



2005 Code of Conduct Annual Report

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**MEDICINES**  
*Australia*  
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

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# Welcome to the 2004/2005 Code of Conduct Annual Report

This year's annual report provides information on the activities of the Code of Conduct, Appeals and Monitoring Committees during the period 1 July 2004 to 30 June 2005.

The report on all complaints finalised in this period has been prepared from the minutes of the Committee meetings.

To enhance understanding, a glossary of the sections of the Code referred to in this report is included at the end of the Annual Report.

## Commitment

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

- To provide medicines that conform to the highest standards of safety, efficacy and quality;
- To ensure that medicines are supported by comprehensive technical and informational services in accordance with currently accepted medical and scientific knowledge and experience;
- To use professionalism in dealing with National Medicines Policy partners including healthcare professionals, public health officials and consumers; and
- To promote the quality use of medicines and principles within the *National Strategy for Quality Use of Medicines*.

Medicines Australia and its member companies are committed to the quality use of medicines and rational prescribing, and strongly recommend that its medicines are used only in accordance with the directions and advice of healthcare professionals.

## Review of Edition 14 of the Code of Conduct

Medicines Australia believes that for the Code to be a meaningful document it must regularly undergo review. In 2005 Medicines commenced the review of Edition 14 of the Code of Conduct. Submissions were received from member and non member companies and a range of stakeholders. Consultation has been undertaken with stakeholders to promote an understanding of the proposed amendments and provide the opportunity to comment on these provisions. Edition 15 will take effect from 1 January 2006.

Any questions in relation to the Code process or the Annual Report should be referred to the Secretary of the Code of Conduct Committee at Medicines Australia on 02 6282 6888 or via email at [secretarycodecommittee@medicinesaustralia.com.au](mailto:secretarycodecommittee@medicinesaustralia.com.au)

The Code of Conduct and Code of Conduct Guidelines can be viewed on the Medicines Australia website at [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au) or copies can be obtained by contacting Medicines Australia on 02 6282 6888.

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## Summary of Results

### 1 July 2004 - 30 June 2005

Medicines Australia received a total of 51 complaints for evaluation by the Code of Conduct Committee during the 12 months from 1 July 2004 to 30 June 2005.

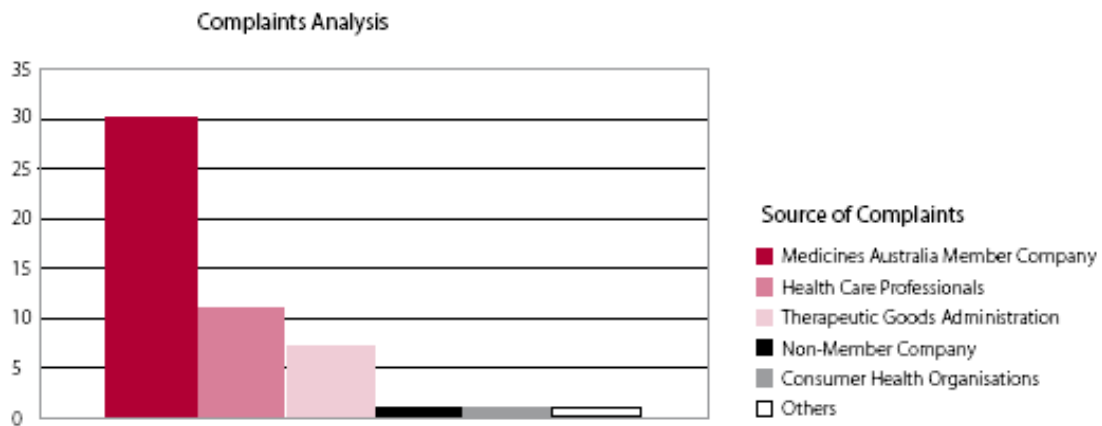
Three of these complaints were not finalised as at 30 June 2005 as the period allowed under the provisions of the Code for a Subject Company to appeal had not expired and have not been included in this report. Two complaints from 2003/2004 that were finalised after 30 June 2004 are included in this report.

Following is a summary of the complaints received by Medicines Australia during this period.

## Complaints Analysis

### Source of Complaints

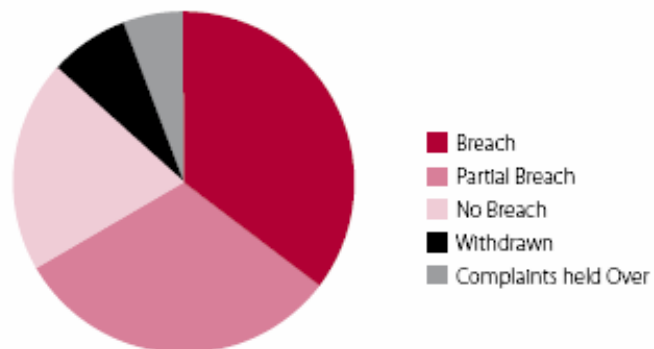
Complainants	Number
Medicines Australia Member Company	30
Non Member Company	1
Therapeutic Goods Administration	7
Healthcare Professional	11
Health Consumer Organisation	1
Others	1
<b>Total of new complaints in 2004/2005</b>	<b>51</b>



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## Result from Consideration of Complaints

Complaints	Number	Percentage
<b>Complaints finalised from 2003/2004</b>	<b>2</b>	
<b>Code of Conduct Committee decision</b>		
Breach	2	100%
Partial Breach	0	0%
No Breach	0	0%
<b>Appeals</b>		
Appeal not upheld - breach confirmed	1	50%
Appeal partially upheld - some aspects confirmed	1	50%
Appeal upheld - no breach	0	0%
<b>Complaints received in 2004/2005</b>		
<b>Code of Conduct Committee decision</b>		
Breach	18	35%
Partial Breach	16	31%
No Breach	10	20%
Complaints withdrawn	4	8%
Complaints withheld until next reporting period	3	6%
<b>Total of new complaints in 2004/2005</b>	<b>51</b>	



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## Appeals

Appeal not upheld - breach confirmed	7	64%
Appeal partially upheld - some aspects confirmed	3	27%
Appeal upheld - no breach	1	9%

## Sanctions imposed on companies found in breach of the Code

### Sanctions

#### Complaints finalised from 2003/2004

Withdrawal of material found in breach	2
Corrective Advertisement	0
Corrective Letter	0

#### Fines

\$0 - \$24,999	0
\$25,000 - \$49,999	0
\$50,000 - \$74,999	0
\$75,000 - \$99,999	0
\$100,000 - \$149,999	0
\$150,000 - \$200,000	0
<b>Total value of fines</b>	<b>\$0,000</b>

#### Complaints received in 2004/2005

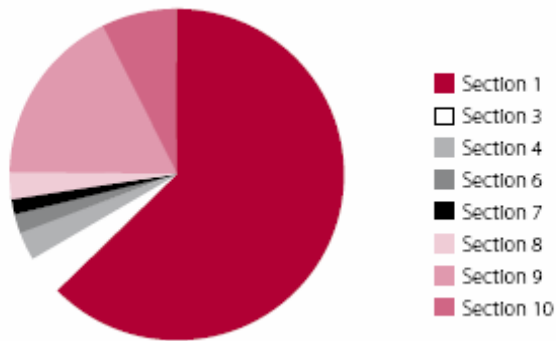
Withdrawal of material found in breach	26
Corrective Advertisement	0
Corrective Letter	7
Other Sanctions	2

#### Fines

\$0 - \$24,999	13
\$25,000 - \$49,999	4
\$50,000 - \$74,999	2
\$75,000 - \$99,999	0
\$100,000 - \$149,999	1
\$150,000 - \$200,000	0
<b>Total value of fines</b>	<b>\$471,500</b>

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## Alleged Breaches of Sections



Length of Time to Resolve Complaints	Days
Shortest	11
Longest	90
Average	35
Average for complaints not subject to appeal	28
Average for complaints subject to appeal	68

## Performance Indicators

The Code of Conduct requires the disclosure of performance indicators regarding the time to consider complaints and the activities undertaken to increase healthcare professionals' awareness of the Code of Conduct.

### Time to consider complaints

The time to consider and finalise the Code of Conduct complaints for the period July 2004 to June 2005 ranged from 11 to 90 days. The average number of days taken to finalise all complaints considered during this period was 35 compared with 37 the previous year. For complaints that were not subject to an appeal, the average number of days taken to finalise these complaints was 35 days compared to 30 days in the previous year. The cause for delays in the finalisation of complaints subject to an appeal during the year was generally in relation to finding a mutually acceptable Appeals Committee meeting date for the subject company and complainant and the sourcing of external experts for the Code of Conduct Appeals Committee meetings.

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## Activities undertaken to increase awareness of the Code of Conduct

Educational seminars and meetings are provided by Medicines Australia throughout the year to increase industry and stakeholder awareness of Edition 14 of the Code. Presentations were made to member and non member companies; advertising, marketing and public relations agencies; conference organisers; pharmacy and medical organisations and international delegations. Medicines Australia made 39 presentations during 2004/2005 to a total of 891 individuals representing 38 organisations.

Organisation	Number of Presentations
Member Companies	8
Non Member Companies	5
Combined Member/ Non Member	3
Healthcare Professional/Pharmacy	3
Consumers	4
Agencies	12
Seminars	2
International Delegations	2
Total number of presentations	39
Total number of participants	891

## Acknowledgments

The success of both the Code of Conduct and Code of Conduct Appeals Committees can be attributed to the participation and assiduousness of their Chairmen and members. Medicines Australia would like to thank these individuals for their continued commitment and diligence in administering the Medicines Australia Code of Conduct.

Thanks also go to the Medicines Australia staff who ensure these Committees are supported in a professional, responsive and timely manner.

## Committee Membership

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

### Code of Conduct Committee

#### Full Members

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

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## Observers

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

## Advisors

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

## Medicines Australia Code of Conduct Committee

The Code of Conduct Committee met 12 times during this reporting period. The following table indicates the attendance of the external members of the Committee. Edition 14 of the Code of Conduct requires the participation of an ASCEPT member at each Committee meeting and a minimum of two Medicines Australia member company representatives to ensure a quorum of six full members.

External Organisation	Number of Meetings Attended
Australian Divisions of General Practice (ADGP)	10
Australian Medical Association (AMA)	11
Royal Australian College of General Practitioners (RACGP)	12
Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)	12
Patient Support Group	11
Therapeutic Goods Administration (TGA)	12
Consumer Representative	12

## Code of Conduct Appeals Committee

### Full Members

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

### Advisors

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

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## Pariet (742)

*Promotional material for healthcare professionals*

### Complaint

A complaint was received from Wyeth Australia Pty Ltd (Wyeth) alleging that the promotional tagline

“There’s no parroting Pariet”, both alone and juxtapositioned with other promotional claims contained in promotional materials for Pariet by Janssen-Cilag Pty Ltd (Janssen-Cilag) were in breach of Sections 1.1, 1.2.2, 1.3, 1.5 and 1.7 of the Code.

### Response

A response was received from Janssen-Cilag denying that it had breached the Code of Conduct.

Janssen-Cilag maintained that they had undertaken intercompany dialogue in good faith and that the tagline was a play on words and did not imply any claim.

### Committee Ruling

#### Promotional Tagline: There’s no parroting Pariet

The Committee was of the view that the tagline was comparative as the reference to ‘parroting’ could be interpreted as meaning ‘to mimic’ or ‘to imitate’ and this was making a claim that there was no other product similar to or the same as Pariet, therefore claiming it to be unique in its class. Members considered that the tagline was promotional in the context of positioning with the promotional claims.

Members were particularly concerned that the claim by Janssen-Cilag that Pariet has a different metabolic pathway (a predominantly non-enzymatic/non-P450 metabolism) directly conflicts with the Product Information which states “Rabeprazole sodium is metabolized through the cytochrome P450 (CYP450) hepatic drug metabolism system (See interactions)” and “Demonstrated interactions. In vitro studies on human liver microsomes indicated that rabeprazole sodium is metabolised by isoenzymes of CYP450 (CYP2C19 and CYP3A4).”

With regard to the undertaking by Janssen-Cilag to reference the tagline in new advertising materials, members were of the view that the qualification provided on the advertisement in the 2 April edition of Australian Doctor Weekly (provided by Janssen-Cilag in their response) “Mimicking. PARIET is a second generation PPI, with a differing metabolic pathway, fast acid suppression and high pKa” only added to their concerns that the tagline was promotional, comparative, misleading and not supported by the PI. None of these four qualities were apparently supported by clinical evidence to demonstrate a clinical benefit. Also there are no studies comparing proton pump inhibitors regarding each of these points.

One of the healthcare professional members of the Committee expressed great concern that Janssen-Cilag representatives were promoting this product to general practitioners on the basis that it has a different metabolic pathway to all other products in the class and that this information may cause a prescriber to change their prescribing on the basis of incorrect and misleading information.

Members commented that if the different metabolic pathway could be substantiated by new data not available at the time of registration, Janssen-Cilag should submit the data to the TGA to update the PI. However it was noted that the PI had recently been updated in October 2003.

The Committee found a breach of Section 1.1 as the company has a responsibility to ensure that the content of all promotional and medical claims is balanced, accurate and fully supported by the PI. Further the Committee found a breach of Section 1.2.2 as there was a lack of evidence to support the claim that Pariet is metabolised in a different manner to other PPIs. A breach of Sections 1.3 and 1.7 was also found as the claim was misleading and made a misleading comparison to other products in the class. A breach of Section 1.5 was also found as the Committee was of the view that the claim implied uniqueness that could not be substantiated. Each finding of breaches of the Code was unanimous.

**Promotional claims: “For fast reflux relief...” and “For first class reflux relief ....” juxtaposed with the claim “... there’s no parroting Pariet”**

Members of the Committee agreed with the view expressed by Wyeth that the use of these claims juxtaposed with the claim “... there’s no parroting Pariet” could infer that Pariet was different and superior to other PPIs. Members noted that in intercompany dialogue Janssen-Cilag had agreed to comply with Wyeth’s request to cease using the claims “For fast reflux relief...” and “First class

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relief...” juxtaposed with “... there’s no parroting Pariet”.

For the reasons stated in relation to part 1 of this complaint, the Committee unanimously found that the material was in breach of Sections 1.1, 1.2.2, 1.3, 1.5 and 1.7 of the Code.

Members commented that all companies should be encouraged to make claims that are meaningful and can be supported by sufficient levels of evidence if the industry is to gain respect and be acknowledged as a reliable source of information to support the quality use of medicines. Medicines Australia was asked to pass these comments on to their members.

### Promotional Images: Pariet Parrot

The Committee was of the view that the images of the parrot in the various advertisements by themselves were not promotional nor in breach of the Code. No breach of Sections 1.1, 1.2.2, 1.3 or 1.7 was found. However, the advertisements as a whole (image, tagline and the promotional claims) did present an unbalanced and misleading representation to a healthcare professional and were in breach of the Code.

## Sanction

The Code of Conduct Committee resolved that Janssen-Cilag should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form. The Committee considered that the amended advertisement that included a qualification of the term “parroting” did not resolve the breaches found. The Committee was also of the view that as there was an implication of a clinical benefit for Pariet over other medicines in the class that was misleading and may encourage a healthcare professional to change their prescribing, Janssen-Cilag should publish a half page corrective advertisement in all journals where this material had been published.

## Appeal

An appeal was lodged by Janssen-Cilag against the findings of the Code of Conduct Committee. Janssen-Cilag contended that the findings of the Code of Conduct Committee were based on errors of fact and procedural errors because matters that had been resolved through intercompany dialogue had been considered by the Committee.

