

Medicines Australia
Code of Conduct

Outcomes of Monitoring Committee Review 2010/2011



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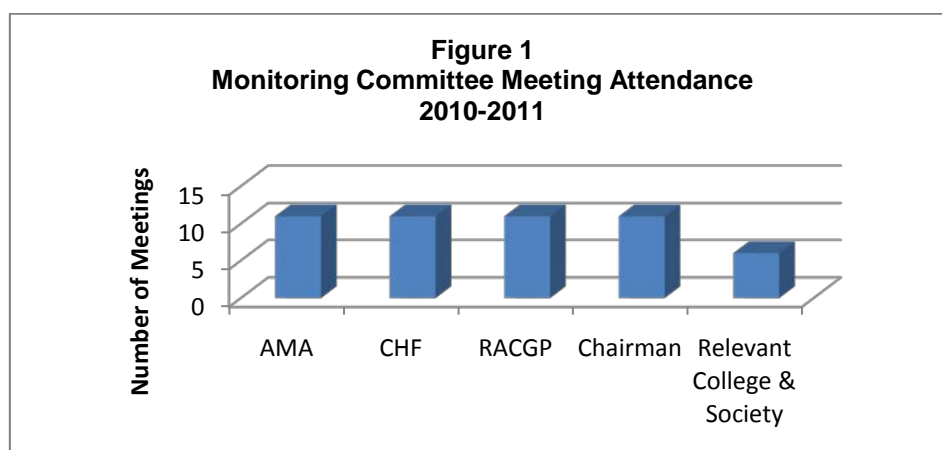
Monitoring Committee

Monitoring Committee meetings are held regularly on the third Monday of each month. A list of meeting dates is available from the Medicines Australia website at:

<http://medicinesaustralia.com.au/code-of-conduct/code-and-monitoring-meeting-dates/>

Table 1 Monitoring Committee Members	
Organisation	Nominee/s
Full Members (Voting rights)	
Chairman (Selected from a panel of three consultants with industry experience in marketing and knowledge of the Code of Conduct)	Mr Russell Edwards Dr Mike Wyer (to April 2011) Ms Helen Maxwell-Wright (2011) Mr Wayne Strong (2011)
Australian Medical Association (AMA)	Dr Robyn Napier
Royal Australian College of General Practitioners (RACGP)	Dr Sue Whicker
Consumers Health Forum (Two CHF representatives to participate in reviews where activities are directed at the general public or patients)	Ms Sheila Rimmer AM (2010) Mr Henry Ko Ms Patricia Greenway (Alternate) Mr Brian Stafford (Alternate)
The College and/or Society associated with the therapeutic class of the product(s) subject to review	Various, depending on the materials or conduct being reviewed
Medicines Australia Member Company Medical/Scientific Director	Various, depending on the materials or conduct being reviewed
Medicines Australia Member Company Marketing Director	Various, depending on the materials or conduct being reviewed
Medicines Australia Advisors (No voting rights)	
Secretary, Code of Conduct Committee	Mrs Sophie Hibburd
Medicines Australia Officer responsible for Ethical Conduct	Ms Deborah Monk

The Committee held 11 meetings in 2010-2011. As shown in Figure 1, all permanent members of the Monitoring Committee attended the scheduled meetings. Two consumer representatives participated in the reviews of activities directed at the general public.



The aims of the Monitoring Committee are to encourage compliance with the Code, provide advice on compliance where necessary, obtain and publish statistical data on the degree of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code.

The Monitoring Committee may review materials across a range of therapeutic areas and types of activities. If the Committee has concerns about an activity or material, or wishes to seek further information, Committee members must direct the Secretariat to write to the company identifying the issues of concern and what additional information should be provided to the Committee. After the review of this additional information, if the Committee still has significant concerns, a formal complaint may be lodged with the Code Committee for a determination. The Monitoring Committee cannot find a company in breach of the Code.

The therapeutic classes for the Monitoring Committee reviews are derived from the Therapeutic Class Index used by MIMS Australia:

- Alimentary System
- Cardiovascular System
- Central Nervous System
- Analgesia
- Musculoskeletal System
- Endocrine and Metabolic Disorders
- Genitourinary System
- Infections and Infestations
- Neoplastic Disorders
- Immunology
- Respiratory System
- Ear, Nose and Oropharynx
- Eye
- Skin
- Surgical Preparations
- Contraceptive Agents

In each financial year the Monitoring Committee reviews three types of promotional material (for example advertisements, printed promotional material, brand name reminders) across three different therapeutic classes (for example alimentary system, eye and contraceptive agents); and three different types of conduct covered by the Code across all therapeutic classes (for example websites, education events and starter packs).

Table 2 provides a summary of the Monitoring Committee reviews of materials and activities over the past six years. Table 3 provides a snapshot of the materials and activities reviewed by the Monitoring Committee in 2010-2011.

Educational Event Reports

In accordance with Section 28.2.2 of Edition 16 of the Code of Conduct, the Monitoring Committee commenced its annual review of educational event reports. The Chairman randomly selected three months from the preceding 12 month review period, and in May 2011 the Monitoring Committee commenced this review with a subsequent meeting held in June 2011. The Monitoring Committee reviewed reports from the months July 2010, November 2010 and March 2011 which included over 9,000 events for review, from 38 companies. At the time of this report, the Monitoring Committee has sought further information from 25 companies regarding events held during the reviewed months. The Monitoring Committee anticipates the completion of this review at the end of August 2011, with any events which may be in breach of the Code of Conduct referred to the September 2011 Code of Conduct Committee meeting for its decision.

Table 2
Summary of materials and activities reviewed by the Monitoring Committee
2005-2011

	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011
Alimentary System						
Cardiovascular System						
Central Nervous System						
Analgesia						
Musculoskeletal System						
Endocrine & Metabolic Disorders						
Genitourinary System						
Infections & Infestations						
Neoplastic Disorders						
Immunology						
Respiratory System						
Allergic Disorders						
Ear, Nose & Oropharynx						
Eye						
Skin						
Surgical Preparations						
Contraceptive Agents						
Reviews across all therapeutic classes	Invitations to educational meetings Websites Patient education	Invitations to educational meetings Patient support programs Brand name reminders Websites	Invitations to educational meetings Patient websites Corporate websites Competitions Prescribing software Educational event reports	Company websites for healthcare professionals Educational event reports Product familiarisation programs Starter packs	Educational event reports x 2 Media releases Disease education activities Brand Name Reminders	Educational Event Reports Company controlled Websites Market Research with Healthcare Professionals Prescribing Software

Table 3				
Summary of materials and activities reviewed by the Monitoring Committee in 2010-2011				
Therapeutic Class	Types of material or activity subject to review	Number of companies	Number of items	Number of meetings to undertake review
Endocrine and Metabolic Disorders	Advertisements	11	110	1
Musculoskeletal	Competitions	5	18	1
Skin	Printed Advertisements	2	4	0.5
All therapeutic classes	General Company Websites	29	29	1.5
All therapeutic classes	Market Research with healthcare professionals	26	150	2
Analgesia	Printed promotional material	8	30	1
Neoplastic	Advertisements	9	25	1
All therapeutic classes	Prescribing Software	5	5	1
Contraceptive Agents	Printed Promotional Material	3	20	1
Nose and Oropharynx & Eye	Printed Promotional Material	6	31	1
TOTAL			402	11

Referrals to the Code of Conduct Committee

The Monitoring Committee may refer any material or activity to the Code of Conduct Committee for review if it considers there is a potential breach of the Code of Conduct.

