not enough (PB4023/05.09)*' contained claims that are inaccurate, false and/or misleading.

Part 1: Alcon stated that the dosage claims '*once a day*' and '*once daily*' are not consistent with the Dosage and Administration section in the Ganfort approved Product Information (PI).

Part 2: Alcon alleged that the cited reference material does not support the Allergan claim '*Ganfort 0.3/5 once a day as effective as the non-fixed combination of bimatoprost and timolol*', which is therefore false and misleading. This major claim, which also could not be supported by the Ganfort PI, could not be supported by unequivocal evidence.

Alleged breach 3: Alcon alleged that the comparative claim '*When a fixed combination is needed go straight to Ganfort 0.3/5 One drop - once daily*' was inaccurate and misleading.

Sections of the Code

Materials alleged to be in breach of the following Sections of the Code:

- 1.1 Responsibility
- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 1.7 Comparative Statements

Response

Part 1: Allergan responded that the TGA approved dosage regimen is 'once daily'. Further, the full PI is reproduced within the promotional material so a healthcare professional can read the entire dosage instructions. The dosage claim 'once daily', with additional information contained in the PI, is an accepted style of advertisement for prescription medicines. The ability to dose an eye drop either morning or evening

compared to just morning does not infer an advantage for the former.

Allergan denied that the claim is misleading, false or inaccurate or in breach of Sections 1.1, 1.3 or 1.7 of the Code of Conduct.

Part 2: Allergan responded that the clinical trials section of the approved PI includes the non-inferiority study included in the marketing application. Allergan asserted it is therefore appropriate to include the PI as a reference for the claim.

Allergan further stated that the study by Hommer et al, 2007 had been accepted by the European Medicines Agency (EMA), the TGA and the Pharmaceutical Benefits Advisory Committee (PBAC) and had been published in a peer reviewed journal.

Allergan denied that the claim was in breach of Sections 1.1, 1.2.2 or 1.3 of the Code.

Allergan asserted that this complaint was frivolous and vexatious and asked the Committee to consider whether Alcon was in breach of Section 12.3 of the Code.

Part 3: Allergan responded that the claim '*When a fixed combination is needed go straight to Ganfort 0.3/5 One drop - once daily*', is a call to action for healthcare professionals to consider Ganfort as part of their treatment regimen, when a fixed combination is required. Allergan stated that the claim is consistent with the approved use of Ganfort and the PBS listing and disagreed that it implied by-passing all other combination products. Allergan stated that it had agreed during inter-company dialogue not to use the claim in future.

Code of Conduct Committee determination

- Part 1 - in a unanimous decision no breach of Sections 1.1, 1.3 and 1.7 of the Code
- Part 2 - in a majority decision no breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code
- Part 3 - in a unanimous decision no breach of Sections 1.1, 1.2.2 and 1.7 of the Code

Alleged breach of Section 12.3 by Alcon -
The Committee did not find any cause to ask Alcon to respond to this allegation.

Consideration of the complaint

Part 1 - Once a day

The Committee noted the dosage stated in the Ganfort Product Information – “one drop of Ganfort in the affected eye(s) once daily, in the morning”.

Members were of the view that the ‘once daily’ claim was consistent with the approved dosage for Ganfort and with similar dose-related claims for prescription medicines. The claim appeared on printed promotional material that included the full Product Information. The Committee concluded that a health professional would not be misled by the claim and in a unanimous decision did not find a breach of Sections 1.1, 1.3 or 1.7 of the Code.

Part 2 - Ganfort 0.3/5 once a day as effective as the non-fixed combination of bimatoprost and timolol

Members noted that the accepted criteria to show non-inferiority in studies in glaucoma or ocular hypertension patients is that the difference in intraocular pressure (IOP) between the fixed combination product and the individual components administered concomitantly should be not more than 1.5mmHg at each time point. The Committee also noted that these criteria have been accepted by the European Medicines Agency (EMA), the Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Advisory Committee (PBAC).

While some members commented that the relevant supporting study is a Phase 2 study, which is not referred to in the Product Information, it had been submitted to the TGA in the Ganfort marketing application. In reviewing the Hommer et al, 2007 paper members agreed that it was adequate to support the claim.

In a majority decision the Committee did not find a breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code.

The Committee noted that Allergan had acknowledged an error in the referencing for this claim on the promotional item and that this would be corrected. The Committee urged Allergan to action this correction promptly.

Part 3 - When a fixed combination is needed go straight to Ganfort 0.3/5 One drop - once daily

Based on the materials reviewed by the Committee in the complaint and response documents, members understood that the approved indications for Ganfort, and the PBS restrictions, are for patients who are not adequately controlled with monotherapy with either timolol maleate eye drops (0.5%) or prostaglandin or prostamide analogue. Members did not consider that the claim implied that Ganfort was the only first line fixed combination eye drop available to prescribers. The Committee considered that a prescriber would be aware of the indications and PBS restrictions for Ganfort. The Committee noted that Allergan had agreed during intercompany dialogue not to use this claim in future.

In a unanimous decision the Committee did not find a breach of Sections 1.1, 1.2.2 and 1.7 of the Code.

Pentasa 1036

Subject Company: Ferring

Complainant: Healthcare Professional

Complaint

The complainant alleged that the advertisement states that Pentasa is for inflammatory bowel disease which incorporates Crohn's disease and ulcerative colitis. Pentasa enemas and suppositories are only registered for the treatment of ulcerative colitis. It was alleged that the advertisement is therefore misleading and ambiguous.

Sections of the Code

The Secretariat asked Ferring to respond to the complaint with regard to the following Sections of the Code:

- 1.1 Responsibility
- 1.3 False and misleading claims
- 1.3.1 Unapproved products and indications

Response

Ferring stated that the advertisement had been assessed and approved as a short advertisement under Section 3.1.3 of the Code. As required in this section there were no claims only a list of all Pentasa formulations. The approved indications for the various products in the Pentasa range are all sub-sets of the therapeutic class 'Inflammatory Bowel Disease' (IBD).

Ferring denied that the advertisement was in breach of the Code.

Code of Conduct Committee determination

- In a unanimous decision no breach of Sections 1.1, 1.3 or 1.3.1 of the Code was found.

Consideration of the complaint

The Committee was of the view that healthcare professionals would understand that not all formulations of medicines for IBD are appropriate for all sub-sets of IBD. Members noted that Pentasa tablets, sachets, suppositories and enemas are only available on the PBS as either a 'restricted benefit' or 'authority required'. A healthcare professional would be sufficiently informed that Pentasa enemas are only registered to

treat ulcerative proctosigmoiditis and/or left sided ulcerative colitis, the suppositories registered for the treatment of ulcerative proctitis, and the tablets and sachets are for the treatment of mild to moderate ulcerative colitis and Crohn's disease. The Committee did not agree that the statement "For Inflammatory Bowel Disease" meant that all dosage forms were approved for all forms of IBD. The term 'inflammatory bowel disease' is a recognised umbrella term that is used in the PBS Schedule to encompass medicines approved for different subsets of IBD.

The Committee was of the view that the advertisement did not include any claims or state that all formulations were to treat all sub-sets of IBD and healthcare professionals would be well informed of the appropriate route of administration for different forms of IBD. The Committee unanimously determined that there was no breach of Sections 1.1, 1.3 of 1.3.1 of the Code.