## Appeals Committee ruling

The Appeals Committee discussed taglines and was of the view that it was not their role to say whether companies should reference or qualify them as this was a decision a company should make in relation to each tagline. The fundamental point remained in each case whether the promotional material was misleading, and this had to be considered in the context of the particular case, so that no absolute rules could be laid down. It was noted from the record of intercompany dialogue that Janssen-Cilag had agreed not to use the tagline “There’s no parroting Pariet” and the claim “Fast acid suppression” together in any future promotional materials. However it would appear from Wyeth’s comments that Wyeth considered Janssen-Cilag was slow to implement the agreed changes and Wyeth was not satisfied that there was sufficient evidence to support any qualification and that the tagline could be used alone. It therefore proceeded with the complaint to Medicines Australia.

In relation to the original complaint by Wyeth members noted that it did not relate to the advertisement dated 2 April 2004, which included a reference for the tagline, which had been provided by Janssen-Cilag in their original response to the complaint. Therefore it may have been a procedural error by the Code of Conduct Committee to have been influenced in their decisions by this item.

When considering Janssen-Cilag’s comments that the PI may not be sufficiently clear when describing the metabolic pathway for rabeprazole, Members were of the view that it was the responsibility of the company to ensure that the PI was up to date and of sufficient clarity for a healthcare professional.

Members accepted that Pariet is metabolised predominantly by a non-P450 metabolic pathway, which may be clinically significant in terms of drug interactions. Whilst some drug interactions are mentioned in the Pariet PI, these are relatively minor in terms of interactions due to P450 enzyme metabolism. However in terms of the other three points of differentiation for Pariet, members were not convinced by the differentiation of Pariet on the basis of fast acid suppression, higher pKa, second generation PPI or lack of generic competitors.

The Appeals Committee considered that the Code of Conduct Committee was apparently influenced in its findings by its understanding that the metabolic pathway was not predominantly non-enzymatic P450.

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## Promotional Tagline

The Committee concluded by a majority that the tagline in the context of the various visual images of the 'Pariet parrot' was misleading because it suggested superiority in comparison to other PPIs that could not be substantiated and was therefore in breach of Section 1.3 of the Code. However the Committee was unanimous in agreeing that the findings of breaches of Sections 1.1, 1.2.2, 1.5 and 1.7 of the Code should be set aside.

### Promotional Claims "For fast reflux relief..." and "For first class reflux relief..." juxtapositioned with the tagline "There's no parroting Pariet"

Members commented that Janssen-Cilag had acknowledged that the use of the tagline juxtapositioned with the promotional claims was in breach of the Code. The Committee determined that this was in breach of Sections 1.1, 1.3 and 1.7 of the Code but found no breach of sections 1.2.2 or 1.5 of the Code.

On the procedural issue of this being resolved through intercompany dialogue, the Committee was of the view that it is unusual for a company to submit a complaint following agreement from intercompany dialogue. Janssen-Cilag had acknowledged that they were in breach and had undertaken not to continue to use the tagline and claims together.

## Sanction

It was agreed that it was appropriate that the material found in breach should be withdrawn and not used in a manner that conveys the same or similar meaning. It was noted that Janssen-Cilag should not use the tagline "No parroting Pariet" without being able to substantiate it and ensuring that the message it implies in the context of the advertisement is not misleading.

The Appeals Committee was not persuaded that corrective advertising was required. Whilst the Appeals Committee did not agree that the amended advertisement that included a reference for the tagline resolved the breach found, it considered that the Code of Conduct Committee was unduly influenced by taking into consideration the advertisement of 2 April 2004 in requiring corrective advertising. The Appeals Committee concluded that the requirement for a corrective advertisement should be set aside.

## Avandia (747)

*Promotional materials for healthcare professionals*

## Complaint

A complaint was received from Servier Laboratories (Australia) Pty Ltd (Servier) alleging that GlaxoSmithKline Australia Pty Ltd (GSK) was in breach of Sections 1.1, 1.3 and 3.3.1 of the Code in relation to a campaign for Avandia. Servier alleged that the materials had the potential for inappropriate PBS prescribing.

## Response

A response was received from GSK denying that it had breached the Code of Conduct. GSK maintained that the purpose of the material was to provide advice to prescribers following the complex PBS listing of Avandia.

## Committee Ruling

### Misleading table content

The inclusion of contraindications for sulphonylurea and metformin such as "Hepatic impairment" and "ketoacidosis" under the table heading 'Contraindications' implied that Avandia could be prescribed in the presence of these conditions whereas the Avandia approved PI states "Avandia is not recommended in patients with moderate to severe hepatic impairment". The table was therefore considered misleading.

On review of the sulphonylurea approved PIs, the Committee agreed that the risk of acute attacks of porphyria was not listed as a contraindication for these products.

Members were of the view that this misleading information was a severe breach of the Code. The Committee unanimously found the table to be in breach of Sections 1.1 and 1.3 of the Code.

### Factually incorrect table

The Committee referred to the information on sulphonylureas and metformin in the Australian *Medicines Handbook*, which GSK had stated was the source of the table information. It was noted that only two contraindications were listed for sulphonylureas. The text then refers to "special considerations" which includes "severe renal

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impairment” for which dosage adjustment may be required. This precaution is not equivalent to a contraindication as stated in the Avandia Body Balance Program book.

The Committee further noted that the listing of “renal impairment” as a contraindication in the table was not a correct representation of “severe renal impairment” as stated in the sulphonylurea PIs. The Committee unanimously confirmed its view that the table was in breach of Sections 1.1 and 1.3 of the Code.

### Misleading table presentation

The Committee was of the view that the table ‘List of Contraindications and Intolerances’ was not referenced to the Australian Medicines Handbook and gave the impression that the page titled “Avandia PBS authority listing” including the table was a direct quotation from the Schedule of Pharmaceutical Benefits rather than a company generated table. Members unanimously agreed that this was a breach of Section 1.3 of the Code.

### Unbalanced negative statements

While acknowledging GSK’s claim that the table was designed as a guide for healthcare professionals to assess patients for eligibility for Avandia under the authority conditions listed in the PBS book, members considered that it was unbalanced to omit information about the contraindications, precautions and warnings for Avandia from the Body Balance Program book. The Committee unanimously considered that the book was therefore unbalanced and misleading and in breach of Section 1.3.

In relation to the Servier’s complaint that the PI was not offered to healthcare professionals, GSK denied this in their response, advising that all healthcare professionals were offered the PI whenever the Body Balance Program booklet was provided. The Committee found this complaint unproven.

### Technical breach

While it was clear that the Avandia Body Balance Program book provided detailed information about the PBS listing and authority requirements for Avandia, there was no PBS box on the book as required in the Code. The Committee was of the view that as the Avandia Body Balance Program book was an item of printed promotional material it should contain the PBS box and was therefore in breach of Section 3.3.1.2 (e).

## Sanction

The Code of Conduct Committee resolved that GSK should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form. GSK was also directed to instruct their medical representatives to retrieve the Avandia Body Balance booklets from healthcare professionals.

The Committee also resolved that GSK should send a corrective letter to all doctors who had received the Avandia Body Balance Program book. It was further resolved that a corrective advertisement should be placed in Australian Doctor Weekly and Medical Observer.

## Appeal

An appeal was lodged by GSK against the findings of the Code of Conduct Committee. GSK objected to the finding of a severe breach and the extent of the penalties imposed.

## Appeals Committee ruling

Members of the Committee were of the view that the impact of the Body Balance Program seemed minimal and did not warrant a finding of a severe breach. The Authority requirements were very tough and doctors phoning the HIC for an authority for Avandia would certainly be advised and refused authority if the proposed use was inappropriate.

However, the onus is on GSK to provide accurate and balanced information to healthcare professionals especially as the information was the only information available to doctors because it had not been able to be included in the November 2003 edition of the Schedule of Pharmaceutical Benefits.

Members did note that the PBB did not request any amendments to the Body Balance Program book following their review. In relation to safety implications, these, too, were minimal. The Committee noted that while some general practitioners may not be aware of the contraindications to the glitazones, specialists would certainly have this knowledge.

While agreeing that the material was in breach of Sections 1.1, 1.3, 1.5 and 3.3.1.2(e), clearly the Code of Conduct Committee did not have the same information available to it to inform its decision. The Appeals Committee was of the

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view that the finding of a severe breach should be removed and the sanction amended.

## Sanction

Having agreed that the finding of a severe breach should be removed, the Appeals Committee agreed that the requirement for a corrective advertisement should also be removed. However a corrective letter should be sent to all healthcare professionals who had attended the education seminars for the Body Balance Program advising them that the material had been found in breach of the Code and correcting the information found in breach. The letter should also request healthcare professionals to destroy any materials containing the information found in breach of the Code.

The Appeals Committee was of the view that it was appropriate that the material found in breach should be withdrawn and not used in a manner that conveys the same or similar meaning. This applied to any items where the same information may appear.

## Levitra (753)

*Website for the general public*

## Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Bayer Australia Pty Ltd (Bayer) and GlaxoSmithKline Australia Pty Ltd (GSK) were in breach of the Medicines Australia Code of Conduct. The TGA was of the view that by including the name of a prescription medicine on the website providing information about erectile dysfunction problems this was specifically advertising Levitra. The TGA also referred to the encouragement in the website information to contact a doctor to receive a starter pack. Bayer and GSK were requested to respond to the complaint under Sections 3.9 (excluding 3.9.2), 9.3, 9.4, 9.5 and 9.8 of the Code.

## Response

A response was received from Bayer and GSK denying that they had breached the Code of Conduct. Bayer & GSK maintained that the website site was educational and access to the patient site *"Click here if you have been prescribed Levitra (vardenafil) or have received a starter pack from your doctor"* was only available to patients who had been prescribed the product (who are required to enter the product barcode) thereby complying with the requirements of the Code. Bayer & GSK had agreed to remove the product name and include a more general statement *"Click here if you have been prescribed an ED treatment or have received a starter pack from your doctor"*.

## Committee Ruling

Members considered that there should be no promotion of a specific prescription medicine in association with a disease state website or educational information. In relation to the box containing *"Click here if you have been prescribe Levitra (vardenafil) or have received a starter pack from your doctor"* the Committee considered that reference to Levitra should be removed because it may be considered to be promoting that product to members of the general public. The Committee noted that Bayer and GSK had already agreed to remove the product name from the website.

Members also noted several statements under *"Treatment Options"* on the website which they considered tended towards being promotional

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rather than being purely educational, such as:  
*You should consider the following aspects in relation to achieving an erection with treatment:*

1. ...
2. ...
3. *Your treatment should work first time and time after time*
4. *Your treatment should work when you want it to work*

The Committee requested that Bayer and GSK review the website and ensure that no statements were included that could be construed as being promotional.

Members commented that the website did not recommend readers to *“ask your doctor for a starter pack”*. The website stated *“For more information ask for a performance pack”* and then provided information on contents of the Performance Pack.

In relation to the contents of the Performance Pack, some members were of the view that the provision of the included discount voucher could be regarded as an inducement to request the Performance Pack. Members also raised some issues in relation to the questions asked in the included survey form that readers were asked to complete in return for a \$10 Roses Only Gift Voucher. While noting that it was voluntary to respond to the survey, it was the relevance of the questions to patient education that concerned the Committee. Members were of the view that promoting the Performance Pack could be regarded as a surrogate for promoting the product because one version of the Performance Pack (which was provided to doctors) contained a starter pack.

In relation to the “Roll in the hay” website, the Committee found it in breach of Sections 3.9.1, 9.4 and 9.5.2 of the Code as the use of a product name Levitra within a disease awareness website may be considered to be promotion of a specific prescription medicine. The Committee was of the view that it may not be sufficiently clear to companies that they should not include the name of a specific prescription medicine on a disease awareness website even under the circumstances of providing a link to password protected product-specific information. The Committee found no breach of Section 9.8 of the Code in relation to the information provided on the website.

The Committee requested that Medicines Australia provide further guidance to members in relation the use of product names on disease state websites.

## Sanction

The Code of Conduct Committee resolved that Bayer and GSK should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

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## Pfizer Health Report (754)

Information to the General Public via a Website

### Complaint

A complaint was received from the Consumers' Health Forum (CHF) alleging that Pfizer Australia Pty Ltd (Pfizer) was in breach of Section 9.5.1 of the Medicines Australia Code of Conduct. CHF was of the view that the use of *"your growing one stop shop for information on health issues"* was not a balanced and accurate assessment of the breadth of health information currently available in Australia.

### Response

A response was received from Pfizer denying that it had breached the Code of Conduct. Pfizer maintained that the likelihood that a consumer who accessed the site would take this statement as a literal claim of universality was extremely small. While maintaining that the site was educational Pfizer agreed to remove the reference to "one stop shop" from their website.

### Committee Ruling

The Committee noted that the CHF complaint related to the use of the claim that the website was a *"one stop shop"* on the Pfizer Health Report website. Members agreed that this was hyperbole and noted that Pfizer had already removed the words from their website.

By a majority the Committee found no breach of Section 9.5.1 of the Code as the information in the Health Report was considered to be current accurate and balanced. The Committee requested that Medicines Australia provide advice to members that there was no room for puffery or hyperbolic statements in information to members of the general public or indeed to healthcare professionals.

## NovoMix 30 (755)

Information to members of the General Public

### Complaint

A complaint was received from a healthcare professional alleging that Novo Nordisk Pty Ltd (Novo Nordisk) was in breach of Sections 9.2.3 and 10 of the Medicines Australia Code of Conduct. The healthcare professional stated that a representative from Novo Nordisk had actively promoted his company's new insulin mix to members of the general public. Novo Nordisk was requested by the Medicines Australia Secretariat to also respond to the complaint under Sections 9.4, 9.5, 9.6 and 9.8 of the Code.

### Response

A response was received from Novo Nordisk accepting that it had breached Section 9.4 but denying that it had breached other sections of the Code of Conduct. Novo Nordisk maintained that the representative had acted contrary to company policy and that this action was taken very seriously by the company and corrective action was taken.

### Committee Ruling

#### Section 9.4

The Committee accepted the explanation provided by Novo Nordisk that a company representative had breached Section 9.4 of the Code by discussing a prescription medicine with a member of the general public. Any occasion where a company representative may have access to patient details was viewed by members of the Committee as a severe breach of patient confidentiality. The Committee commented that there did not appear to be any inducements to the pharmacist to provide a mailing list or facilitate the meeting in terms of financial or material benefits.

In relation to the use of the NovoMix Patient Information sheet at the insulin information meeting, this was considered to be promotion of a particular prescription medicine to members of the general public and was also regarded as a severe breach of Section 9.4 of the Code.

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### Section 9.2.3

The Committee was of the view that Section 9.2.3 of the Code was not relevant to the complaint as there had been no media release issued and found no breach of this section.

### Section 9.5

Members considered the NovoMix Patient Information sheet and were of the view that this was not an item of Patient Education as defined by the Code. Rather the material was a product specific patient aid that had been incorrectly used by the representative. No breach of Section 9.5 of the Code was found.

### Section 9.6

This section of the Code relates to Patient Aids with the intention that product specific information is only provided to a patient once a decision has been made to prescribe a specific prescription medicine. Members were of the view that as the NovoMix Patient information sheet was comparative, albeit between two Novo Nordisk products, it would not be suitable for distribution as a Patient Aid. In Novo Nordisk's response the item had been classified as a consultation aid for healthcare professionals to use when explaining the decision to change from the Novo Nordisk Mixtard 30/70 to NovoMix 30. It was also noted that the Patient Information sheet contained a statement that

*"This patient information should only be given to patients by healthcare professionals. Verbal or written advice from healthcare professionals supersedes information provided herein."*

The Committee found a breach of Section 9.6 as the Patient Information sheet contained comparative promotional statements and there was insufficient information on the contraindications, precautions etc as required by Section 9.6. The breach also related to the incorrect use of this item.

### Section 9.8

Members were of the view that these activities were severe breaches of the Code of Conduct and as such are likely to bring the industry into disrepute. A breach of Section 9.8 of the Code was found by the Committee.

Members noted that Novo Nordisk had taken corrective action within the company and provided additional training to the representatives in this field. The matter of senior management responsibility was also discussed. The Committee considered that Novo Nordisk managers must take responsibility for the

activities of their staff and ensure adequate training and updates.