From its reviews in 2010-2011 the Monitoring Committee referred promotional material and an advertisement from Ipsen and Bayer pertaining to the Endocrine and Metabolic Disorders Review to the Code of Conduct Committee for determination. The outcomes of these complaints can be found on page 26 and 24 of this report respectively.

Endocrine and Metabolic Disorders

The Committee reviewed 110 advertisements from member companies with products in this therapeutic area.

Items were provided by the following companies:

- Bayer
- Eli Lilly Australia
- GSK
- Ipsen
- Janssen
- MSD
- Novartis
- Novo Nordisk
- Roche
- Sanofi-aventis
- Servier

The Monitoring Committee did not identify any general issues across the advertisements. The Committee sought feedback in relation to items from Bayer, Ipsen and MSD. Following the review of company responses, the Committee determined that promotional material and an advertisement submitted by Ipsen and Bayer should be forwarded to the Code of Conduct Committee for a determination on a potential breaches of the Code. The outcomes of these complaints can be found on page 26 and 24 of this report respectively.

Musculoskeletal System

The Monitoring Committee reviewed 18 competitions in the musculoskeletal system therapeutic class.

Submissions were received from the following companies:

- Abbott
- Boehringer Ingelheim
- Ipsen
- MSD
- Pfizer

The Monitoring Committee did not identify any general issues across the competitions. The Committee sought feedback from Abbott relating to educational content and prize value. Following the review of company responses, the Committee determined that no competitions should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Skin

The Monitoring Committee reviewed 4 advertisements.

Items of printed promotional material were received from the following companies:

- CSL
- Sanofi-aventis

The Monitoring Committee did not identify any general issues across the advertisements. The Committee sought feedback from CSL regarding two items submitted. Following the review of CSL's

response, the Committee determined that no items of promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Corporate Websites

The Monitoring Committee reviewed 29 corporate websites from the following companies:

- Abbott Australasia
- Abbott Products (Solvay)
- Alcon
- Allergan
- Amgen
- AstraZeneca
- Baxter
- Bayer
- Biogen Idec
- BMS
- Celgene
- CSL
- Eli Lilly
- GlaxoSmithKline Australia
- MSD
- Novartis
- Pfizer
- Roche
- Sanofi-aventis
- Invida
- Ipsen
- Janssen
- Lundbeck
- Merck Serono
- Norgine
- Novo Nordisk
- Nycomed
- Shire
- Smith & Nephew
- UCB

The Monitoring Committee did not identify any general issues across the promotional material. The Committee sought feedback in relation to 15 websites. The Committee noted the considerable improvement in corporate websites when compared to those reviewed in 2008-2009.

Following the review of company responses, the Committee determined that no items of websites should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Market Research with Healthcare Professionals

The Monitoring Committee reviewed 150 items of market research from the following companies:

- Abbott Australasia
- Abbott Products
- Allergan
- Amgen
- AstraZeneca
- Baxter
- Bayer
- Biogen Idec
- BMS
- Boehringer Ingelheim
- Celgene
- CSL
- Eli Lilly
- Gilead
- GSK
- iNova
- Janssen
- Merck Serono
- MSD
- Mundipharma
- Nycomed
- Pfizer
- Roche
- Sanofi-aventis
- Servier
- Shire
- UCB

The Monitoring Committee sought feedback from Abbott Products, AstraZeneca, and Roche. Following the review of company responses, the Committee determined that no items of market research should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Analgesia

The Monitoring Committee reviewed 30 items of printed promotional material from the following companies:

- AstraZeneca
- BMS
- CSL
- Janssen
- iNova
- Mundipharma
- Pfizer
- Sanofi-aventis

The Monitoring Committee sought feedback on from BMS, CSL, iNova and Janssen. Following the review of company responses, the Committee determined that none of the printed promotional material should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code

Neoplastic

The Monitoring Committee reviewed 25 advertisements from the following companies:

- AstraZeneca
- Celgene
- GSK
- Ipsen
- Janssen
- Novartis
- Pfizer
- Sanofi-aventis
- Shire

The Monitoring Committee sought feedback from AstraZeneca, Celgene, Ipsen, Novartis, Pfizer, Sanofi-aventis and Shire.

Following the review of company responses, the Committee determined that no advertisements should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Prescribing Software

The Monitoring Committee reviewed 5 pop-up communications published in prescribing software from the following companies:

- Alphapharm
- Eli Lilly
- MSD
- Pfizer
- Sanofi-aventis

The Monitoring Committee did not identify any general issues with the pop-ups in the prescribing software. During the course of this review, the Monitoring Committee also viewed a pop-up reminder from Alphapharm. As Alphapharm is not a member of Medicines Australia, the Committee referred comments regarding the material to the Generic Medicines Industry Association for their consideration.

The Committee determined that no pop-up communication should be forwarded to the Code of Conduct Committee for a determination on a potential breach of the Code.

Contraceptive Agents

The Committee reviewed 20 items of printed promotional material from the following companies.

- Bayer
- MSD
- Pfizer

The Committee sought clarification from all three companies. Responses to these requests are due to be reviewed at the July 2011 Monitoring Committee meeting.

Eye, Ear, Nose and Oropharynx

The Committee reviewed 31 items of printed promotional material from the following companies:

- | | |
|------------------------|------------------|
| ▪ Alcon | ▪ iNova |
| ▪ Allergan | ▪ MSD |
| ▪ AstraZeneca | ▪ Norgine |
| ▪ Bayer | ▪ Novartis |
| ▪ Boehringer Ingelheim | ▪ Pfizer |
| ▪ GSK | ▪ Sanofi-aventis |

The Committee sought clarification from Alcon, Allergan, GSK and Pfizer. Responses to these requests are due to be reviewed at the August 2011 Monitoring Committee meeting.

Complaint determinations

This section of the Monitoring Committee Annual Report provides the decisions and reasons for decisions of all complaints that were referred by the Monitoring Committee to the Code of Conduct Committee and finalised in 2010-2011. Table 4 provides a summary of each complaint finalised in 2010-2011. To view the detailed reasons for the decision please click on the complaint number in column 1.