## Sanction

The Code of Conduct Committee resolved that Novo Nordisk should pay a fine of \$50,000 and refrain from undertaking activities with the general public of a similar nature. The Patient Aid found in breach should be promptly withdrawn and should not be used again in the same or similar form.

The Committee requested that Novo Nordisk write to the healthcare professional and the pharmacy where the activity had taken place apologizing for this breach of the Code of Conduct. In this letter Novo Nordisk should acknowledge the breaches of the Code and advise that they have undertaken additional training and that this activity will not happen again.

The Committee also requested that Medicines Australia write to the Pharmaceutical Society of Australia (PSA) and the Pharmacy Guild of Australia (PGA) explaining that Medicines Australia had recently upheld a complaint in relation to a medical representative obtaining patient details from a pharmacist in order to send invitations to an educational meeting on a particular prescription medicine and that the activity had been found in breach of the Medicines Australia Code of Conduct. The letters should seek the support of the PSA and Guild in emphasising the requirements for patient confidentiality and adherence to the Pharmacists professional code of practice.

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# Pfizer Meeting (756)

*Invitation to meeting for healthcare Professionals*

## Complaint

A complaint was received from a healthcare professional alleging that an invitation to a meeting organised by Pfizer Australia Pty Ltd (Pfizer) was in breach of Sections 6.2.1, 10.2, 10.4 and 10.5 of the Medicines Australia Code of Conduct. Pfizer was requested by the Medicines Australia Secretariat to also respond to Sections 6.5, 7.1.2 and the preamble to Section 10 of the Code. The healthcare professional alleged that the proposed payment of \$500 was excessive for participating.

## Response

A response was received from Pfizer denying that it had breached the Code of Conduct. Pfizer maintained that the invitations were sent to clinical leaders in the fields of rheumatology, cardiology and gastroenterology. The honorarium was for participation in the multidisciplinary round table discussion relating to the selective COX-2 inhibitors.

## Committee ruling

Members commented that it was not clear how many Celebrex Roundtable meetings were to be held around the country, although the invitation letter suggested that there would be at least one in each State. The Committee was of the opinion that the invitation was fairly impersonal and appeared to have been sent to many rheumatologists rather than the usual form of invitation to an Advisory Board, which targets specific people and confirms prior discussions about the person's interest and availability. The use of passive language in the invitation eg 'attend' was not indicative of active participation or providing valuable feedback to the company. While the opening sentence of the letter mentions a roundtable meeting, overall the invitation gave the impression that it was to one of a series of meetings where two experts would provide an update on new data in areas of cardiology, gastroenterology and rheumatology to healthcare professionals. The majority of the Committee was also of the view that it was not usual to have Advisory Boards in every state, but rather to have one national Advisory Board.

The Committee also considered that the agenda for the roundtable meetings provided in Pfizer's response to the complaint did not provide sufficient evidence to persuade the Committee that the roundtable meetings were Advisory Board meetings.

Members were concerned that the excessive use of Advisory Boards could be used by companies as a vehicle for paying healthcare professionals to attend educational meetings.

In relation to the offer of payment of \$500 for attendance, members were of the belief that for a genuine Advisory Board meeting this fee would have been appropriate remuneration for an evening meeting of 3 hours duration. However no timeframe or agenda was included with the invitation.

Members of the Committee were of the view that Sections 6.2.1, 6.5, 7.1.2 and 10.2 of the Code were not relevant to the complaint and found no breach of these Sections.

### Section 10.4

The Committee was unanimous in its decision that this invitation offering payment of \$500 was in breach of Section 10.4 of the Code as the payment could be regarded as exceeding a level commensurate with the service provided. The Committee was not persuaded that the invitation was to actively participate and contribute knowledge to an Advisory Board, but was to an educational meeting. The letter of invitation was not clear that the payment was for being a member of an Advisory Board.

### Section 10.5

By a majority the Committee found no breach of Section 10.5 of the Code but expressed concern that this activity did have the potential to bring the industry into disrepute and that Medicines Australia should reinforce these views to member companies. Members also commented that if companies were to use Advisory Boards as a way of circumventing the Code it would be considered a severe breach of Section 10.5. The Code was intended to ensure a level playing field and there should be no financial inducements to attend educational meetings.

## Sanction

The Code of Conduct Committee resolved that Pfizer should pay a fine of \$50,000 and refrain from repeating the same or similar offer.

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## Appeal

An appeal was lodged by Pfizer against the findings of the Code of Conduct Committee. Pfizer indicated that they were appealing on the grounds that their strategy was to invest in getting advice from a cohort of people to explain how doctors would respond to the conflicting information and to understand the impact of the medico-political, safety and efficacy issues that had developed post launch. The Celebrex Advisory Board had been dissolved, and therefore was not available to consult. Pfizer had also identified regional issues and the need to assist in developing CME educational programs for GP's. The intention was to prepare Round Table members to facilitate GP meetings.

## Appeals Committee ruling

The Committee questioned the requirement for a Confidentiality Agreement to be signed by participants when the papers provided were all published studies and data. Members agreed that clarification should be sought from the Pfizer representatives.

In reviewing the letter of invitation on which the complaint was entirely founded, members were of the view that it used passive language and was not what is usually expected of an invitation requesting a healthcare professional to become a member of an Advisory Board.

Pfizer advised that they had received very positive feedback from all attendees at the five meetings.

Pfizer argued that the Pfizer 'Round Table Meetings' were more closely aligned with an Advisory Board than an educational meeting and that the honorarium paid to participants was appropriate to the service provided, which included:

- Pre-reading (2 hours)
- Attend meeting (3 hours)
- Review minutes (1 hour)

Further, feedback from the specialist participants was that the honorarium was either appropriate or too low. Also, the Code of Conduct Committee had considered the amount appropriate, if the meetings were an Advisory Board.

Following questions from members of the Committee Pfizer reiterated that this series of 'Round Table Meetings' were different to the regular educational meetings that Pfizer might conduct to provide information on Celebrex in that for the 'Round Table Meetings':

- Not all invitees were prescribers of Celebrex eg cardiologists, gastroenterologists,
- There was a Confidentiality Agreement to be signed by attendees as material provided at the meeting (not the published pre-reading materials) was confidential
- Significant amount of pre reading materials - at least 2 hours
- Degree of interaction required by attendees
- Number of attendees considerably smaller than an educational meeting
- Extensive commentary from attendees - reflected in the minutes of the meeting
- While not a single meeting, as may be more usual for an Advisory Board, this series of meetings reflected the differences in opinion in each state and required more in-depth commentary from each state
- The focus of the meeting was on providing Pfizer with advice and not Pfizer telling healthcare professionals about their product.

Members commented that while they appreciated the environment of concern in relation to Celebrex there was still disquiet that five meetings had been held and a significant number of healthcare professionals had been invited to attend that did not appear to be opinion leaders. Pfizer asserted that many of the people invited had published a paper or had a particular point of view and this was necessary to cover the breadth of the issues in relation to the safety and efficacy for Celebrex. Pfizer wished to get a range of opinions from different medical disciplines. If these meetings had been educational meetings, many more meetings would have been conducted, a significantly greater number of people would have been invited to attend and no payments would have been made to healthcare professionals. In Pfizer's opinion the Code of Conduct Committee had made a number of assumptions without being fully conversant with all the aspects of the 'Round Table Meetings'.

Members commented that many educational meetings have a requirement for pre-reading or post meeting activities, especially when there are CPD points allocated by the RACGP. The general consensus was that this requirement was not sufficient to differentiate between an Advisory Board meeting and an educational meeting.

In relation to the use of a Confidentiality Agreement at this series of 'Round Table Meetings' for Celebrex, members commented that it was a normal that a Business Agreement be signed by members of an Advisory Board.

Members also commented that the actual invitation and the use of the name 'Round Table Meeting' was confusing as the implication from the tone and the passive language used perhaps did not confer the actual purpose of the meetings.

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While not disagreeing that the matters of safety and efficacy were of extreme importance to Pfizer and many healthcare professionals, the Committee was of the view that Pfizer should have taken more care in the preparation of the invitation and in their response to the Code of Conduct Committee. One member of the Committee stated there have been other 'Round Table Meetings' held by companies to discuss matters of importance but these have not been portrayed as Advisory Boards or attracted an honorarium. It was further noted that Advisory Boards usually comprise a smaller number of members with each having a role in relation to particular scientific aspects and that the Advisory Board is usually disbanded following the launch of a product.

Members commented that this was a unique set of circumstances and any decision in relation to a finding in this case should not set a precedent for any future complaints. The 'Round Table Meetings' were distinct from older style educational meetings which may have been quite didactic, but in terms of what is expected of a more modern educational meeting the Pfizer meetings may straddle the middle ground between an Advisory Board and an educational meeting and members were of the view that the Code may not be sufficiently clear to find a breach.

Members of the Committee agreed that based on the invitation alone and the information provided by Pfizer to the Code of Conduct Committee it was understandable that the Committee found a breach of Section 10.4 of the Code, particularly in relation to the language used in the invitation. Pfizer had conceded to the Appeals Committee that the invitation may have given a misleading impression regarding the actual content of the 'Round Table Meetings'.

The Committee concluded that given the concerns previously expressed, the potentially grey area of the Code and the additional information provided by Pfizer, the appeal should be upheld. While finding no breach of Section 10.4 of the Code, the Committee stated that they were upholding the appeal on the basis of what Pfizer had now disclosed about the conduct of the meetings.

Members encouraged Pfizer to review their internal processes to ensure that the content and purpose of any future meetings were more clearly enunciated to invitees and to distinguish between educational meetings and Advisory Board meetings.

## Sanction

The Appeals Committee agreed that as the appeal had been upheld the requirement that Pfizer pay a fine of \$50,000 should be withdrawn.

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# Puregon Pen (757)

*Promotional materials to healthcare Professionals*

## Complaint

A complaint was received from Serono Australia Pty Ltd (Serono) alleging that Organon Australia Pty Ltd (Organon) was in breach of Sections 1.1, 1.3, 1.6, 1.7, 3.1.2.2 and 3.1.2.3 of the Medicines Australia Code of Conduct. Serono contended that the Puregon Pen was a delivery method for Puregon and fell within the Medicines Australia definition of a 'product' and therefore all marketing should comply with the Code.

## Response

A response was received from Organon denying that it had breached the Code of Conduct as the Puregon Pen was a device and therefore not subject to the provisions of the Code of Conduct. Organon provided evidence of the TGA approval of the Puregon Pen as a device.

## Committee ruling

The Committee was advised that the Puregon Pen was registered as a device by the TGA and had also received approval to advertise the Puregon Pen in relation to a restricted representation under s.42DF (1) of the Therapeutic Goods Act 1989.

In granting an exemption for the use of a restricted representation under s.42DF (1), the TGA considered:

- Information must be accurate and balanced
- Information must not be misleading
- Information should be in the public interest

In granting an exemption under this Section of the Act, TGA was not empowered to take into account whether advertising the device was equivalent to advertising the prescription medicine delivered by the device. In addition the TGA was required to take into consideration advice from the Therapeutic Goods Advertising Code Council (TGACC) which had included the consumer view that consumers had a right to be advised of this new IVF drug delivery device.

After reviewing the definition of 'product' in the Code the Committee discussed whether the Therapeutic Goods Act and the Code of Conduct

may conflict in this instance, however members considered that the Code can be more restrictive than any requirement under the legislation.

Members were of the view that while the TGA had granted an exemption for the BD Pen Injector II (Puregon) branded as the 'Puregon Pen' to be advertised directly to consumers for infertility, any advertisement to healthcare professionals should still comply with the Medicines Australia Code of Conduct. Because the Puregon Pen can only be used to administer Puregon, an advertisement for the Puregon Pen was a surrogate for advertising the prescription medicine Puregon.

## Reduce the pain of IVF

Organon had been advised by the TGACC that it had some concern that the claim "Take the pain out of IVF" was misleading because it did not specify that the reduction in pain related to reduction in the pain of injection. Organon had agreed to amend the advertisement to "Reduce the injection pain of IVF".

The Committee was of the view that at the time of publication the advertisement did not make it clear that the reduction in pain related to injection pain and was therefore misleading and implied a misleading comparison with other injectable IVF treatments. The claim was found in breach of Sections 1.3 and 1.7 of the Code. No breach of Section 1.1 was found.

## Introducing the Puregon Pen

Members commented that Section 1.6 specifically refers to use of the word 'new' and not synonyms for new. It was the Committee's view that 'introducing' could have several different meanings that did not necessarily imply something is 'new'. The Committee found no breach of Section 1.6 of the Code as it did not fail the literal test of 'new'.

## Now available at all fertility clinics through Australia

The Committee was of the view that this statement was hyperbolic but the Puregon Pen was potentially available at all fertility clinics and therefore found no breach of Sections 1.3 or 1.6 of the Code.

## Secondary Advertisements

As the Committee had earlier ruled that the Code should apply to this advertisement, the requirements for journal advertising should be adhered to. The committee found a breach of Sections 3.1.2.2 and 3.1.2.3 of the Code as information required by these Sections of the

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Code had not been included in the advertisement.

## Sanction

The Code of Conduct Committee determined that Organon should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form. The Committee also resolved that Organon should pay a fine of \$5,000.

## Humira (758)

*Promotional materials to healthcare Professionals*

## Complaint

A complaint was received from Wyeth Australia Pty Ltd (Wyeth) alleging Abbott Australasia Pty Ltd (Abbott) was in breach of Sections 1.2.2 and 1.3 of the Medicines Australia Code of Conduct. Wyeth alleged that the claims were based on two poster presentations and the graphical representations were not supported by the abstract used as a reference.

## Response

A response was received from Abbott denying that it had breached the Code of Conduct. Abbott maintained that the claims were referenced for convenience to the abstract and that the major claim formed part of the TGA approved PI.

## Committee ruling

Members of the Committee were of the view that any claim, whether considered a major or minor claim by a company, which would significantly influence how a medicine was prescribed or dispensed should be supported by the highest level of evidence available. Abbott Australasia had accepted that the claim "*Proven to inhibit radiographic progression*" was a major claim.

The Committee agreed that it is not prohibited to use an abstract or poster which had not undergone significant peer review or been accepted for publication, but an abstract or poster must not be the sole supporting evidence for a promotional claim. Members noted that the data from the abstract had been revised during peer review prior to publication. While on this occasion the minor change in the numerical data did not alter the study conclusions, it is further reason why companies should be cautious about using abstracts or posters to support promotional claims. The Committee accepted that the data for the 1-year, double-blind, randomised, controlled trial had since been published, however the data from the open-label extension is only available in the abstract and poster. Members noted that the one year data as published was included in the Humira PI and that the claims were consistent with the PI. The open label extension study was not included in the PI or in the published paper.

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Members commented that there was no mention of a p-value in the abstract, while the Abbott Humira poster quotes a p-value of  $p < 0.001$  for Humira plus methotrexate versus placebo + methotrexate for the change in total sharp scores.

The Committee was of the view that the claims *“Proven to inhibit radiographic progression”, “No significance increase in mean JSN and joint erosion scores” and “No radiographic progression in majority of patients”* in association with graphical representation of the two year open label data were referenced to an abstract as the sole supporting evidence and were therefore in breach of Section 1.2.2 of the Code.

The Committee was of the view that in light of the different numerical data presented in the referenced original abstract, the updated abstract, the published paper and adaptation in the Abbott poster in relation to the change in total sharp score over time, the company poster presentation was misleading. The Committee therefore found a minor breach of Section 1.3. The Committee noted that the overall thrust of the claims were consistent with the Humira PI.

## Sanction

The Code of Conduct Committee resolved that Abbott should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

The Committee having determined that corrective action was not required nevertheless imposed a fine of \$5,000.

## Efexor-XR (759)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from the Pfizer Australia Pty Ltd (Pfizer) alleging that Wyeth Australia Pty Ltd (Wyeth) was in breach of Sections 1.3 and 1.7 of the Medicines Australia Code of Conduct. Pfizer alleged that the description of the clinical effectiveness of Efexor-XR and linked claims ‘dual action’ and ‘dual action efficacy’ were not supported by the highest level of evidence.

### Response

A response was received from Wyeth denying that it had breached the Code of Conduct. Wyeth contended that the use of the words ‘dual action’ was an acceptable non-comparative descriptor.

### Committee ruling

Members of the Committee questioned the meaning of “dual action efficacy” and were concerned that healthcare professionals could be misled that the unqualified superlative meant having a dual action on anxiety and depression as well as a dual pharmacological action on serotonin and noradrenaline reuptake.

In referring to the approved PI, members noted that in the Pharmacology section it is stated that “preclinical studies have shown that venlafaxine and its major metabolite, O-desmethylvenlafaxine (ODV), are potent inhibitors of serotonin and noradrenaline reuptake, and also inhibit dopamine reuptake”.

In reviewing the conclusions from referenced papers, members considered that while it is acceptable to state that there is a dual pharmacological action, there is insufficient evidence to support a claim or inference that the dual pharmacological action determines greater clinical efficacy than SSRIs.

Members commented that efficacy specifically refers to the ‘amount of effect’ and that the term was frequently misused. It was quite reasonable to say that it is a serotonin-noradrenalin reuptake inhibitor, it was not correct on current evidence to infer this dual pharmacological action related to efficacy advantages or uniqueness.

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The Committee unanimously found that as there was insufficient clinical evidence that the dual pharmacological action on serotonin-noradrenalin reuptake specifically confers a clinical benefit, the claim “dual action efficacy” was in breach of Section 1.3 of the Code.

The Committee did not find that the claim was comparative and found no breach of Section 1.7 of the Code.

## Sanction

The Code of Conduct Committee resolved that Wyeth should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

The Committee determined that corrective action was not required, however imposed a fine of \$15,000.

## Appeal

An appeal was lodged by Wyeth against severity of the fine imposed by the Code of Conduct Committee. Further Wyeth was concerned that the minutes of the Code of Conduct Committee meeting did not make any reference to the fact that Wyeth had agreed to cease using the term ‘dual action efficacy’ in intercompany dialogue with Pfizer Australia. Wyeth inferred that the Code of Conduct Committee did not give this fact due consideration in their adjudication of the complaint.

Wyeth was also concerned that the Code of Conduct Committee had made a judgment in relation to a matter which was not subject to complaint by Pfizer Australia and which Wyeth had not had the opportunity to respond to.

## Appeals Committee ruling

Wyeth stated that as the claim was not comparative, there was no mention of an unqualified superlative and giving consideration to previous fines imposed by the Code of Conduct Committee the fine of \$15,000 was unreasonable and should be reduced.

Pfizer agreed that Wyeth and Pfizer had reached some degree of resolution on this complaint in intercompany dialogue but Pfizer was not totally satisfied with the outcome and therefore had lodged a complaint with Medicines Australia.

In relation to the reference to an unqualified superlative in the minutes, Pfizer acknowledged this was not part of the original complaint to Medicines Australia.

Pfizer maintained that the core of the complaint in relation to ‘dual action efficacy’ was the existence of a paper which refuted the concept of dual action efficacy. This was an independent study which concluded “this analysis does not provide evidence that antidepressants acting at more than one pharmacological site differ in efficacy from drugs selective for serotonin reuptake in the treatment of major depression.”

Some members of the Committee were of the view that once companies reach an agreement during intercompany dialogue a complaint should not be brought to the Code of Conduct Committee. However other members commented that, as in this case, full agreement may not be reached and the complainant is entitled to have the matter considered by the Code of Conduct Committee. Members agreed that this complaint was more about possible future activities, as there appeared to have been agreement on the withdrawal of the claims.

Some healthcare professional members of the Appeals Committee commented that the claim ‘dual action efficacy’ has been the primary marketing tool for Efexor-XR although the claim was not supported by the literature.

Members commented that it is acceptable to state how a drug is believed to work, but should not link this pharmacological action to efficacy. The Appeals Committee agreed with the Code of Conduct Committee that the material was in breach of the Code.

As the Appeals Committee was uncertain whether the Code of Conduct Committee had taken into consideration that Wyeth had agreed not to use the claims ‘dual action efficacy’ and ‘dual action’ in future promotional materials, it was reasonable that this Committee reconsider the severity of the fine.

In addition, as the minutes had included a reference to the claim being an unqualified superlative which was not part of the complaint from Pfizer Australia, and this may have contributed to Wyeth’s reasons for lodging an appeal, the Appeals Committee determined that the amount of the fine should be reduced.

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## Sanction

Due to the uncertainty about what weight, if any, the Code of Conduct Committee had given to the undertaking by Wyeth to not use either claim in future promotional materials, and that minutes of the meeting in the form received by Wyeth were inaccurate in their reference to the claim being an unqualified superlative, the Appeals Committee considered that the fine of \$15,000 as proposed by the Code of Conduct Committee should be reduced to \$14,000. The Committee considered such a level of penalty was not out of line either with the range prescribed by the Code, or with penalties which had been imposed in the past for this type of conduct.

## Recombinate (760)

*Information to members of the General Public*

### Complaint

A complaint was received from Bayer Australia Pty Ltd (Bayer) alleging that Baxter Healthcare Pty Ltd (Baxter) was in breach of Sections 9.4 and 9.8 of the Medicines Australia Code of Conduct. Bayer was concerned that a representative from Baxter had contacted the parent of a patient with Haemophilia A.

### Response

A response was received from Baxter denying that it had breached the Code of Conduct. Baxter commented that they had undertaken an intensive investigation and were satisfied that no one from Baxter had contacted any patient or their family.

### Committee Ruling

In reviewing the email from the member of the public supplied by Bayer and the response from Baxter members were of the view that there was insufficient evidence at this time that Baxter had undertaken the alleged conduct. The alleged breaches of Sections 9.4 and 9.8 of the Code were not proven.

Members raised concern in relation to privacy of the member of the public and whether their consent had been provided to forward the e-mail to Baxter and the Code of Conduct Committee.

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## Levitra (761)

*Information to members of the general public*

### Complaint

A complaint was received from Pfizer Australia Pty Ltd (Pfizer) alleging that Bayer Australia Pty Ltd (Bayer) and GlaxoSmithKline Australia Pty Ltd (GSK) were in breach of Sections 3.9.1, 9.4 and 9.5 of the Medicines Australia Code of Conduct. Pfizer alleged that the campaign amounted to specific promotion of Levitra to the general public.

### Response

A response was received from Bayer and GSK denying that they had breached the Code of Conduct. Bayer and GSK maintained that the campaign was designed to raise awareness of erectile dysfunction and to encourage men to go and see their doctor for more information.

### Committee Ruling

The Committee stated that there should be no promotion of a specific prescription medicine in association with a disease state website or educational information.

In relation to the box containing “Click here if you have been prescribed Levitra (vardenafil) or have received a starter pack from your doctor” the Committee considered that reference to Levitra should be removed because it may be considered to be promoting the product to members of the general public. The Committee noted that Bayer and GSK had already agreed to remove the product name from the website.

The Committee found a breach of Sections 3.9.1, 9.4 and 9.5.2 of the Code as the use of a product name linked to a disease state website may be regarded as promoting a specific prescription medicine.

In relation to the offer of the Performance Pack, because there were two versions of the Performance Pack, one including a starter pack, it was possible for a patient who requested a Performance Pack to be given the Pack that contains a starter pack of Levitra. Therefore, the linking of the Performance Pack to the advertising material where there is a version of the Performance Pack that includes a sample of a prescription medicine was in breach of the Code.

(This aspect of the complaint was also discussed in relation to complaint Levitra (753)). The Committee considered that this was a severe breach of the Code as the advertising campaign was effectively promoting a prescription medicine to members of the general public.

Members considered that there should be a clear differentiation between starter packs and educational information for members of the general public, that is, that starter packs should not be packaged together with educational material. The Committee further considered that any educational material promoted to the general public to obtain from a health professional should be easily clearly distinguishable from starter packs provided to healthcare professionals. The Committee noted that Bayer and GSK had agreed to cease distribution of the Performance Pack which contained the starter pack.

In relation to the allegation that the advertisements extended beyond what is considered disease awareness information, the Committee commented that statements such as “Current erection treatment letting you down” and “looking for erection treatments that work” in association with the words “Ask for a Performance Pack”, where there is one version of the Performance Pack that includes a starter pack, was a surrogate for seeking a prescription for a specific prescription medicine.

The Committee found breaches of Sections 3.9.1, 9.4 and 9.5 of the Code.

### Sanction

The Code of Conduct Committee determined that Bayer and GSK should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

In considering the severe breach of Section 9.4 and of Sections 3.9.1 and 9.5.2 of the Code, the Committee members were also cognisant of the issues raised in complaint Levitra 753. Members were of the view that promoting the Performance Pack could be regarded as a surrogate for promoting the product because one version of the Performance Pack contained a starter pack. It was resolved that Bayer and GSK should pay a fine of \$100,000.

### Appeal

An appeal was lodged by Bayer and GSK against the findings by the Code of Conduct Committee

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of breaches of section 9.5.2 and 9.4 and the sanctions imposed. Bayer and GSK strongly disagreed with the finding of a severe breach and that a patient requesting an “information only” Performance Pack could inadvertently be given a Performance Pack containing a Levitra starter pack.

Bayer and GSK argued that a patient does not know what product is associated with the ‘Performance Pack’ nor are they aware that there is a ‘Performance Pack’ containing a starter pack of Levitra. Therefore there was no promotion of a specific prescription medicine to members of the general public and no breach of Section 9.4 of the Code.

In relation to the breach of Section 9.5.2 of the Code, Bayer and GSK maintained that the information in the ‘Performance Pack’ was not focused on a specific prescription medicine. It contained information of a general nature about erectile dysfunction and could be used as a tool to aid consultation with the doctor.

Bayer and GSK had already agreed to cease the supply of the ‘Performance Pack’ containing a starter pack to healthcare professionals.

## Appeals Committee ruling

The Committee accepted that a patient would not know that there were two versions of the ‘Performance Pack’. However Members did make reference to the use of the product name on the website which would have enabled some members of the general public to link the product to the campaign and the ‘Performance Pack’.

The Committee was of the view that it was not a breach of the Code to advise members of the general public to ask their doctor for more information or ask for an information package. The provision of educational information on a particular disease state which does not focus on a particular product was not a breach of the Code. The Committee determined that Bayer and GSK were not in breach of Section 9.5.2 in relation to the ‘Performance Pack’ information as it did not focus on a particular prescription medicine and therefore agreed to uphold this aspect of the appeal.

Members of the Committee considered a company should not produce materials such as a ‘Performance Pack’ containing information only and a ‘Performance Pack’ containing a starter pack plus information with very similar packaging and indicia which may cause confusion for a healthcare professional. Members commented that some doctors may not have been aware that there were two versions of the ‘Performance

Pack’, one containing a starter pack. The potential use of Levitra by a patient after mistakenly receiving a starter pack when the doctor had not assessed the patient for possible contraindications with other medications and discussed the possible risks and side effects could put a patient at risk.

The Code Appeals Committee was not convinced that the Code of Conduct Committee had erred in their finding and did not uphold the appeal in relation to the finding of a severe breach of Section 9.4.

In relation to the Code of Conduct Committee’s comments that information should not be provided with starter packs, the Appeals Committee was of the view that perhaps the minutes did not clearly articulate their concerns. The Appeals Committee considered that it was acceptable to include information with starter packs, but it was essential that there be a clear differentiation between starter packs which contain prescription products together with educational information, on the one hand, and packs which contain only patient education/disease awareness information. In this case the failure of Bayer and GSK to distinguish clearly between the two packs was the cause for concern.

## Sanction

Having considered the appeal and upholding the appeal in relation to Section 9.5.2 and not upholding the appeal against a severe breach of Section 9.4, the Committee reviewed the sanction to ensure that it was appropriate. In view of the concern that patients could potentially receive a ‘Performance Pack’ which contained a starter pack without a conscious decision on the behalf of the doctor, the Committee agreed that a fine was appropriate.

Members considered that the fine of \$100,000 as proposed by the Code of Conduct Committee should remain.

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## Teveten (762)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from a healthcare professional alleging that Solvay Pharmaceuticals Pty Ltd (Solvay) was in breach of the Medicines Australia Code of Conduct. Medicines Australia had requested that Solvay respond to the complaint under Sections 8.1 and 8.2 of the Code. The healthcare professional alleged that the payment to doctors for participating in the program amounted to 'blatant bribery' and was an inducement to prescribe Teveten.

### Response

A response was received from Solvay denying that it had breached the Code of Conduct. Solvay maintained that the program was a Post Marketing Surveillance Study entitled "Observational study of cognitive function associated with the tolerability of Teveten (OSCAR)" and had appropriate protocols and rationale.

### Committee ruling

Members of the Committee discussed various aspects of OSCAR and noted that it was a worldwide study (22 participating countries) and included a detailed protocol, case report forms and doctor agreement/registration forms. It was further noted that the protocol identified that for each doctor five patients would be sought and that they would require three visits (Baseline, Follow Up and Final Patient Visit) to the healthcare professional.

Members also commented on the patient inclusion and exclusion criteria for participation in OSCAR and noted that they seemed appropriate and consistent with the approved PI for Teveten.

The Committee agreed that patients taking part in this study would have had to be recently initiated on Teveten as the baseline measures would not be meaningful if a patient was already stabilised on this medicine. While some members of the Committee were concerned that there could be subtle encouragement to start patients on Teveten, it was generally agreed that if the study provided some further evidence in relation to tolerability, adherence and adverse reactions, the

benefit may outweigh any possible excess in prescribing.

Having agreed that OSCAR was a PMS Study, members of the Committee addressed the concerns of the healthcare professional in relation to the payment to prescribers for participation in the study. It was the unanimous view of the Committee that the payment of \$200 (GST inclusive) per patient was appropriate. Members noted that this payment was calculated using the published AMA rates (November 2003) for Level B and C and that the prescriber was also required to complete 15 pages of data for each Case Report Form (CRF).

In relation to the healthcare professional's concerns that this study was a "blatant bribery scheme" by a healthcare professional making a claim against the HIC for these visits, members of the Committee commented that there was no evidence that Solvay had in any way encouraged this behaviour.

Further, members noted that the OSCAR Study was focused on cognitive function as affected by the tolerability of the product using the Mini Mental State Examination (MMSE) not blood pressure therefore it was quite possible that a doctor may see a newly diagnosed hypertensive patient more frequently than the three visits in six months that are part of the OSCAR Study. Payment for these visits would be considered as part of the normal billing process. Some members of the Committee expressed some concern regarding the ability of the MMSE to provide meaningful results given both the age of the patient population being studied, the relatively short duration of the study and the uncontrolled prospective cohort design. The protocol provided was not reassuring in respect to the analysis; however on balance, the merits of the observational study, if well analysed, would probably be worthwhile.

At the conclusion of the discussion of the study and being unclear as to exactly what information was provided to health care professionals, the Committee encouraged Solvay to ensure that healthcare professionals received the full complement of information to enable them to make an informed decision on taking part in the OSCAR Study.

Having determined that the OSCAR Study fulfilled the requirements of the PMS Study the Committee reviewed each requirement of Section of 8.1 and Solvay's response and agreed that no breach of Section 8.1 or 8.2 should be found.

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## Solian (764)

*Promotional materials to healthcare professionals*

### Complaint

A letter was received from the Therapeutic Goods Administration (TGA) forwarding a complaint received from a medical practitioner concerning an advertisement for Solian by Sanofi-Synthelabo Australia Pty Ltd (Sanofi Synthelabo). The TGA had requested that the Code of Conduct Committee review the complaint under Section 1.4 of the Code. Medicines Australia had also requested Sanofi Synthelabo respond to the complaint under Section 1.3 of the Code. The complainant was of the view that the advertisement was in poor taste and inappropriate to be used in therapeutic advertising.