The Monitoring Committee referred 4 complaints relating to media releases, 3 complaints relating to disease education activities or materials and 1 complaint relating to an educational event to the Code Committee following reviews of these activities in 2009-2010. The 4 complaints relating to media releases were considered under Edition 15 of the Code, the relevant Code at the time the media releases were issued. All other complaints referred by the Monitoring Committee and finalised in 2010-2011 were considered under Edition 16 of the Code.

The Monitoring Committee referred two complaints relating to an advertisement and promotional material following its review of advertisements and promotional material in the Endocrine and Metabolic Disorders therapeutic class in 2010-2011.

Table 4 Complaints finalised in 2010-2011						
No.	Subject Company	Material or information subject to complaint	Product	Complainant	Outcomes	Sanction
1049	AstraZeneca	Media Release	Nexium	Monitoring Committee	Edition 15: Breach 9.2 No breach 9.10	<ul style="list-style-type: none"> ▪ Do not distribute the media release again in the same or similar form ▪ Pay a fine of \$75,000
1050	Janssen-Cilag	Media Release	Concerta	Monitoring Committee	Edition 15: Breach 9.2 No breach 9.10	<ul style="list-style-type: none"> ▪ Do not distribute the media release again ▪ Pay a fine of \$15,000
1051	Roche Products	Media Release	MabThera	Monitoring Committee	Edition 15: Breach 9.2.1 Breach 9.2.3 No breach 9.10	<ul style="list-style-type: none"> ▪ Pay a fine of \$30,000
1052	Sanofi-aventis	Media Release	Actonel	Monitoring Committee	Edition 15: Breach 9.2 No breach 9.10	<ul style="list-style-type: none"> ▪ Do not distribute the media release again ▪ Pay a fine of \$20,000

Table 4
Complaints finalised in 2010-2011

No.	Subject Company	Material or information subject to complaint	Product	Complainant	Outcomes	Sanction
1054	Alcon Laboratories Australia	Disease education booklet	Not applicable	Monitoring Committee	No breach 12.7.2 Breach 12.7.5 No breach 16	<ul style="list-style-type: none"> ▪ Withdraw the Glaucoma Information booklet and not use it again in the same or similar form ▪ Pay a fine of \$5,000
1056	Novartis Australia	DVD	Clozaril	Monitoring Committee	No breach 12.6 No breach 16	<ul style="list-style-type: none"> ▪ Not applicable
1057	Roche Products	Website	Pegasys RBV	Monitoring Committee	No breach 1.3 No breach 12.7 No breach 12.7.4	<ul style="list-style-type: none"> ▪ Not applicable
1058	AstraZeneca	Educational Event	N/A	Monitoring Committee	Breach 9.3 Breach 9.4.3 No breach 9.13	<ul style="list-style-type: none"> ▪ Pay a fine of \$15,000
1068	Bayer Australia	Promotional material	Testogel and Reandron 1000	Monitoring Committee	No breach of Section 1.3 or 1.7	<ul style="list-style-type: none"> ▪ Not applicable
1071	Ipsen	Advertisement	Somatuline Autogel	Monitoring Committee	No breach of 1.2, 1.2.2 and 1.3	<ul style="list-style-type: none"> ▪ Not applicable

AstraZeneca Media Release – 1049

Subject Company: AstraZeneca

Complainant: Monitoring Committee

Product: Nexium

Complaint

The Monitoring Committee was of the view that the AstraZeneca media release relating to Nexium was promoting the product to the general public and that the indications for Nexium stated in the media release were not fully consistent with the newly approved indications.

Sections of the Code

Media release alleged to be in breach of the following Sections of Edition 15 of the Code:

- 9.2 Product Specific Media Statements
- 10.8 Discredit to and reduction of confidence in the Industry

Response

AstraZeneca strongly disagreed that the Media Release was promotional or linked Nexium with the reduction of GI risks from aspirin. AstraZeneca's intention for the media release was educational – to announce the new indication for Nexium for the prevention of gastric/duodenal ulcer re-bleeding and to inform the public of the known risks associated with the prolonged use of low dose aspirin. AstraZeneca also argued that the messages that were picked up by the media could not be construed as bringing discredit to the industry.

Code Committee decision

- By a unanimous decision, breach of Section 9.2
- By a majority decision, no breach of Section 9.10

Sanction

- Do not distribute the media release again in the same or similar form to that found in breach of the Code
- Pay a fine of \$75,000

Consideration of the complaint

The Committee noted that the media release was issued following TGA approval of a new indication for the intravenous (IV) and tablet forms of Nexium to be used following therapeutic gastroscopy for acute, bleeding gastric or duodenal ulcers to prevent re-bleeding. In this indication the oral form of Nexium would follow IV treatment. However, the media release on 9 November 2009 focussed on the use of proton pump inhibitors (PPI) to reduce the risk of peptic ulcers in patients taking low dose aspirin, which is not a new indication for Nexium.

The Committee agreed with the Monitoring Committee that the media release was promoting a prescription-only medicine to the general public. The media release referred to the use of PPIs to reduce the risk of peptic ulcers in people taking aspirin and specifically identified Nexium as a PPI. The media release encouraged consumers to talk to their doctor about minimising the risk of peptic ulcers if they are taking aspirin, and the included reference to Nexium made a link to a specific PPI, which may have the effect of encouraging members of the public to seek a prescription for Nexium if they are taking aspirin. The Committee considered that AstraZeneca had used the opportunity of the approval of a new indication for Nexium oral and IV to promote a different use of their product – for the prevention of peptic ulcers in people taking non-steroidal anti-inflammatory medicines, such as aspirin.

The Committee reviewed the new approved indication for Nexium oral and IV and agreed with the Monitoring Committee that the new approved indication had not been adequately communicated in the body of the media release. The media release stated that Nexium was approved for use in adults with a peptic ulcer to prevent re-bleeding whereas the actual indication for prevention of re-bleeding

is only following therapeutic endoscopy. The Committee considered that this was an important qualification of the indication which had not been accurately reflected in the media release. Whilst the Minimum Product Information for Nexium oral and Nexium IV had been attached to the media release, the indication should have been fully and accurately stated in the body of the release. The Committee did not accept AstraZeneca's explanation that the indication had been abbreviated to avoid formal or technical terms. The Committee considered that the media release gave a misleading impression of the approved use of Nexium.

The Committee unanimously determined that the AstraZeneca media release was not accurate or balanced and included statements that could be considered to be promotion of a prescription-only medicine to the general public. In a unanimous decision a breach of Section 9.2.1 was found.

The Committee discussed whether the media release would bring the industry into disrepute. In a majority decision the Committee determined that no breach of Section 9.10 should be found.

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

Sanction

The Committee noted that the media release was an activity that had been concluded. The Committee determined that AstraZeneca should:

- Not distribute the media release again in the same or similar form to that found in breach of the Code
- Pay a fine of \$75,000

Janssen-Cilag Media Release – 1050

Subject Company: Janssen-Cilag

Complainant: Monitoring Committee

Product: Concerta

Complaint

The Monitoring Committee was of the view that by issuing two product specific media releases to the general public about the PBS availability of Concerta, on 1 October and 18 December 2009, Janssen Cilag was potentially in breach of Section 9.2 of the Medicines Australia Code of Conduct.