### Response

A response was received from Sanofi Synthelabo denying that it had breached the Code of Conduct. Sanofi Synthelabo maintained that the advertisement was not in poor taste and, while confronting, the words used had been taken from a personal account by a young person with schizophrenia.

### Committee ruling

Members of the Committee agreed that the metaphor of feeling like you are 'drowning' as applied to patients suffering from schizophrenia or psychosis was not in poor taste and that this feeling had been sourced from a personal account from young patient with schizophrenia.

The Committee found no breach of Section 1.4 of the Code. Members commented that Sanofi Synthelabo could highlight the origin of the metaphor by more clearly referencing the source in *Understanding Troubled Minds*.

The Committee did not consider the advertisement misleading as it was possible that this was how some people suffering from schizophrenia or psychosis may feel. No breach of Section 1.3 of the Code was found.

## Zoloft (765)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from Wyeth Australia Pty Ltd (Wyeth) alleging that Pfizer Australia Pty Ltd (Pfizer) was in breach of Section 1.3 of the Medicines Australia Code of Conduct. Wyeth alleged that Pfizer had previously agreed to withdraw material containing the same claims and that the production of new material with similar breaches constituted a repeat breach of the Code.

### Response

A response was received from Pfizer advising of their acknowledgement of a breach of Section 1.3 of the Code in relation to one aspect of the complaint but denying that they had breached the Code in relation to all other aspects of the complaint. Pfizer also alleged that two points in the complaint were introduced only at a late stage of intercompany dialogue and that this had precluded full discussion that may have achieved resolution to the complaint.

### Committee ruling

#### Placement and presentation of qualifying statements

Members of the Committee noted that Pfizer had acknowledged that the qualifying statement had not been placed on the same page as the claim as required by the Code. The Committee found a minor breach of Section 1.3 of the Code. As this had not previously been subject to a Code of Conduct Committee ruling it was not a repeat breach of the Code.

#### Inconsistency between the "recent MI/unstable angina" claim and qualifying statement

The Committee acknowledged the quality of the SADHART study, which was conducted in patients with a recent MI and no other co morbidities.

Treatment with Zoloft did not induce a greater incidence in any of the surrogate end points (such as effects on the QT interval). However, the Committee did not consider the study was sufficient to support the generalisation to the

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strong claim that Zoloft was an “*excellent choice for patients with a recent MI or unstable angina*”. The Committee was of the view that the use of the word ‘excellent’ in the claim was too strong and was not able to be sufficiently substantiated at this time as further evidence was required.

Some members of the Committee commented that whilst the study is inadequate to support the strong claim, it is useful information to bring to prescribers’ attention. The Committee found a breach of Section 1.3 as the use of ‘excellent’ was an overstatement and an inappropriate generalisation from the referenced study and therefore misleading.

### Inadequate disclosure of study details in the medically ill patient population

The Committee agreed that because of the strength of the claim that Zoloft is an excellent choice in patients with a recent MI or unstable angina, prescribers should have been provided with more information regarding the patients excluded from the SADHART trial, especially the cardiovascular exclusions.

Members agreed that the claim was unbalanced because it was a strong claim that was inadequately qualified by the provision of information on the study’s cardiovascular exclusion criteria. By a unanimous decision the Committee found a breach of Section 1.3 of the Code.

### Inconsistency between claim and Zoloft Product Information

The Committee was of the view that while the SADHART outcomes aren’t contradictory to the PI, it is the strength of the claim based on the study that is inconsistent with the precaution stated in the PI. The fact that the qualifying statement associated with the claim appeared on the wrong page of the promotional material and was hard to find compounded the lack of balance of the claim. The Committee found a breach of Section 1.3 of the Code.

## Sanction

The Code of Conduct Committee resolved that Pfizer should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

The Committee determined that a corrective letter to all healthcare professionals who may have received this promotional item was required.

The Committee also imposed a fine of \$20,000.

## Evista (766)

*Promotional materials to healthcare professionals*

### Complaint

A letter was received from the Therapeutic Goods Administration (TGA) forwarding a complaint received from a medical practitioner concerning promotional material for Evista by Eli Lilly Australia Pty Ltd (ELA). The TGA requested that the Code of Conduct Committee review the complaint under Sections 1.1, 1.2, 1.3, 1.7, 9.4 and 9.5 of the Code. The original complainant maintained that the material was comparative, promotional and direct to consumer advertising.

### Response

A response was received from ELA denying that it had breached the Code of Conduct. ELA maintained that the material was personally handed to doctors and the use and purpose was expressly communicated. It was not intended to be left in doctor’s waiting rooms.

### Committee ruling

The majority of the Committee was of the view that the material would have been intended to be used as a tool for use in discussions between the healthcare professional and a patient once a decision had been made to prescribe a treatment for osteoporosis. However some members of the Committee were concerned that the statement “*The following is a summary of three effective therapies for osteoporosis. Please take a moment to discuss each with your doctor.*” could imply that a patient would have accessed this item prior to seeing their doctor and hence it could be argued that this material might be promotional. In noting that the magazine jacket contained promotional claims with a tear off patient education item inside, members encouraged ELA to take more care to highlight or emphasis that this material was for healthcare professionals only and should not be placed in the waiting room. It was suggested that a statement in bold print to this effect would be a useful addition to this material.

Although agreeing that the material contained in the tear off page may be of value to a patient, the Committee was concerned that it should not be left where members of the general public could access it without the advice of a health care professional. The Committee noted the circumstances described in the letter of complaint

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but considered that in the absence of any other complaints this could have been an isolated incident and not habitual behaviour on the part of ELA. The Committee speculated that the material might have been placed in the waiting room in error by practice staff.

### Section 1.1

The Committee did not find a breach of Section 1.1 as members were of the view that the material was balanced and discussed all potential treatments for osteoporosis and was supported by the PI.

### Section 1.2

No breach of Section 1.2 of the Code was found although members of the Committee did raise some concern in relation to the claim “cardiovascular risk reduction” however members noted that there is reference in the approved PI that raloxifene had a significant effect on a number of cardiovascular factors that are associated with atherosclerotic cardiovascular disease.

### Section 1.3

The Committee did not find a breach of Section 1.3 of the Code as members did not consider the material to be false or misleading.

### Section 1.7

The Committee did not consider that the comparisons between products was misleading or was unfair to the competitor products and found no breach of Section 1.7 of the Code.

### Section 9.4

The Committee was of the view that when used appropriately i.e. by the healthcare professional in consultation with a patient following a decision to prescribe Evista, this material was not encouraging a patient to seek a prescription for a specific prescription medicine and was therefore not in breach of Section 9.4 of the Code.

### Section 9.5

In considering the various provisions of Section 9.5 of the Code the Committee determined that this item was not in breach as it provided information on all available treatments and was only to be provided to a patient following a consultation with a healthcare professional.

## Meningococcal C Vaccine (767)

*Information to members of the General Public*

### Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging Baxter Healthcare Pty Ltd (Baxter) was in breach of the Medicines Australia Code of Conduct. The TGA alleged that the advertisement displayed a lack of taste and could be potentially offensive to members of the Australian community. It was further alleged that the advertisement was misleading and encouraged consumers to approach their doctor to obtain vaccination against meningococcal disease. Baxter was requested by the Medicines Australia Secretariat to respond to the complaint under Sections 1.4, 9.3, 9.4, 9.5 and 9.8 of the Code.

### Response

A response was received from Baxter denying that it had breached the Code of Conduct. Baxter maintained that the awareness campaign was to highlight that all members of the community are at risk of contracting meningococcal disease.

### Committee Ruling

In relation to the matter of good taste (Section 1.4) members commented that this was a subjective decision, but referred to other current consumer campaigns that included graphic images of car accidents and drownings that had been allowed to be aired. The Committee was of the view that although it may be disturbing to some members of the community, the image in the advertisement should not cause serious or widespread offence and was therefore not in breach of Section 1.4 of the Code.

The Committee agreed that no breach of Section 9.3 should be found as the advertisement was not a General Media Article as covered by the Code of Conduct. No breach of Section 9.3 was found. The Committee considered this section carefully and on balance agreed to consider the advertisement as an item of educational material and referred to Section 9.5. No breach of Section 9.4 was found.

The Committee was, however, apprehensive that the advertisement may cause serious alarm or

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concern within the general public by implying a high prevalence of meningococcal C disease. While acknowledging that it is a disease that can lead to serious illness with debilitating and life threatening consequences and death, members of the Committee were concerned that the statistics relating to meningococcal C disease may give the reader the impression that the chance of contracting this disease is more likely than is actually the case.

In addition, the Committee noted that the 'community message' did not provide genuine educational information about meningococcal C disease to the general public as required by Section 9.5 of the Code. Particular concern was expressed regarding the lack of information regarding the prevalence of this disease, the risks related to vaccination and any possible side effects.

The Committee was of the view that the material in the 'community message' could not be considered to be balanced as it did not include information on issues such as the prevalence of this disease or any side effects or risks relating to vaccination. It was unanimously agreed that a breach of Section 9.5.1 should be found as the material was not balanced. The Committee was concerned regarding the accuracy of the statements made and their relevance to the Australian community.

This section states that educational material should not focus on a particular product. However in the view of the Committee this 'community message' with the wording "Don't wait to VacCinate. Cut out and take this coupon to your GP and ask about vaccination today", the highlighting, colouring and capitalization of the C and the prominent usage of the name 'Baxter' was focusing on a particular vaccine supplied by Baxter. Healthcare professional members of the Committee noted that a member of the general public may bring in the coupon (information on the coupons had been provided to healthcare professionals) and ask for the Baxter vaccine for the prevention of meningococcal C disease. Due to these linkages the Committee found a breach of Section 9.5.2 of the Code.

The Committee considered that the requirement to include the name and address of the registered company in educational material had been included in the Code for the information of readers and not for promotional purposes. The Committee considered that the unnecessary prominence of the name 'Baxter' on the cut out tag, particularly when linked to the highlighted and coloured "VacCinate" resulted in a breach of Section 9.5.4 of the Code that requires that this information should not be given prominence.

Members of the Committee were of the view that the statement on the cut out tag to take this information including the highlighted and coloured "VacCinate" and the name of the company was an encouragement to a member of the general public to ask their doctor to prescribe a product. A breach of Section 9.5.5 of the Code was found.

Given the lack of balance regarding issues such as the prevalence of meningococcal C disease and the inability of the Committee to verify the statements made and their relevance to the Australian community, it was the view of the Committee that the 'community message' was presented in a way that could cause alarm or misunderstanding in the community and was therefore in breach of Section 9.5.6 of the Code.

The Committee considered that no breach of Section 9.8 should be found.

## Sanction

The Code of Conduct Committee resolved that Baxter should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

The Committee resolved that Baxter should pay the cost (design and publication) of providing a full page genuine education advertisement on meningococcal C disease in the three magazines mentioned in the Baxter response:

- Family Circle
- Womens Day
- Good Health

In relation to the development of this educational material the Committee imposed the following requirements:

- The draft materials must be submitted to Medicines Australia for final approval
- Prior to publication, Medicines Australia will arrange to have this material reviewed by relevant healthcare professional in the field of infectious diseases.
- The 'community message' will not make reference to Baxter or Baxter as a manufacturer of meningococcal vaccines. If required, Medicines Australia could be mentioned in the advertisement as the contact point for further information regarding the sponsor of this material.
- The presentation of the advertisement will be appealing to readers
- The advertisement should be at least one full page in size
- The publication of the advertisement should be not later than one month following the resolution of this complaint

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- This educational material must also appear on Baxter’s website and be included in any further consumer educational material.

## BMS Education Meeting (769)

*Educational Meeting*

### Complaint

A complaint was received from Sanofi Synthelabo Australia Pty Ltd (Sanofi Synthelabo) alleging that Bristol Myers Squibb Pharmaceuticals Pty Ltd (BMS) was in breach of Section 10.2 of the Medicines Australia Code of Conduct. Sanofi Synthelabo contended that Bondi Icebergs was an inappropriate venue for an educational meeting.

### Response

A response was received from BMS denying that it had breached the Code of Conduct. BMS stated that the venue on the invitation was Bondi Icebergs Function Room whereas it is the Icebergs Dining Room and Bar that has received recognition for fine dining. BMS also advised that the dining room/bar and function room were separately managed.

### Committee ruling

Members considered that while it may be possible for a casual reader to assume that the meeting was to be held at the restaurant, there was no emphasis on the venue in the design of the invitation. One member of the Committee was of the view that it was potentially misleading and was intended to draw attention to the venue to have it listed before the speaker and topic for the meeting and recommended that companies focus on the educational content before listing the venue. However the majority of members were of the view that a healthcare professional will be discerning and as a priority will consider the meeting date, topic and speaker and then consider whether the venue is within an area that is easily accessed from their practice/home. Healthcare professional members of the Committee commented that if they are interested in attending an educational meeting, they take into consideration the venue in terms of its suitability for a meeting. All commented that having attended meetings in venues where it was difficult to hear or see the speaker or where there were outside noises which distracted from the presentation, they would choose not to return to that particular venue. Members were of the view that this information would certainly be included

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in any evaluation of the meeting and companies would be cautious in using this type of venue for future educational meetings.

Members commented that having reviewed the menu and cost for the function room meal, it was not extravagant and the educational content of the meeting was acceptable. Members noted the requirement that a venue must be chosen on the basis of its ability to contribute to the enhancement of medical knowledge and the quality use of medicines.

The Committee found no breach of Section 10.2 of the Code, however recommended that in future BMS consider placing the name of the speaker and the topic at the top of an invitation and provide more detail on the agenda, including the length of the educational component, so as to emphasise that the purpose of the event is to provide education.

## Permax (771)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from a healthcare professional alleging Aspen Pharmacare Australia Pty Ltd (Aspen) was in breach of Section 1.3.1 of the Medicines Australia Code of Conduct. The healthcare professional alleged that the 'Dear Doctor' letter was promoting a non approved indication for Permax.

### Response

A response was received from Aspen denying that it had breached the Code of Conduct. Aspen contended that the information in the letter clearly stated "Permax is not indicated for use in this condition" and the PI was included.

### Committee ruling

The Committee was unanimous in its view that while some healthcare professionals may have requested information about the use of Permax in restless legs syndrome, to provide information about this unapproved indication to doctors through an unsolicited mailing is promotion outside the approved indications for Permax and therefore in breach of Section 1.3.1 of the Code. Members did note the reference to the approved indication for Permax in the letter to doctors; however they did not consider that this avoided the finding of a breach of Section 1.3.1 of the Code. Further, the Committee noted that the letter had been sent to 600 doctors, and that it did not appear to have been exclusively directed to neurologists as the complainant is not, to the Committee's knowledge, a neurologist.

In relation to the argument that Aspen is a small company and unable to answer queries on a one on one basis, the Committee did not accept this justified the proactive promotion of an unapproved indication. Further the Committee did not accept the argument that because the mailing was a one-off and not part of a broader promotional campaign that it was not promotional.

Section 3.3.4 of the Code also refers to the distribution of non approved indications and states that such information must not be unsolicited. While Aspen was not requested to respond to Section 3.3.4 of the Code the

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company was encouraged to familiarise staff with the requirements of all provisions of the Code.

## Sanction

Members commented that it is a serious matter to promote outside the approved indications and requested that Aspen undertake a Code education program with Medicines Australia.

The Code of Conduct Committee resolved that Aspen should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

The Committee determined that corrective action was not appropriate as this may provide another opportunity to advise doctors of unapproved use of Permax. It determined that Aspen should pay a fine of \$2,500.

## Metvix PDT (772)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from 3M Health Care (3M) alleging that Galderma Australia (Galderma) was in breach of Sections 1.1 and 1.3 of the Medicines Australia Code of Conduct. 3M alleged that the tagline was making an explicit claim which was inaccurate, misleading and all encompassing to health professionals by both implication and omission.