Sections of the Code

Media Releases alleged to be in breach of the following Sections of Edition 15 of the Code:

- 9.2 Product Specific Media Statements
- 9.10 Discredit to and reduction of confidence in the Industry

Response

Janssen-Cilag responded that it had not breached the Code and that the information contained within the media release was appropriate, non-promotional and educational in tone and substance. The first media release was issued on the day of the Asian tsunami, and all media engagement was therefore halted. The second media release in December was issued following Janssen-Cilag's analysis that there was a very small risk of the general public hearing the same message twice. It was in the public interest to be informed of the PBS listing changes for Concerta.

Code Committee decision

- By a unanimous decision, breach of Section 9.2
- By a unanimous decision, no breach of Section 9.10

Sanction

- Do not distribute the media release again
- Pay a fine of \$15,000

Consideration of the complaint

The Committee noted that two media releases had been issued by Janssen-Cilag – one on 1 October 2009 and the second on 18 December 2009. Whilst the content of the two releases differed, each refers to the PBS listing of Concerta for adults with ADHD from 1 October 2009. Janssen-Cilag's response acknowledged that the two media releases were part of the one attempt to inform the public of the PBS reimbursement of Concerta.

Section 9.2.1 of the Code permits the publication of a media release to announce to the public the availability of a new product or major indication approval. This announcement occurred with the publication of the media release on 1 October 2009. Section 9.2.2 of the Code states that no other media releases relating to a specific medicine are permitted.

The Committee considered Janssen-Cilag's response that it had halted media engagement following the release of the media release on 1 October when it became aware of the Samoan tsunami tragedy. The Committee did not accept that the cessation of further media engagement in October was adequate justification for issuing a second media release two and a half months later. The Committee noted that the first media release had received some media coverage, primarily in regional NSW and Queensland and on Sydney radio and in the *West Australian*. The Committee considered that the limited coverage of the first media release did not justify the publication of the second release.

The Committee unanimously determined that the publication of a second media release regarding the PBS listing of Concerta was a breach of Section 9.2 of the Code. The Committee unanimously determined that the conduct would not bring the industry into disrepute and was not in breach of Section 9.10 of the Code.

Sanction

The Committee considered that this was a minor breach of the Code. The limited media coverage was taken into consideration and was a mitigating factor in determining the sanction. The Committee determined that Janssen-Cilag should:

- Not distribute the media release again
- Pay a fine of \$15,000

Roche Media Release – 1051

Subject Company: Roche Products

Complainant: Monitoring Committee

Product: MabThera

Complaint

The Monitoring Committee considered that some statements included in the Media Alert and Media Release issued by Roche on 8 September 2009 were false and misleading. These statements were the use of 'new hope' in the Media Release "*New hope for people with most common form of adult leukaemia*", which the Monitoring Committee considered created a false impression of the likelihood of achieving a cure, and statements that the use of MabThera in combination with chemotherapy extended time in remission compared with chemotherapy alone.

The Monitoring Committee also considered that a number of statements in the Media Release were promotional and may encourage a patient with CLL to seek treatment with MabThera.

The Monitoring Committee considered that the Media Alert and Media Release were in breach of Sections 9.2.1 and 9.2.3 of the Code and may bring discredit to the industry and was therefore in breach of Section 9.10.

Sections of the Code

Material was alleged to be in breach of the following Sections of Edition 15 of the Code:

- 9.2 Product Specific Media Releases
- 9.10 Discredit to and reduction of confidence in the Industry

Response

Roche did not agree that the Media Alert and Media Release (released on 8 September 2009) were promotional or that it is likely that the average audience would be prompted by it to seek a prescription for MabThera. Roche contended that the Media Alert and Media Release documents should not be read in isolation, but rather form part of the same package of material.

Roche argued that the statements identified by the Monitoring Committee were taken out of context by reading the two documents in isolation, and therefore the statements could not be regarded as being promotional.

Roche denied that the use of the word “hope” is misleading as “hope” did not refer to cure but an extended remission time. Additionally “hope” is commonly used when reporting on advances in the treatment of cancer.

Code Committee decision

- In a majority decision a breach of Sections 9.2.1 and 9.2.3 of the Code
- In a majority decision no breach of Section 9.10 of the Code

Sanction

- In a majority decision, pay a fine of \$30,000.

Consideration of the complaint

The Committee discussed whether the words ‘new hope’ would be understood by members of the general public to mean MabThera would provide a cure for CLL. Some members of the Committee considered that the term would have its generally understood meaning – that there was another treatment option that offered some chance of successful treatment, which was a factual statement. Other members considered that the words

would be read as making a stronger claim about the chance of being cured. By majority decision, the Committee accepted that the statement ‘new hope’ did not imply that patients with CLL would be cured with MabThera and it was found not to be in breach of the Code.

The Committee considered the statement that ‘*MabThera in combination with chemotherapy prolongs the time patients battling CLL remain in remission compared to chemotherapy alone*’. The Committee accepted that the statement was consistent with the clinical evidence, which was also included in the approved Product Information. The Committee therefore concluded that the statement was not false or misleading. Whilst the statement was not false or misleading, the Committee considered that the statement was promotional because it would encourage patients to seek treatment with MabThera in addition to chemotherapy. The statement was found to be in breach of Section 9.2.1. This statement was also included in the Media Alert which accompanied the Media Release. The Media Alert was therefore found to be in breach of Section 9.2.3 of the Code. In relation to the statement ‘*The hundreds of Australians living with this often life-threatening disease can now be offered a treatment proven to prolong time in remission*’, the Committee accepted that this statement was also consistent with the clinical evidence and the approved Product Information. The Committee concluded that the statement was not false or misleading.

The Committee considered the four statements in the Media Release which the Monitoring Committee had considered were promotional:

- *The hundreds of Australians living with this often life-threatening disease can now be offered a treatment proven to prolong time in remission*
- *MabThera allows previously untreated patients with CLL to live symptom free for longer, helping them to rebuild their lives and start looking to the future.*
- *MabThera presents a long-awaited advance in CLL management and a*

significant step forward for people battling this deadly disease.

- *We have seen how MabThera has greatly improved the treatment of other blood cancers, and through what we have seen by participating in these important clinical studies, we are confident it will achieve similar benefits for patients with CLL.*

The Code Committee agreed that the statements were promotional because they conveyed the positive attributes and benefits of MabThera treatment and may encourage patients with CLL to seek treatment with this medicine. The Committee did not accept Roche's arguments that these statements were taken out of context by the Monitoring Committee. In context the statements remain promotional. The Committee was also concerned that the fourth statement (above) implied that the efficacy of MabThera in CLL will be equal to its efficacy in blood cancers such as non-Hodgkin's lymphoma, whereas there was no evidence to support this. The Committee determined by a majority decision that the Media Information was promotional and in breach of Section 9.2.1 of the Code. The Committee determined that there was no evidence that the Media Release or Media Alert had brought discredit to the industry. No breach of Section 9.10 of the Code was found.