### Response

A response was received from Galderma denying that it had breached the Code of Conduct. Galderma contended that the tagline would not mislead a healthcare professional and that all doctors using the cream in conjunction with the activating light were trained and aware of all indications.

### Committee ruling

Members of the Committee discussed how Metvix cream was accessed and the manner in which it was used by a healthcare professional. It was noted that Metvix cream was not available by prescription and may only be obtained from Galderma by healthcare professionals who have attended a training program on Metvix and the use of the Aktelite® lamp.

Members considered that the tagline "*Destroys skin cancer, not skin*" was more than mere 'puffery', (a statement which really has no meaning especially a medical implication). Members considered that there was the potential that a healthcare professional could be misled that Metvix was suitable for all skin cancers and that there were no adverse effects or the potential for any skin damage. Members noted that the contraindication of use in morpheaform BCC did not appear in every promotional item where the tagline claim was made, which was also considered to be misleading. Also, the side effects of Metvix, and particularly the phototoxic effects, were omitted from the Metvix PDT brochure, which was considered to be misleading as the tagline gave the incorrect impression that Metvix had no adverse effects on skin.

The Committee concurred with the view that if a tagline is promotional, it should be treated in the

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same way as any other promotional claim and be referenced or qualified appropriately.

The Committee also noted that in accordance with the provisions of the Code all items of printed promotional material must be accompanied by the approved PI or, in the case of an advertisement, include all the relevant mandatory requirements, including the PBS disclosure box.

As the tagline was considered to be promotional, members reviewed the supporting evidence to assess whether there was evidence to support the claim.

While the average GP would probably not believe that Metvix PDT could cure all skin cancers, there may be a greater level of uncertainty about the degree of skin damage. By a majority the Committee found a breach of Sections 1.1 and 1.3 of the Code because the tagline gave the misleading impression that Metvix PDT could be used for all types of skin cancer and that there was no skin damage following treatment with Metvix PDT.

## Sanction

Members were of the view that as a healthcare professional cannot access the product until they have undertaken a training program on the use of the cream and lamp this may minimize any potential problems or correct any misconceptions.

The Code of Conduct Committee resolved that Galderma should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

## Plavix (773)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from Boehringer Ingelheim Pty Limited (BI) alleging Sanofi Synthelabo Australia Pty Ltd (Sanofi Synthelabo) was in breach of Sections 1.3, 1.5 and 1.7 of the Medicines Australia Code of Conduct. BI alleged that the campaign failed to adequately communicate the serious bleeding risk associated with the combination of clopidogrel and aspirin for the secondary prevention of ischemic stroke as reported in the MATCH trial.

### Response

A response was received from Sanofi Synthelabo denying that it had breached the Code of Conduct. Sanofi maintained that that the materials in question serve to adequately communicate the important results from the MATCH trial.

### Committee ruling

#### Perfect Match

Members of the Committee were of the view that the use of the term “Perfect Match” would create an impression and expectation in the mind of healthcare professionals that the outcome of the MATCH Study was positive in terms of the use of clopidogrel plus aspirin for patients with recent ischemic stroke or TIA.

The Committee also agreed that it was misleading to imply that this combination of drugs was a perfect match when there was no published evidence available to support this claim.

The Committee found a breach of Section 1.3 of the Code as the claim “Perfect Match” was considered to be misleading to a prescriber.

#### Bright Idea

The Committee was of the view that this advertisement was focused on promoting Sanofi Synthelabo’s investment in research and did not refer to clopidogrel plus aspirin. The only product named in the advertisement was Plavix and there was no promotional claim about the study, although it was acknowledged by members of the

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Committee that this advertisement was part of a series promoting the outcome of the MATCH Study.

As there was no promotional claim the Committee found no breach of Section 1.3 of the Code.

### Match Point

Prior to considering the aspects of this complaint the Committee reviewed the background and findings of the MATCH study published in the July 2004 edition of The Lancet. It was noted that the study's aim was to assess whether the addition of aspirin to clopidogrel could have a greater benefit than clopidogrel alone in prevention of vascular events with potentially higher bleeding risk.

### Clinical value of Plavix Monotherapy has been confirmed by the newly released Match clinical trial

Members commented that the key finding of the MATCH study, which was the reference for this claim, was that adding aspirin to clopidogrel in high risk patients with recent ischemic stroke or transient ischemic attack is associated with a non significant difference in reducing major vascular events. However, the risk of life-threatening or major bleeding was increased by the addition of aspirin.

Members were of the view that the advertisement implied that it was aspirin monotherapy that was responsible for the significantly increased risk of life threatening and major bleeding although there was no evidence to support this claim.

While some of the statements in the advertisements were not untrue in isolation, it was the overall presentation of the findings of the MATCH study that had the potential to mislead a prescriber. Therefore the claim was found in breach of Section 1.3 of the Code.

### Graphical representation

The reference to all patients having received clopidogrel is only included in the qualification statement *"All patients received clopidogrel 75mg and other standard therapies"*. Members commented that it would have been of greater benefit to a prescriber to have included clopidogrel on the graphical representation eg. clopidogrel 75mg + aspirin 75mg o.d. and clopidogrel 75mg + placebo o.d.

The Committee found a breach of Section 1.3 of the Code as it failed to clearly convey that the increased risk is due to the combination of

clopidogrel plus aspirin and a breach of Section 1.7 as the advertisement was disparaging to aspirin.

### Aspirin did not bring additional benefit compared to the placebo group ...but significantly more life threatening and major bleeding

Members considered that the advertisement raised concern for patient safety as it was not clear that it was the combination of clopidogrel plus aspirin that was found to have the increased risk of bleeding and not aspirin monotherapy. This could result in a patient inappropriately being taken off aspirin where it would not be a risk to the patient's health.

The Committee found a breach of Sections 1.3 and 1.7 of the Code as members considered the statement to be misleading and potentially disparaging to aspirin.

### Prevent more events

The Committee was of the view that this claim required further clarification - prevent more events of what and in whom? Members also noted that Sanofi Synthelabo had acknowledged that the tagline was usually referenced to the Plavix PI. The Committee found a breach of Section 1.5 of the Code as in the view of members this statement was implying a special merit without being qualified.

### Sanction

The Code of Conduct Committee resolved that Sanofi Synthelabo should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

In consideration of the patient safety issues, the Committee also resolved that Sanofi Synthelabo should publish a full page corrective advertisement in the journal where this material had been published.

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## Iscover (774)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from Boehringer Ingelheim Pty Limited (BI) alleging that Bristol Myers Squibb Pharmaceuticals Pty Ltd (BMS) was in breach of Section 1.3 of the Medicines Australia Code of Conduct. BI alleged that the treatment algorithm for the use of antiplatelet medications in patients following a stroke or transient ischaemic attack was misleading.

### Response

A response was received from BMS denying that it had breached the Code of Conduct. BMS maintained that the promotional piece was not misleading and did not agree with BI's view of the prevailing interpretations of the MATCH trial.

### Committee ruling

The Committee discussed the use of '*at the physicians discretion*' in the treatment algorithm for Iscover +/- aspirin. Members were of the view that this was acceptable as it was not advising a healthcare professional that they had to stop treating a patient with the combination therapy. Various healthcare professional members of the Committee offered the view that in some individual cases where a patient was well established on a particular treatment regime and the patient was counselled as to the possible side effects and change in risk, a decision may be made to continue the patient on this combination.

Members also commented that the algorithm was quite specific in stating "*History of CAD/stent in last 12 months*" prior to the recommendation to use Iscover +/- aspirin. Members noted that the MATCH study was undertaken in high risk subjects with recent ischaemic stroke or TIAs, which was a different patient population from those with a history of CAD/stent.

Members were of the view that it was acceptable for a company to develop a treatment algorithm on the understanding that it would have been developed in association with an Advisory Board, key opinion leaders or relevant professional college or society, as it was in this instance.

Members also commented that it was extremely difficult for a general practitioner to be fully

versed in all the current studies and issues in this area and it is therefore critical that all company materials are current, accurate and balanced with no potential to mislead a prescriber.

The Committee found no breach of Section 1.3 of the Code as the promotional item was not considered misleading as it was appropriate to state "*at physicians discretion*" for the combination of Iscover and aspirin and that it was distributed prior to the publication of the MATCH study in July 2004, which had placed into the public arena the issues surrounding the increased risk of bleeding in patients on combination therapy with clopidogrel and aspirin.

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## Asasantin (775)

### Complaint

A complaint was received from Sanofi Synthelabo Australia Pty Ltd (Sanofi Synthelabo) alleging Boehringer Ingelheim Pty Limited (Boehringer Ingelheim) was in breach of Sections 1.3 and 1.7 of the Code in relation to claims within a promotional item for Asasantin. Sanofi Synthelabo alleged that the mailer contained claims that were false and misleading, disparaging and not supported by the body of evidence.

### Response

A response was received from Boehringer Ingelheim denying that it had breached the Code of Conduct. Boehringer Ingelheim maintained that the material was factual, clear and easy to understand.

### Committee Ruling

#### Fact. Strokes prevented vs aspirin

The Committee considered that the graphical representation of the two studies was misleading because it inferred that Asasantin SR was more effective because the Asasantin SR column height was much greater than for clopidogrel. Further, the omission of the dosage of aspirin used in the two trials was considered to add to the misleading impression that may be gained from the graph. In addition, as there was no mention of the Cochrane analysis of dipyridamole for the prevention of stroke, important data had been ignored in the preparation of the promotional item.

The Committee found a breach of Section 1.3 of the Code as the graph was considered to be misleading to a prescriber and a breach of Section 1.7 of the Code as it was disparaging to clopidogrel.

#### Twice the protection of Aspirin alone

The Committee agreed that the claim was not consistent with the body of evidence. It considered that there appeared to be no scientific basis for the claim. The Committee determined that the statement was in breach of Sections 1.3 and 1.7 of the Code because it is misleading and disparaging to aspirin.

### FACT

The Committee was of the view that the use of 'FACT' throughout the promotional piece was misleading as it implied in an unequivocal manner that Asasantin SR was superior in all aspects to all other available antiplatelet products and was therefore in breach of Section 1.3 of the Code.

### Sanction

The Code of Conduct Committee resolved that Boehringer Ingelheim should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

### Appeal

An appeal was lodged by Boehringer Ingelheim in relation to the findings of the Code of Conduct Committee. Boehringer Ingelheim maintained that while some materials could perhaps be clearer, the Code of Conduct Committee had not considered the claims in the context of secondary stroke prevention.

### Appeals Committee ruling

Members discussed whether it was misleading for Boehringer Ingelheim not to have included the aspirin doses in the promotional material. Based on the evidence submitted by both companies, the majority of trials on aspirin looked at vascular events and not secondary prevention of stroke *per se*. Therefore it is not clear that there is no dose response in the efficacy of aspirin in secondary prevention of stroke.

Quite apart from this uncertainty, and whilst acknowledging that the mailer was used in the context of secondary stroke prevention, members of the Committee considered that the omission of any reference to the doses of aspirin would lead prescribers to believe the dose was the same in both the CAPRIE and ESPS-2 studies and was the usual dose used in clinical practice in Australia of 75mg - 150mg per day. Accordingly the failure to specify the doses of aspirin used in the studies was unbalanced and was likely to mislead the audience. The appeal against the finding of a breach of Section 1.3 of the Code in relation to the graph was not upheld.

The Committee did not consider the graph to be disparaging to aspirin and therefore upheld the

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appeal in relation to the finding of a breach of Section 1.7 of the Code.

In relation to the Code of Conduct Committee's finding that the graphical representation of Asasantin SR and clopidogrel was misleading based on the column heights, which had not been subject to complaint by Sanofi, the Appeals Committee agreed that Boehringer Ingelheim had been denied procedural fairness and upheld this aspect of the appeal. In relation to the Code of Conduct Committee's finding that the claim "*twice the protection of aspirin alone*" was inconsistent with the body of evidence, the Appeals Committee, having reviewed the mailer in its original form, accepted that the claim should be understood in the context of stroke prevention.

The Appeals Committee considered whether, in this context, the claim was consistent with the body of evidence. The claim is based on a single study, ESPS-2, using a very low dose of aspirin not used in clinical practice in Australia. Given the uncertainty as to whether there is a dose-related difference in efficacy at different aspirin doses, it is not known whether the protection offered by Asasantin would be twice that of aspirin alone across all the doses of aspirin that may be used in clinical practice. Although the claim was referenced to ESPS-2, the audience would understand from the promotional material that the aspirin dose used was a dose used in clinical practice in Australia, which was not the case. The Committee concluded that, by omission of the aspirin dosage used in the study, the claim was unbalanced and was therefore likely to mislead the audience in the same way as the graphical representation and was also disparaging of aspirin. The Appeals Committee therefore found the claim to be in breach of Sections 1.3 and 1.7 of the Code. The appeal was not upheld.

Members commented that companies should take particular care when using what is factually correct data but which may mislead prescribers through lack of balance or detail which can only be understood from reading the referenced studies.

## Sanction

Having considered this appeal and given reasons why the appeal should for the most part not be upheld, the Appeals Committee then reviewed the proposed sanction to ensure it was appropriate to the breach found. The graph found in breach should not be used again without qualification or disclosing the doses of aspirin and the claim "*twice the protection of aspirin alone*" should not be used again without disclosing the dose of aspirin.

## Seretide (776)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from AstraZeneca Pty Ltd (AstraZeneca) alleging GlaxoSmithKline Australia Pty Limited (GSK) was in breach of Sections 1.1, 1.2 and 1.3 of the Medicines Australia Code of Conduct. AstraZeneca alleged that the claims would have a major impact on general practitioners' prescribing given the misleading nature of the claims.

### Response

A response was received from GSK denying that it had breached the Code of Conduct. GSK maintained that a prescriber would not interpret these claims as suggesting that Seretide cures asthma and that the findings are supported by the outcomes of the GOAL study.

### Committee ruling

*Asthma? What asthma?*

The Committee was of the view that this tagline or statement was not a promotional claim. Members considered that while it is not possible to eradicate asthma, it was possible through good management to achieve the best quality of life for the patient with asthma as described in the National Asthma Council of Australia "Asthma Management Handbook". Members concluded that "*Asthma? What asthma?*" was not a promotional claim and therefore not in breach of Sections 1.1, 1.2 or 1.3 of the Code.

*NO Night Time Awakenings?*

*NO Exacerbations?*

*NO Asthma Symptoms?*

*NO Reliever Use?*

*YES It is possible.*

Some members of the Committee were of the view that the use of questions marks at the end of each statement and their sequential linking to the final statement of "*Yes It is possible*" there was little chance that a prescriber could be misled that Seretide could cure asthma.

However other members of the Committee were of the view that the statements implied that there was excellent control with Seretide in the majority of patients. Members noted the qualification

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*“Guideline defined asthma control was maintained for 7 out of 8 weeks”* which was included below the PBS Information box.

The majority of members were of the view that it would be more appropriate to position this qualifier closer to the claims and in larger font to ensure that it was recognised as qualifying the claim.

In discussing the use of the word ‘possible’ members expressed concern that there was no indication provided regarding the number of patients in whom this degree of control could be achieved. Members referred to the Goal Study in which the cumulative results for total control with Seretide were 41% and well controlled with Seretide 71%. While acknowledging the literal interpretation of ‘possible’, members of the Committee were of the view that when providing promotional items or advertisements to healthcare professionals the information should be current, accurate and balanced and offer the reader information which will assist in their prescribing decision. Therefore it would have been more appropriate to include a reference to the actual percentages of total control and well controlled with Seretide in the promotional item.

The Committee considered that the claim lacked balance because it did not provide information about the proportion of patients in whom this degree of control could be obtained. By a majority, the Committee found a minor breach of Sections 1.1 and 1.3 of the Code.

## Sanction

The Code of Conduct Committee resolved that GSK should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

## Gonal F Pen (778)

*Promotional materials for healthcare professionals*

### Complaint

A complaint was received from Organon Australia Pty Ltd (Organon) alleging that Serono Australia Pty Ltd (Serono) was in breach of Sections 1.2 and 1.3 of the Code in relation to promotional materials for the Gonal-F Pen. Serono alleged that the data used to support claims was misleading and insufficient to support the claim.

### Response

A response was received from Serono denying that it had breached the Code of Conduct. Serono maintained that the claim was supported by the latest scientific information and was accurate and balanced.

### Committee Ruling

**There is a large difference in dosage variation between r-hFSH batches Filled-by-Mass and those Filled-by-Bioassay**

Members noted that it is factual to state that there is a difference in dosage variability between ‘Filled-by-Mass’ and ‘Filled-by-Bioassay’ technology, but only where this comparison is confined to a comparison between Serono’s own products. Members commented that the referenced study was only conducted with Serono’s products, with no reference to other products within this therapeutic area. The majority of members were of the view that there was an implied generalisation from the claim that the dosage of the Serono product is less variable than the competitor product, rather than making it clear that the claim related to the dosage of the newer Serono product being more accurate than the older Serono product. There was also a view that the use of the present tense rather than past tense in the claim (“There is .... “ instead of “There was ....”) also implied that the comparison was with a competitor product and did not reflect that the study compared two methods of quantification of the Serono products. Members were of the view that the claim should have been made in the past tense to indicate that the result was observed in a particular study rather than being generally applicable.

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A minority view was also expressed, that the statement did not use the term 'product' but 'batches' and therefore there was no implied comparison to other products.

The Committee found a breach of Section 1.3 as the claim was found to be misleading as there was no qualification that it applied only to Gonal-f filled-by-bioassay in comparison to Gonal-f filled-by-mass.

**The new quantification technology of Gonal-f (FbM) improves clinical consistency Gonal-f (FbM) gives statistically superior consistency of response, particularly (sic) for clinical pregnancy rates**

The Committee was of the view that these claims were similar to the claim reviewed in the previous section. Members were concerned that there was no explanation that the comparators relevant to the claims were 'old' and 'new' Serono products.

Members commented that the primary purpose of the cited study was follicular development. The term "clinical consistency" was not explained in association with the claim, and use of the term "clinical pregnancy rates" implied that the study was of pregnancy rates. Members also noted that the "worst batch" in terms of follicular development resulted in the highest pregnancy rate and the "best batch" resulted in the lowest pregnancy rate. Members considered that the claims potentially gave the misleading impression that Gonal-f (FbM) results in higher pregnancy rates rather than a higher consistency of pregnancy rates. Further, the terms "clinical pregnancy" and "overall pregnancy" were not defined in the study report.

Members considered that Serono had misleadingly conveyed the results of the study as though the primary endpoint was pregnancy rates, which was misleading. There had been no statistical difference in relation to the primary outcome measure and Serono had made a claim of superiority based on a posthoc analysis.

Members were also of the view that in this instance the one referenced study was insufficient evidence to support the claims of statistically superior consistency of response or clinical consistency. Several members commented that the study was not designed to detect a difference in pregnancy rates. The analysis of results had also demonstrated unusual statistical methods and there was no information provided in the study methodology to allow an evaluation of the validity of this statistical analysis.

Members further noted that the paper stated *"In conclusion, the consistent quality of the*

*recombinant DNA technology manufacturing process for human FSH has allowed for the first time, the delivery of FSH based on µg of protein. This new method results in further improvement r-hFSH preparations be delivering increased consistency in clinical outcome."* In addition the study abstract states *"This new method for quantifying rhFSH delivers an improved consistency in clinical outcome."* Members were of the view that the claim *"statistically superior consistency of response, particularly for clinical pregnancy rates"* did not accurately reflect the study outcomes.

Members stated that that the claims conveyed a misleading generalisation from a study, highlighting a secondary outcome with insufficient qualification to enable a clear meaning to be gained by the reader and were therefore in breach of Sections 1.2.2 and 1.3 of the Code.

**Gonal-f (FbM) pens may be conveniently stored by patients out of the refrigerator.**

The Committee noted that the Gonal-f Product Information stated that the product should be refrigerated between 2 - 8o C and can be stored at less than 25oC for three months. Once the product has been opened it must be used within 21 days. Members therefore considered that qualification was required as to the temperature conditions at which the pen may be stored without refrigeration.

Due to this lack of qualification the claim was found to be misleading and was found in breach of Section 1.3 of the Code.

## Sanction

The Committee resolved that Serono should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

The Committee also resolved that Serono should circulate a corrective letter to all recipients of the promotional item highlighting the aspects found in breach of the Code. The corrective letter should qualify the comparators in the referenced studies, state the primary purpose of the studies and correct the misleading impression with respect to appropriate refrigeration and storage.

The Committee also determined that a fine of \$15,000 should be imposed.

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## Appeal

An appeal was lodged by Serono against the findings of the Code of Conduct Committee. Serono contended that the promotional claims were made in the context of transitioning clinics from the use of the older Serono formulation to the newer FbM formulation. In addition considerable education had been proved to a range of healthcare professionals.

## Appeals Committee ruling

**“There is a large difference in dosage variation between r-hFSH batches ‘filled by mass’ and those ‘filled by bioassay’”**

The Appeals Committee determined that the appeal in relation to finding the first claim in breach of Section 1.3 of the Code should not be upheld.

Members were of the view that Serono had not made it clear in the promotional material that the comparators were the two Serono products FbB and FbM. While acknowledging that new technology is important in the development of any pharmaceutical product, a company should ensure that a reader can distinguish between an intracompany and an intercompany product comparison.

The promotional item was given out after the educational campaign aimed at transitioning clinics to the FbB product. There is no guarantee that a recipient of the promotional item would recollect the earlier educational message, or that the recipient had attended the educational program. The Committee also considered that it was insufficient to rely on recipients reading the references to understand that the comparison was between two Gonal-f products.

The Committee considered that if there is some ambiguity in a promotional item, any reasonable interpretation must be considered. Here the material could reasonably be interpreted as making an implied comparison with another product even though some recipients who had been exposed to the educational campaign might reasonably understand it as making a comparison between the two Gonal-f products. The use of the term ‘r-hFSH batches’ did not make it clear that the dosage variation was between two Serono products.

**“The new quantification technology of Gonal-f (FbM) improves clinical consistency. Gonal-f (FbM) gives statistically superior consistency of response, particularly (sic) for clinical pregnancy rates”**

The Appeals Committee determined that the appeal in relation to finding the second two claims in breach of Sections 1.2.2 and 1.3 of the Code should not be upheld.

The Appeals Committee was of the view that the claims were ambiguous and gave the misleading impression that use of Gonal-f FbM results in higher pregnancy rates. The statements did not make it sufficiently clear to a reader that the primary purpose of the supporting study was consistency rather than absolute pregnancy rates.

Members considered that the statistical methodology in the referenced paper was questionable. The result that was the basis for the claims was a *post-hoc* secondary and tertiary analysis of endpoints; the analysis was per-protocol rather than intention to treat; the study was one sided, not two-sided; no confidence intervals were disclosed and the statistical methodology was not adequately described in the paper. Members further noted that there is a difference between ‘statistically significant’ and ‘clinically significant’, noting that there was no difference in clinical pregnancy rates between the different batches.

## Sanction

The Appeals Committee agreed that the material found in breach should be withdrawn and not used again or in a manner which conveyed the same or a similar meaning. Further, Serono should not repeat the representations found to have been implied in the promotional material and should take care that the results of the study are not misrepresented.

Serono was also encouraged to retrieve any remaining copies of the promotional item if still in existence in an IVF clinic.

The Appeals Committee agreed that a corrective letter should be sent to all recipients of the promotional item, including all staff of the IVF clinics, highlighting the aspects of the promotional item found in breach of the Code. It would not be sufficient compliance with the decision of the Committee to write to the IVF Clinic Managers/Directors. The corrective letter should explain that the referenced studies were making the comparison between two Gonal-f products and did not find a difference in overall outcomes

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in terms of clinical pregnancy rates between Gonal-f FbB and FbM. In addition the corrective letter should correct the misleading impression with respect to appropriate refrigeration and storage of Gonal-f.

The Committee further agreed that the fine of \$15,000 should remain.

## Celebrex (779)

*Media release to the general public*

### Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Pfizer Australia Pty Ltd (Pfizer) was in breach of Sections 1.3 and 9.2.1 of the Code in relation to a media release for Celebrex. The TGA alleged that the media release contained misleading information about the gastrointestinal side effects for Celebrex and that the media release did not provide balanced information about Celebrex to members of the general public.

### Response

A response was received from Pfizer denying that it had breached the Code of Conduct. Pfizer maintained that the media release did not contain false or misleading claims and was provided to the general public in exceptional circumstances following the withdrawal of Vioxx from the market.

### Committee Ruling

The Committee observed that the media releases were made at a time when patients on a COX-2 medication may have been concerned about the withdrawal of Vioxx and the implications for other medicines. Members were of the view that any media release must be current, accurate and balanced. Members further considered that at a time of an important event such as a product withdrawal for safety reasons, when patients may be more confused, a company has a responsibility to ensure that there is a balanced and accurate response to this unusual circumstance.

Members of the Committee noted that there were some differences between the media release intended for the medical media and that intended for the general press.

The Committee commented that the media releases implied that there was no risk of any side effects from Celebrex, including gastrointestinal side effects. The media releases also stated that there was no increased risk of cardiac events compared to background rates which may lead to misinterpretation of the currently approved PI.

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While it is true that a number of studies, particularly observational studies, have not shown an increase in cardiac events in patients on celecoxib, especially compared to patients on rofecoxib, the PI states *“Fluid retention and oedema have been observed in some patients taking Celebrex (See Adverse Events). Therefore, Celebrex should be used with caution in patients with fluid retention, hypertension, heart failure and other conditions predisposing to, or worsened by, fluid retention. Patients with pre-existing congestive heart failure or hypertension should be closely monitored.”*

Members were of the view that the term ‘background rates’ may not be understood by a member of the general public and this was also misleading.

While there was no specific complaint in relation to use of the term ‘safe’ in an unqualified manner, members noted that this would lead a member of the general public to believe that there was no risk associated with Celebrex, which is also misleading. If the complaint had included a complaint in relation to Section 1.5 of the Code, a breach of this Section may have been found. The statement ‘safe’ compounded the misleading inferences in respect to gastrointestinal and cardiovascular safety.

The Committee unanimously found that the media releases were in breach of Section 1.3 as they were not accurate or balanced and could mislead members of the general public or healthcare practitioners in relation to the safety of Celebrex.

In discussing the media release to the general public, in response to the unusual circumstance of Vioxx’s withdrawal, the Committee was of the view that it must still fulfill the requirements of Section 9.2.1 of the Code. As the media release did not include information about the product’s precautions, adverse reactions, warnings, contraindications and interactions as required in Section 9.2.1 of the Code, members found that it was in breach of this section.

Members also stated that any company should think carefully and consider their position when directing information to the general public. Given that Celebrex is one of the highest volume items on the PBS, Pfizer should have been even more cautious when communicating to the general public and ensured that it provided balanced information.

The Committee considered that the breaches of Sections 1.3 and 9.2.1 should be considered as severe.

## Sanction

As the activity had ceased and no corrective action would be appropriate as it may further inflame the issue, by a clear majority the Committee determined to impose a fine of \$150,000.

## Appeal

An appeal was lodged by Pfizer in relation to the findings of the Code of Conduct Committee. Pfizer maintained that the media release was developed in accordance with the provisions of the Code and even if a breach had occurred the sanction was excessive and unprecedented.

## Appeals Committee ruling

In relation to the issue of side effects, members of the Committee discussed the statement in the media release *“Celebrex was the first COX-2 inhibitor, a class of medicine designed to relieve pain without the serious gastrointestinal side effects associated with older non-steroidal anti-inflammatory medicines.”* and the Pfizer argument during their presentation that this was factual as it specifically stated ‘was designed to’, which is different to claiming that there are no serious gastrointestinal side effects. There was some concern that the statement did not reflect current knowledge - whilst the Cox-2 inhibitors were designed to avoid the serious GI side effects of the older NSAIDs, this was not fully achieved, as was known at the time of the media release. However taken as a complete sentence the statement was not incorrect, however it was open to misinterpretation.

When considering Pfizer’s claims that the Code of Conduct Committee was biased against Celebrex, it was noted that Appeals Committee members included representatives of the same organisations that were alleged to have made statements in relation to prescribing patterns and sales of Celebrex. Members were of the view that this was not a relevant objection on grounds of bias and that as professionals they were capable of making an informed and objective decision based on the facts before them. However the presence at the meeting of a representative of the TGA, when that body had made the original complaint, left open the inference that other members of the Code Committee could be influenced inappropriately, and should be avoided in future.

While there may have been discussion in the Code of Conduct Committee on PBS volumes,

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the context did not appear clear from the minutes. It could have been raised to indicate that Pfizer should have taken particular care in issuing its media release due to the large number of patients taking Celebrex. There was no evidence to establish that this discussion had biased the Code of Conduct Committee in their finding of a breach of Section 1.3 of the Code. However, it would have been preferable if the Code of Conduct Committee had recorded in the minutes that their decision had not been influenced by these discussions.

The Appeals Committee discussed the context of the media release and accepted that there was a need for a statement to be provided about Celebrex. However, members considered that the terms used in the media release, as identified in the complaint, may be read and interpreted by the media and the public as suggesting that there was no risk from Celebrex. The specialist rheumatologist member noted that patients do experience problems with aggravated oedema, hypertension, renal impairment and heart failure. The media release did not sufficiently warn of these possibilities. The Appeals Committee considered that a company should take care to provide accurate and balanced information to members of the general public and healthcare professionals, especially at a time of uncertainty. Members did not accept the argument that the media release was going only to patients already prescribed Celebrex when it was a media release to the general media. While those patients taking Celebrex would be most interested, it was a requirement that all media releases contain information about a product's precautions, adverse reactions, warnings etc. Further, a version of the media release had been provided directly to patients who had contacted Pfizer Medical Affairs.

While the language of the media release in relation to CV and GI risks had the potential to be misleading, having regard to the context in which the release was issued and the statement in the same terms and at the same time from Dr McEwen (TGA), these may place the breach at the lower end of the scale. The Appeals Committee determined that the breach of Section 1.3 should be confirmed, but that the breach was not as severe as the Code of Conduct Committee considered. The appeal against a finding of a breach of Section 1.3 was not upheld.

In relation to the use of the term 'background rates', the Appeals Committee did not consider that this term was of itself misleading in the context in question. In determining whether a severe breach of Section 1.3 should be found, members referred to the definition which defines severe as *"a breach that will have safety implications to the patients well being, and/or will*

*have a major effect on how the medical professional will prescribe the product and/or will have a significant commercial impact on the relevant market. A severe breach of the Code will also be found for companies that bring discredit upon or reduce confidence in the pharmaceutical industry."* Members commented that it was not possible to reduce the finding to a moderate breach which was a breach for which there were no safety implications. Therefore the finding of a severe breach was found because there were some safety concerns in relation to the media release.

The Appeals Committee wished to confirm to Pfizer that in making its decision it only took into account information available at the time of publication of the media release. In relation to the breach of Section 9.2.1 the Code the Committee was of the view that as the information on precautions, adverse reactions, warnings, contraindications and interactions as required by this section were not included in the media release to balance the statements in relation to the safety of Celebrex a breach was confirmed. It was not sufficient to give a reference to where that information could be sourced. The appeal against a finding of a breach of Section 9.2.1 was therefore not upheld.

The Appeals Committee considered that the issue of whether there were one or two documents did not alter the level of the sanction.