Sanction

The Committee determined in a majority decision that the breach was moderate to minor and determined that Roche should:

- Pay a fine of \$30,000.
-

Sanofi-aventis Media Release – 1052

Subject Company: Sanofi-aventis

Complainant: Monitoring Committee

Product: Actonel

Complaint

The Monitoring Committee was of the view that the sanofi-aventis media release for Actonel dated 21 July 2009 was promotional when considered under the definition of promotion in the Code. The Monitoring Committee considered that whilst comparisons made in the media release were between sanofi-aventis' products, statements in the media release could encourage a member of the public to seek a prescription for a specific prescription-only product which was in breach of Section 9.2 of the Code.

Sections of the Code

Material alleged to be in breach of the following Sections of Edition 15 of the Code:

- 9.2 Product Specific Media Statements
- 9.10 Discredit to and reduction of confidence in the Industry

Response

Sanofi-aventis did not agree that the media release was promotional or that it is likely that the average audience would be prompted by it to seek a prescription for Actonel. Rather sanofi-aventis believe it would prompt a reader to ask their doctor if they are at risk of osteoporosis.

Sanofi-aventis disagreed that the statements in the media release have the potential to bring discredit to the industry because the statements are accurate and provide useful information about an under-diagnosed and under-treated condition

Code Committee decision

- By a unanimous decision, breach of Section 9.2
- By a majority decision, no breach of Section 9.10

Sanction

- Do not distribute the media release again
- Pay a fine of \$20,000

Consideration of the complaint

The Committee considered that the media release issued on 21 July 2009 included a number of statements that would be regarded as promotional under the definition of promotion in the Code. The Committee regarded the statements such as 'first once-a-month osteoporosis treatment now on PBS', 'a simpler and more convenient dosing regimen', 'a once a month treatment on the PBS, that is as well tolerated and just as effective as its daily counterpart' and 'the advantage of a once a month treatment ... rather than 52 tablets per year for a weekly treatment or 365 tablets per year for a daily treatment' as clearly promotional.

The Committee considered that the content of the media release may encourage a member of the general public to seek a prescription for the specific 'monthly' Actonel Once-a-Month prescription-only medicine. In a unanimous decision the Committee determined that the media release was in breach of Section 9.2 of the Code.

The Committee also noted that the media release did not include information about the product's precautions, adverse reactions, contraindications or interactions, as is required under Section 9.2.1 of the Code, however this was not raised by the Monitoring Committee as part of the complaint and was therefore only noted to provide feedback to sanofi-aventis. It was subsequently brought to the attention of the Committee that the media release did in fact contain the required safety information. However due to a photocopying error it had appeared, from the materials before the Committee, that the release did not include

such information. The Committee was pleased that such information was in fact included as required, but noted that the absence of the information was not taken into account in its original decision.

The Committee determined by a majority decision that the conduct would not bring the industry into disrepute and was not in breach of Section 9.10 of the Code.

Sanction

The Committee unanimously determined that sanofi-aventis should:

- Not distribute the media release again
- Pay a fine of \$20,000

Glaucoma Information Book – 1054

Subject Company: Alcon Laboratories Australia

Complainant: Monitoring Committee

Product: N/A

Complaint

The Monitoring Committee considered that certain text in the Glaucoma Information booklet was potentially making a claim and a comparison between different products for the treatment of glaucoma.

The Monitoring Committee noted that Section 12.7.2 of the Code allows that a disease education activity may make reference to the availability of different treatment options, but this information should not be of such a nature that an individual would be encouraged to seek a prescription for a prescription-only product. Further, the Monitoring Committee noted Section 12.7.5 of the Code requires that management options should be presented in a comprehensive, balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment. The Committee considered that the identified

passage of text was not consistent with these requirements.

If the booklet was to be regarded as a patient aid, the Monitoring Committee did not consider that the booklet was compliant with Section 16 which requires that patient aids must not make comparisons between products or include promotional claims.

Sections of the Code

Material was alleged to be in breach of the following Sections of Edition 16 of the Code:

- 12.7.2 Disease education activities in any media
- 12.7.5 Disease education activities in any media
- 16 Materials for use with patients (patient aids)

Response

Alcon in its response contended:

- that the relevant section of the booklet does not refer to any specific product and no product claims are made.
- The statements about new treatments should be considered in the context of the whole booklet, where different treatment options are discussed, both pharmacological and surgical.
- The first line treatment option is prostaglandin eye drops in the majority of patients.
- No direct comparisons between different products or product specific promotional claims were made.

Notwithstanding its disagreement that the booklet had breached the Code, Alcon had advised that the section on new treatments will be deleted from the booklet and Alcon has ceased supplying the booklet and all current stock has been destroyed.

Code Committee decision

- In a majority decision no breach of Section 12.7.2 of the Code
- In a majority decision a breach of Section 12.7.5 of the Code

- In a unanimous decision no breach of section 16 of the Code

Sanction

- Withdraw the Glaucoma Information booklet and not use it again in the same or similar form.
- Pay a fine of \$5,000.

Consideration of the complaint

The Committee noted Alcon's advice that the booklet was made available to doctors and ophthalmologists for them to give to patients with glaucoma. A patient does not need to be prescribed a particular medicine to receive the booklet.

Page 10 of the booklet, under the heading 'New treatments for Glaucoma' refers to 'a powerful class of drugs (prostaglandins)', being able to 'manage glaucoma more effectively' and that 'these newer drops ... used just once a day ...easier for people to remember to use them'. The Committee noted that there are a number of eye drops available which contain prostaglandin, supplied by Alcon and other companies. The booklet did not refer to a product by brand name; it only referred to the class of medicines.

The Committee considered whether the booklet would encourage a person to seek a prescription for a prescription-only product. A minority of members of the Committee considered that the statements on page 10 (identified above) would encourage a person to seek a prescription for prostaglandin eye drops for their glaucoma. These members thought that because there are other classes of eye drop available to treat glaucoma, members of the public with glaucoma would be encouraged to ask for prostaglandin eye drops. The majority of members of the Committee considered that the statements referring to new treatments for glaucoma should be considered in light of the entire contents of the booklet, which referred generally to the management of glaucoma with eye drops. These members did not consider that the text on page 10 of the

booklet encouraged a member of the public to seek a prescription for a prescription-only medicine. These members considered that the reference to prostaglandin eye drops was sufficiently general and it was understood that most people newly diagnosed with glaucoma will be prescribed a prostaglandin eye drop.

In a majority decision, no breach of Section 12.7.2 of the Code was found.

In relation to Section 12.7.5 of the Code, a majority of members considered that the booklet was not balanced. These members considered that the booklet unduly emphasised treatment with prostaglandin eye drops and did not mention other treatment options such as other classes of eye drop. Surgical management of glaucoma was also inadequately covered. Members considered that whilst the booklet emphasised one treatment approach, this was not sufficient to encourage a member of the public to seek a prescription for a prescription-only product. In a majority decision a breach of section 12.7.5 of the Code was found.

The Committee accepted that the booklet should not be regarded as a patient aid because its distribution was not restricted to patients prescribed a particular product. In a unanimous decision, no breach of Section 16 was found.

The Committee noted that Alcon had withdrawn the booklet from distribution.

Sanction

The Committee determined that the breach found was minor, having no safety implications for patients and no effect on how the medical professional would prescribe any product.

The Code Committee determined that Alcon Laboratories should:

- Withdraw the Glaucoma Information booklet and not use it again in the same or similar form.
- Pay a fine of \$5,000

'An Early Psychosis' DVD – 1056

Subject Company: Novartis Australia

Complainant: Monitoring Committee

Product: Clozaril

Complaint

The Monitoring Committee considered that the DVD included statements and testimonials that were praising the product Clozaril which were promotional in nature in a material intended for distribution to consumers.

Novartis had stated that the DVD is not currently being distributed. However, the Committee was concerned that the VHS (videotape) version containing the same content had been distributed to healthcare professionals to give to consumers and was potentially in breach of the Code.

If the DVD/tape was intended to be given to a patient after the decision to prescribe Clozaril has been made, the Monitoring Committee considered that the content of the DVD/tape was not just educational but included statements that were promotional and may be in breach of Section 12.6 of the Code.

If the DVD/tape should be regarded as a patient aid, the Monitoring Committee did not consider that it was compliant with Section 16 of the Code. Section 16 requires that patient aids must not make comparisons between products or include promotional claims.

Sections of the Code

Material alleged to be in breach of the following Sections of Edition 16 of the Code:

- 12.6 Educational information to the general public
- 16 Materials for use with patients (patient aids)

Response

Novartis apologised for any confusion regarding the DVD, which it said should not

have been submitted to the Monitoring Committee because it had not been in use within the last 24 months. Novartis stated that the VHS version of the material had been produced in 2003, but hasn't been available for a number of years.

In its response, Novartis referred to Appendix 1 of the Code, which states that complaints will not be accepted where the promotional material or activity had occurred at a time more than 24 months before the lodgement of the complaint.

Novartis stated that the DVD had been produced and had been under review through the internal copy clearance system when it was provided to the Monitoring Committee. The DVD has never been distributed.

Code Committee decision

No breach of Section 12.6 or 16 was found, in recognition that the videotape had not been distributed for more than two years and the DVD version had not yet been distributed. The complaint exceeded the limitation period stated in the Code.

Consideration of the complaint

The Committee considered the circumstances that led to the DVD being reviewed by the Monitoring Committee.

The Committee understood that the videotape version of 'An Early Psychosis' had not been distributed by Novartis since 2007. The Committee was also of the understanding that the DVD version of the videotape was undergoing internal company review prior to further distribution and had been provided in error to the Monitoring Committee for its review of disease education activities. In its response, Novartis had referred to the Limitations on complaints in Appendix 1 of the Code, which states that complaints will not be accepted where the promotional material or activity occurred in a period greater than 24 months from the date of lodgement of the complaint.

The Committee was very concerned by the content of the VHS/DVD and would be inclined to find it in breach of the Code if the complaint had been properly before the Committee.

The Committee concluded that it would accept that the limitation period for complaints had expired if Novartis could provide an assurance that the videotape was no longer in use or being given to patients by clinics. The Committee requested that Novartis write to all clinics which prescribe Clozaril for patients and request that they return any copy of the video to Novartis and that Novartis destroy all copies of the videotape that are returned. Novartis should advise the Committee of the completion of this action by Friday 6 August 2010.

'BeatHepC' website – 1057

Subject Company: Roche Products

Complainant: Monitoring Committee

Product: Pegasys RBV

Complaint

The Monitoring Committee considered that the term 'cure' on the website would have a different meaning for consumers in relation to Hepatitis C than it would for physicians; physicians may understand that a 'cure' means a sustained virological response, whereas a member of the general public may understand 'cure' to mean that they have fully overcome the condition. A member of the general public is unlikely to understand that the term 'cure' is relevant to only 50 to 80 percent of treated people, or that it means a sustained viral response for a period of time demonstrated in clinical trials.

The Monitoring Committee considered that the website was potentially misleading and was not balanced.

Sections of the Code

Website alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.3 False or misleading claims
- 12.7 Disease education activities in any media
- 12.7.4 Disease education activities in any media

Response

Roche had responded that a successful cure from hepatitis C is possible – the disease can be completely overcome and this effect can be sustained. Roche contended that the word ‘cure’ in the context of hepatitis C treatment is appropriate terminology for a general public audience. This contention was supported by publicly-available material using the word ‘cure’ in the same context.

Roche had denied that the website was in breach of the Code. Roche argued that the website was balanced, informative and promoted awareness of all aspects of the disease and its management.

Roche had supported its response to the complaint with advice from Hepatitis Australia that the use of the word ‘cure’ was entirely appropriate and that the website contents were fair, accurate, balanced, was not misleading and provided appropriate hepatitis C disease education information.

Code Committee decision

- By a majority decision, no breach of Section 1.3
- By a majority decision, no breach of Section 12.7
- By a majority decision, no breach of Section 12.7.4

Consideration of the complaint

The Committee discussed what would be meant by ‘cure’ in relation to hepatitis C in the mind of consumers. It was noted that the medical literature consistently used the term ‘sustained virological response’ which is defined as the absence of hepatitis C virus RNA in the serum 24 weeks after therapy has

ceased. Most medical literature did not use the term ‘cure’. Few studies have followed subjects for longer than 24 weeks after treatment cessation. One abstract included in the response from Roche, a study by Swain et al, had followed patients for a mean of 4.1 years after cessation of treatment, with 99 percent remaining serologically negative for the hepatitis C virus. This study claims it validates the use of the term ‘cured’ for people achieving a sustained viral response.

However, the Committee was primarily interested in consumers’ interpretation of the term ‘cure’ in relation to hepatitis C. The BeatHepC website used the term ‘cure’ and stated ‘being cured of hepatitis C means clearing the hepatitis C virus from your blood’. Some members of the Committee considered that members of the public are likely to understand that the term ‘cured’ as having the commonly understood meaning of ‘no longer having the problem’. The Committee was unable to identify any systematic investigation by Roche or another organisation of what consumers would understand by the term ‘cure’ in relation to hepatitis C. Some members also considered that the name of the website ‘beatHepC.com.au’ reinforced the impression that the problems associated with hepatitis C can be ‘beaten’ or eliminated, which they considered was misleading. However, the term ‘beat hepatitis C’ was also used by independent community organisations such as Hepatitis Australia in their communications with the general public.

Members were also concerned that the term ‘cured’ might not convey to members of the general public that they may still have liver damage that will not be ‘cured’ by treatment. The Committee noted that the paper by Ghany et al acknowledged that liver cancer has been identified years after a ‘virological cure’, especially if liver cirrhosis existed at the time of achieving a sustained virological response. Whilst the medical and professional community might properly understand that ‘cure’ means a sustained virological response but the risk of liver disease progression remains, a consumer might not gain this understanding from the term ‘cure’ or ‘cured’.

The Committee considered Roche's advice that many publications from both State and Federal Governments and from community organisations have adopted the term 'cured' in relation to hepatitis C treatment. Although the Committee recognised the importance of pharmaceutical companies aligning their health promotion messages to those communicated by both health departments and peak national community organisations, a pharmaceutical company should not adopt a term without being cognisant of the Code and other standards that apply to their communications.

The Committee reviewed each page of the 'BeatHepC' website, particularly the page headed 'The Chance of a Cure'. A majority of the Committee accepted that this page made it clear to a reader that achieving a 'cure' was not guaranteed and depended on a number of factors, including the degree of liver damage when treatment is started. The use of the word 'chance' with 'cure' provided some moderation of the understanding of the likely outcome of treatment.

The Committee concluded in a majority decision that the use of the terms 'cure' or 'cured' on the BeatHepC website was not misleading and was not in breach of Section 1.3 of the Code. The Committee also concluded by a majority decision that the website was not in breach of Section 12.7.4 or 12.7 of the Code. The Committee accepted that within the environment of hepatitis C treatment the key characteristics of the condition were covered on the BeatHepC website and that the implications of the disease were not alarmist.

Whilst concluding that the website was not in breach of the Code, the Committee wished to convey to Roche that some members of the Committee, particularly the consumer members, had significant concerns about consumers' understanding of the meaning of a 'cure' in relation to hepatitis C. Members encouraged Roche to investigate what consumers actually understand from the term, particularly in populations more vulnerable to hepatitis C such as injecting drug users, prisoners and the culturally and

linguistically diverse community, in order to be confident that a realistic understanding of the outcome of treatment is conveyed.

AstraZeneca Educational Event – 1058

Subject Company: AstraZeneca

Complainant: Monitoring Committee

Product: N/A

Complaint

The Monitoring Committee had reviewed an amended educational event report voluntarily submitted by AstraZeneca in relation to an event held at a medical centre in Queensland in the three month period January to March 2010. The amended report detailed hospitality at a cost of \$160.35 per person in association with a one hour presentation held within the medical centre. The hospitality provided included a private chef and waiter.

The Monitoring Committee considered that the hospitality provided was not secondary to the educational content provided at the educational event and was therefore potentially in breach of Section 9.3 and 9.4.3 of the Code. The educational event costs had exceeded AstraZeneca's internal company policy for the conduct of educational meetings. The Monitoring Committee also considered that this event may bring discredit to the industry and may be in breach of Section 9.13 of the Code.

Sections of the Code

Conduct alleged to be in breach of the following Sections of Edition 16 of the Code:

- 9.3 Educational events
- 9.4.3 Meals and beverages (at company educational events in Australia)
- 9.13 Discredit to and reduction of confidence in the industry

Response

AstraZeneca asserted the value of the educational content provided at the meeting, but acknowledged that the hospitality provided involved a per-head cost that exceeded what would be considered acceptable for a pharmaceutical company educational event and which exceeded its own company limits. The actual hospitality provided was not lavish or excessive and was within normal business standards, although the costs may not have been.

AstraZeneca asked the Committee to take into consideration that it had taken appropriate corrective action to ensure that in future hospitality is always appropriate for its educational events and that the company had proactively disclosed the meeting to the Monitoring Committee, which demonstrates the company's strong commitment to Code compliance.

Code Committee decision

- By a unanimous decision, breach Section 9.3
- By a unanimous decision, breach Section 9.4.3
- By a majority decision, no breach Section 9.13

Sanction

- By a majority decision, pay a fine of \$15,000

Consideration of the complaint

The Committee considered the balance between the educational content of the meeting and the hospitality provided. The Committee considered that the education provided was relatively basic whereas the hospitality on a per-head cost was excessive and not an appropriate form of hospitality for an educational event held in the workplace.

AstraZeneca had acknowledged that the hospitality had exceeded its own company limits and exceeded what would be considered appropriate for pharmaceutical company educational event of this type.

The Committee unanimously determined that the educational event was in breach of Section 9.3 and Section 9.4.3 because there was not an appropriate balance between the educational content and the hospitality provided and the hospitality was not secondary to the educational content. In relation to Section 9.13, the Committee determined by a majority decision that the event did not bring discredit to or reduce confidence in the industry.

Sanction

The Committee debated what would be an appropriate sanction. The Committee agreed that the fine should be reduced from that which would normally be imposed for this conduct because AstraZeneca had openly and proactively self-reported the event, which originally had been misreported. The Committee determined by a majority decision that AstraZeneca should:

- Pay a fine of \$15,000

Testogel and Reandron 1000 – 1068

Subject Company: Bayer Australia

Complainant: Monitoring Committee

Product: Testogel and Reandron 1000

Complaint

The Monitoring Committee had reviewed advertisements in the Endocrine and Metabolic disorders therapeutic class published in the period April – June 2010. It had asked for a further explanation from Bayer regarding the claim 'the gimmicks can go' in advertisements for Testogel and Reandron 1000. The Monitoring Committee considered that the claim was unclear as to its meaning. Did it refer to other treatments that 'can go'? The claim was unreferenced, therefore the Committee could not identify its source or meaning. The Committee requested that Bayer supply the references or evidence to support the claim which appeared in both advertisements.

The Monitoring Committee had reviewed Bayer's response to these concerns but remained of the view that Bayer had not fully addressed them.

The Committee was of the view that the Bayer advertisements for Testogel and Reandron 1000 may not comply with the Medicines Australia Code of Conduct.

Sections of the Code

Materials alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.3 – False or misleading claims
- 1.7 – Comparative statements

Response

Bayer Healthcare denied the advertisements breached either Section 1.3 or 1.7 of the Code. The tagline "When testosterone is restored, the gimmicks can go" is not a comparative claim. The gimmicks referred to in the claim are shown in an unambiguous manner and there is no suggestion in either advertisement that other testosterone replacements are not equally effective to Testogel and Reandron 1000. The tagline is not comparative. Bayer further stated that the tagline is not a claim and is substantiated through market research with GPs.

Bayer had provided substantiating evidence for the fact that when a man's testosterone levels are restored there are positive effects on mood. Bayer denied that the tagline was misleading.

Code Committee decision

In a unanimous decision no breach of Section 1.3 or 1.7 of the Code was found

Consideration of the complaint

The Committee considered the concerns expressed by the Monitoring Committee about the two advertisements for Testogel and Reandron 1000 in which the statement 'When testosterone is restored the Gimmicks can go' is associated with visual images of fishing/hunting trophies being removed and a motorbike up for sale.

The Committee considered that the advertisements were acceptably clear in their message – that restoration of a man's testosterone levels can restore his confidence and reduce the need for 'gimmicks' symbolic of male virility. Members did not consider that a prescriber would interpret the advertisements other than was intended. In a unanimous decision the Committee found that the tagline in the advertisements was not misleading and was not in breach of Section 1.3 of the Code.

The Committee considered whether the tagline was an actual or implied comparison with other treatments. The Committee did not agree with the Monitoring Committee that the tagline was a comparative claim. The Committee agreed with Bayer Healthcare that the tagline was not making a claim about Testogel and Reandron 1000 beyond the fact that both products can restore testosterone levels. The Committee accepted that the tagline was intended to mean that when testosterone was restored the need for symbols of male virility can be reduced and that the advertised products can restore testosterone. There was no suggestion from the tagline, in the Code of Conduct Committee's view, that Testogel or Reandron 1000 were superior to other testosterone replacement therapies. In a unanimous decision no breach of Section 1.7 of the Code was found.

Sanction

The Committee determined by unanimous decision that there was no breach of Sections 1.3 and 1.7, therefore no sanction was imposed.

Somatuline Autogel – 1071

Subject Company: Ipsen

Complainant: Monitoring Committee

Product: Somatuline Autogel

Complaint

As part of its regular review cycle, the Medicines Australia Monitoring Committee reviewed advertisements published between April-June 2010 in the Endocrine and Metabolic Disorders therapeutic class. The Committee's original review took place in August 2010, and the Committee made subsequent requests for further clarification in September 2010 and March 2011. Following its consideration of Ipsen's responses, the Monitoring Committee considered that several claims in the advertisement for Somatuline were potentially misleading and unable to be substantiated and referred the complaint to the Medicines Australia Code of Conduct Committee.

Sections of the Code

Materials were alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.2 Substantiating Data
- 1.2.2 Level of substantiating data
- 1.3 False or misleading claims

Response

Ipsen stated in its response that the data used to substantiate the claims in the Somatuline advertisements had been evaluated by both the TGA and the PBAC. The TGA and PBAC had considered that the referenced study was adequate to support the indication for Somatuline to treat the rare condition carcinoid syndrome. Ipsen contended that the claim and qualifying statements accurately reflected the referenced study, including definitions included therein. Ipsen denied any breach of the Code.

Code Committee decision

- In majority decisions no breaches of Sections 1.2, 1.2.2 and 1.3 of the Code were found.

Consideration of the complaint

The Committee noted that the complaint related to two advertisements for Somatuline, however as the claim referred to in the complaint was identical in both advertisements, only one of the advertisements was included in the agenda papers.

The Committee reviewed the study by Ruzniewski et al used to support the claim "*Rapid and sustained improvement in the symptoms of carcinoid syndrome*" and the qualifying statement "*significant improvement observed within the first week post-treatment and still observed after 6 months of treatment*". The Committee discussed the limited number of subjects included in the study. It accepted that carcinoid syndrome is an orphan disease with a small number of patients, making it difficult to conduct trials in a larger population. The Committee agreed that the sample size should not discount the validity of the study. The Committee considered that the Ruzniewski paper provided limited information for readers to be able to fully understand the statistical analysis, however it accepted that the paper had been published in a peer reviewed publication and was most likely the best available data in the field of carcinoid syndrome. The results reported in the study were statistically significant and were adequate to substantiate the claims for Somatuline. In a majority decision no breach of Section 1.2 or 1.2.2 was found.

The Committee discussed the results reported in the Ruzniewski et al study, which showed that Somatuline (Lanreotide) was effective in reducing the symptoms of diarrhoea or flushing. The Committee noted that the study showed that Lanreotide had greater efficacy in reducing the frequency of flushing than of diarrhoea (65% of patients with flushing as the target symptom and 18% of diarrhoea target patients achieved greater than 50%

reduction from baseline). The Committee discussed whether the claim *“Rapid and sustained improvement in the symptoms of carcinoid syndrome (diarrhoea or flushing)”* implied that Somatuline was effective in reducing both symptoms equally and therefore could be considered to be misleading. A majority of the Committee considered that the claim did not imply that the symptoms were both equally improved by lanreotide. It was also noted that the number of clinicians treating patients with Carcinoid Syndrome is very small and it is a highly specialised area of medicine. Further, Somatuline is only available under Section 100 (highly specialised drugs) of the PBS. The Committee made the assumption that the audience for this advertisement would therefore be aware that diarrhoea is less responsive to this type of treatment than flushing. One Member noted that the claim was directly quoted from the study and that it is supported by the evidence within the study. A minority of the Committee considered that the claim was a broad statement that did imply that Somatuline was equally effective in improving both symptoms and should have been better qualified. In a majority decision the Committee determined that the claim was not misleading and was not in breach of Section 1.3 of the Code.

The Committee discussed the qualifying statement *“significant improvement observed within the first week post-treatment and still observed after 6 months of treatment”*. It was noted that in Figure 1 in the Ruzniewski study showed that the improvement was demonstrated at the end of the first week, rather than ‘within’ the first week, but accepted that this was a pedantic, semantic interpretation of the qualifying statement. The Committee suggested that the qualifying statement could be amended to more accurately reflect the results of the study. In a majority decision the Committee found no breach of Section 1.3 of the Code.

The Chairman raised with the Committee the procedures followed by the Monitoring Committees in reviewing the materials provided by Ipsen and the company’s responses to the Committee’s requests for

further information and explanation. It appeared to the Code Committee that the Monitoring Committee had not made the issues about which it had concerns about sufficiently clear to Ipsen before referring the matter to the Code Committee. The matter of the validity of the Ruzniewski study as substantiating data had arisen following Ipsen’s response. The Code Committee considered that Ipsen should have been given an opportunity to respond to the issue of the validity of the study before the complaint was forwarded to the Code Committee.

One Committee Member noted that the Ipsen’s response to the complaint included a Clinical Expert Statement which supported the company’s response. The member noted that this expert opinion would have been paid for by Ipsen and would only have been submitted to the Code Committee if it supported the company’s position. The Committee considered that it has the appropriate membership to form an opinion on the evidence presented in a complaint and response. It does not assist the Committee in its deliberations to receive an expert opinion prepared at the request of a Complainant or Subject Company.

Decision

The Committee determined by majority decision that the claim and qualifying statements in the advertisements were not in breach of Sections 1.2, 1.2.2 and 1.3 of the Code of Conduct.