## Procedural Issues

As noted above, in relation to the allegation of bias due to the presence of the TGA observer at the Code of Conduct Committee meeting, the Appeals Committee accepted that this could create a perception of bias, however there was nothing to suggest that the TGA observer had influenced the Committee in its decision. A TGA observer is required at Code Committee meetings under Section 11.2 of the Code. An exception should be made where the TGA is the complainant.

Members rejected the proposition that the presence of people representing professional organisations was likely to give rise to the reasonable apprehension of bias or that it was likely to have any influence on other members of the Committee or on the Committee's decision. It wasn't apparent from the minutes whether discussions about the volume of PBS prescriptions for Celebrex or a potential breach of Section 1.5 had influenced the Code of Conduct Committee in their decision to find a severe breach of Section 1.3, but the possibility could not be excluded based on the minutes.

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## Sanction

Having considered this appeal and given reasons why the appeal should not be upheld, the Appeals Committee then reviewed the proposed sanction to ensure it was appropriate to the breaches found. As noted previously, members were of the view that although the finding of two severe breaches was confirmed, they were both at the lower end of the scale. There having been a finding of two breaches (that is a breach of each of Sections 1.3 and 9.2.1 based on a single media release) members agreed that a fine of \$15,000 should be imposed in relation to each breach, resulting in a total fine of \$30,000. The fine was therefore reduced from \$150,000 to \$30,000.

## Perfalgan (780)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from Pfizer Australia Pty Ltd (Pfizer) alleging that Bristol Myers Squibb Pharmaceuticals Pty Ltd (BMS) was in breach of Sections 1.3.1, 6 and 10.5 of the Medicines Australia Code of Conduct. Pfizer alleged that Perfalgan was promoted at a trade display at the Australian Society of Anaesthetists Congress in September 2004 prior to its registration in October 2004.

### Response

A response was received acknowledging that this had been an unintentional indiscretion on the part of BMS. BMS stated that they recognised that while the promotion of the product in the absence of regulatory approval was inappropriate, this promotion had occurred in good faith under the incorrect assumption that the product was TGA approved. As soon as BMS became aware of the regulatory status of Perfalgan, all promotional activities had ceased.

### Committee ruling

While expressing some understanding of the frustration companies may experience in waiting for the final TGA letter of approval, members were of the view that a company cannot undertake any product launch or announcement until they are in possession of the registration certificate from the TGA indicating that the product has been approved.

Members also noted that the invitations to the Perfalgan launch meeting were sent to healthcare professionals when the product was known not to be approved, and when there was a risk that it may not receive final approval by the date of the Australian Society of Anaesthetists congress.

The Committee was of the view that BMS should have had procedures and internal checks in place to avoid this breach of the Code from occurring. Further, if approval has not been achieved as expected, the company should have cancelled the meeting in its entirety.

The Committee acknowledged BMS's attempts to withdraw promotional material from the meeting, however members were extremely concerned that BMS had offered healthcare professionals a

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Perfalgan PI which was dated September 2004 and gave the impression that the product had been approved by the TGA. Members considered that this was misleading.

While recognising that Perfalgan was not a completely new therapeutic agent, members were of the view that it was the principle of the action to promote the product prior to TGA approval that was in question. The Committee was emphatic that companies should not try to pre-empt the approval process and that companies must act within the provisions set down by the Code and the Therapeutic Goods Regulations. Members also commented that there must be a level playing field for the industry and companies must ensure that all staff are made aware of the restrictions on the promotion of unapproved products or indications, whether it is by a day or months.

The Committee also noted that BMS had been in communication with the TGA and Medicines Australia to alert them of the situation. BMS had also sent letters to all attendees of the breakfast meeting, as well as ASA delegates who received a copy of the product information, stating that Perfalgan was not registered at the time of the ASA meeting.

The Committee found a breach of Section 1.3.1 and 6.1 of the Code as BMS had promoted an unapproved product at the ASA meeting through the product launch meeting and trade display signage at the meeting. Members considered that the breaches were moderate rather than severe, noting that the delay in final TGA approval had been administrative rather than due to any questions about product safety. No breach of Section 10.5 of the Code was found.

## Sanction

As the activity had ceased and acknowledging that BMS had already taken action to communicate the error to anaesthetists who had attended the ASA Congress, the Committee imposed a fine of \$10,000.

The Committee commented that on this occasion as the audience was a group of anaesthetists there was no potential for patient harm. Members also stated that as this was not a completely new therapeutic agent, merely an intravenous form of a well know drug, the risk of inappropriate prescribing was minimal. Members warned companies that this was not setting a precedent and that every regulatory affairs section within a company should be aware that the Code of Conduct Committee will treat seriously any complaint relating to the promotion of an unapproved product or indication.

## Ezetrol (781)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from Pfizer Australia Pty Ltd (Pfizer) alleging that Merck Sharp & Dohme (Australia) Pty Ltd (MSD) was in breach of Sections 1.3 and 1.7 of the Medicines Australia Code of Conduct. Pfizer maintained the promotional materials were not supported by the highest levels of evidence available. In addition the materials could mislead by use of opinions significantly more favourable than the body of evidence that was available but not presented.

### Response

A letter of response dated 8 November 2004 had been received from MSD denying that it had breached the Code of Conduct. MSD advised that they had investigated the allegation and determined that the claims were fully consistent with the approved PI.

### Committee ruling

The Committee expressed the view that it was ambiguous to state *"Ezetrol and a statin"* or *"Ezetrol together with a statin"* as it wasn't clear to a reader that in the referenced study Ezetrol had been added to on-going statin therapy. Members commented that the entry criteria for the resulting additional 25% reduction in LDL-C was not clear. Members noted that a second study where subjects were initiated on Ezetrol and a statin at the same time there was a lesser reduction in LDL-C. The promotional material didn't indicate whether Ezetrol was added to existing statin therapy or both Ezetrol and a statin were started at the same time.

The Committee acknowledged that the study stated *"-25% decrease in LDL cholesterol across the dosing range of all statins compared with -4% with the addition of placebo to statin monotherapy"*.

Members concluded that the promotional material was misleading because it did not clearly explain to readers that the result of 25% reduction of LDL-C was from adding Ezetrol to existing statin therapy and that the figure of 25% did not take into account the 4% reduction from the addition of placebo. The Committee found a minor breach of

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Section 1.3 as the claim was insufficiently qualified.

Members of the Committee did not view the use of the word 'statins' in the promotional material as pertaining to any specific statin as several were used in the referenced study. Members did not agree that the claim inferred a particular comparison with simvastatin. The Committee noted that the approved PI also referred to 'statins' collectively. The Committee found no breach of Section 1.7 of the Code.

In relation to Pfizer's complaint that the technique for presenting the comparisons was flawed, members commented that by including the adapted data in one graph there was a possible implication that the outcomes were from a single study. Members considered that the graphical representation was misleading and therefore in breach of Section 1.3 of the Code. In relation to the question about the validity of the average reduction in LDL-C of 6% from doubling the statin dose, members commented that the statin dose response curve is non-linear. However, the approved PI quotes a 2% to 9% reduction in LDL-C from doubling the statin dose. The two references for the claimed 6% reduction in LDL-C from doubling the statin dose are review articles. The Committee accepted MSD's arguments in support of this figure.

## Sanction

The Code of Conduct Committee resolved that MSD should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

## Metvix (782)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from the Therapeutic Goods Administration (TGA) alleging that Galderma Australia Pty Limited (Galderma) was in breach of Sections 1.3 and 1.3.1 of the Medicines Australia Code of Conduct. The TGA alleged that the statements made in the promotional material were not consistent with the PI.

### Response

A response was received from Galderma denying that it had breached the Code of Conduct. Galderma maintained that the statement in the mailer piece *"Metvix PDT is a new non-invasive, physician controlled procedure proven to be effective for the treatment of superficial and nodular basal cell carcinoma and actinic keratoses"* did not suggest or imply that it was the approved indication, only what the product is.

### Committee ruling

Members were of the view that the promotional items lacked clarity in relation to the full approved indications for Metvix. Members noted that the mailer did not state the precise approved indications for Metvix, which do not include hyperkeratotic or pigmented actinic keratoses. While acknowledging that a provider must undergo training in the use of Metvix cream with the specifically designed Aktilite® lamp, members were of the view that if the promotional materials were sent to healthcare professionals who had not been trained, there maybe the potential for them to be misled to understand that Metvix could be used for all types of actinic keratoses and basal cell carcinomas. Members gave the example of a general practitioner receiving this information and referring a patient to a skin clinic or general practitioner who offered Metvix PDT treatment without the knowledge that this treatment was only for use where other treatments are unacceptable (in the case of actinic keratoses) or where surgery is considered inappropriate (in the case of BCCs). Members concluded that the promotional mailers were misleading by the omission of information on the precise approved indications for Metvix.

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One member of the Committee also noted that morpheiform BCC is contraindicated for use with Metvix PDT, but this was not disclosed in the mailer. As the promotional mailers did not provide information on the full approved indications, which were in fact narrower than the indications set out in the mailer, and in particular where surgery is considered inappropriate or where other treatment options are not acceptable, they were determined to be in breach of Sections 1.3 and 1.3.1 of the Code.

Members noted Galderma's argument that it was common practice for pharmaceutical companies to not include the full indication within a promotional piece. The Committee did not support this argument.

## Sanction

The Code of Conduct Committee resolved that Galderma should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

## Celebrex (783)

*Letter to doctors*

### Complaint

A complaint was received from a healthcare professional alleging that Pfizer Australia Pty Limited (Pfizer) was in breach of the Code in relation to a letter to doctors regarding Celebrex. Medicines Australia had asked Pfizer to respond to the complaint in relation to Sections 1.2 and 1.3 of the Code. The complainant alleged that statements in the letter to doctors were misleading.

### Response

A response was received from Pfizer denying that it had breached the Code of Conduct. Pfizer maintained that the body of evidence was consistent with the statements made in the letter to doctors.

### Committee Ruling

The Committee considered the available clinical knowledge regarding the cardiovascular safety of the Cox-2 inhibitors. It was noted that there had been about eighteen publications supporting reasonable cardiovascular safety of Celebrex, although there were some concerns gradually surfacing over time. When Vioxx emerged with significant cardiovascular risk, this precipitated extremely close scrutiny of all Cox-2 inhibitors and cardiovascular risk, especially with higher doses and with longer treatment. Whilst the healthcare professional had highlighted certain evidence that was proven to be correct by more recent studies with Celebrex, in early October these studies were not available. Members noted that randomised trials, adequately powered to detect infrequent cardiovascular events with Celebrex had only recently been accessible (in part). Prior to the recent reporting of increased cardiovascular risk of the selective Cox-2 inhibitors, there had been no requirement for powering studies to pick up the infrequent cardiovascular events and there had been a large number of patients treated in observational studies that had provided a degree of reassurance that had now (since the complaint) proven to be inadequate.

Members considered that the healthcare professional's complaint highlighted certain suspicions, but was somewhat unbalanced in that

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it did not include a reasonable appraisal of the safety data available at that time.

In relation to the statement *“The cardiovascular safety profile of Celebrex has been extensively studied and is summarised below. The data do not indicate significant cardiovascular safety concerns with Celebrex”* members concluded that the statement “extensively studied” was somewhat ambiguous in its meaning, but the letter to doctors should not be found in breach on the basis of the use of these words.

Members noted that the statement regarding cardiovascular risk from the ‘Precautions’ section of the Celebrex PI had been provided at the end of the letter to doctors, under the PBS box. However, members did not consider that the location of this information sufficiently emphasised these precautions. Members considered that these precautions should have been emphasised in the body of the letter adjacent to the statements. The statements should have been balanced by the precautionary statements from the PI.

Members considered that some statements in the letter gave a misleading impression that there were no cardiovascular safety concerns with Celebrex, which is inconsistent with the safety profile of Celebrex as expressed in the PI, in particular the precautions with respect to fluid retention, hypertension and cardiac failure. Members considered the statements were in breach of Section 1.3 of the Code.

Members discussed the statement *“...there was no increase in serious cardiovascular thromboembolic events in patients on Celebrex who were or were not also taking prophylactic low-dose aspirin”* and considered that on the basis of the data available at the time there was not sufficient evidence to show that Celebrex had caused an increase in serious cardiovascular thromboembolic events.

In relation to the argument regarding the rate of serious cardiovascular thromboembolic events in patients taking Celebrex members considered that the data presented in the referenced paper were insufficient to make a generalisation that there was an increase in cardiovascular thromboembolic events in patients taking Celebrex. Further, members considered that it was not appropriate to make a comparison based on the different data presented in tables in this paper. The absolute risk of events with Celebrex was less than stated by the complainant.

By a majority, the Committee determined that the statement *“there was no increase in serious cardiovascular thromboembolic events in patients on Celebrex who were or were not also taking*

*prophylactic low-dose aspirin.”* was not misleading at the time of issuing the letter and therefore was not in breach of Section 1.3.

Members considered that the letter to doctors was not in breach of Section 1.2 of the Code as the data supporting the claims were sufficient and of adequate quality. Members acknowledged that current knowledge about Celebrex had shown the cardiovascular risks were higher than previously known.

However, this new knowledge should not influence the judgment of the complaint concerning the Pfizer letter of 8 October 2004.

## Sanction

The Code of Conduct Committee resolved that Pfizer should take immediate action for the prompt withdrawal of the letter found in breach and should permit no further appearance of it in its present form. The statements found in breach of the Code should not be used again in their present form or in a manner that conveys the same or similar meaning.

The Committee further resolved that Pfizer should be required to send a corrective letter to all recipients of the original letter, stating that it had been found in breach of the Code by failing to appropriately balance the statements regarding cardiovascular safety of Celebrex with the precautionary statements from PI. The Committee accepted that the corrective letter would provide the opportunity to inform prescribers of the most recent information about cardiovascular safety of Celebrex, particularly with doses of 400mg per day and above and long term treatment. Pfizer should ensure that the corrective letter was not misleading and complied with the Code in every respect.

The Committee further resolved that Pfizer should be required to pay a fine of \$25,000.

## Appeal

An appeal was lodged by Pfizer against the findings of the Code of Conduct Committee. Pfizer contended that the letter to doctors was accurate, balanced, not misleading and in accordance with the provisions of the Code.

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## Appeals Committee ruling

The Appeals Committee did not uphold the appeal by Pfizer in relation to the breach of Section 1.3 as determined by the Code of Conduct Committee.

In confirming the finding of the Code of Conduct Committee that the letter was misleading and in breach of Section 1.3 of the Code, members provided the following comments.

Members of the Committee discussed the argument raised in the appeal that there had been a procedural error from the Code of Conduct Committee considering information provided to it by a member of the Committee to which Pfizer had not had the opportunity to respond. The Appeals Committee did not consider that in reaching its conclusions the Code of Conduct Committee was inappropriately influenced by general background information apparently brought to the Committee's attention by a member and which was not inappropriate in the circumstances of the complaint.

Some members were of the view that the Code of Conduct Committee had strayed from their brief when they considered the placement of the qualifying statement as this did form part of the complaint by the healthcare professional. However members did consider that it was important that doctors were reminded of the precautions to consider before prescribing Celebrex. Despite assertions from Pfizer that all doctors would be aware of the side effects and precautions for Celebrex some members commented that a busy general practitioner may not read past the first 3-4 paragraphs and therefore may not have refreshed their knowledge on these aspects of the PI. The climate at the time of the Vioxx withdrawal was such that the company should have been exceptionally careful.

Members confirmed that the Code requirements in relation to qualifying statements apply to all materials, whether advertisements or 'Dear Doctor' letters. Members agreed that the Code of Conduct Committee was not in error in taking into account the need for some qualification of the statement by reference to the precautions in the PI, noting that the Code itself (Explanatory Notes Section 1.3(g)) specifies that qualifying statements should be on the same page. The fact that this was not referred to in the original complaint did not detract from the Code of Conduct Committee having regard to it in the context in which the Dear Doctor letter was published and where the statement in paragraph 3 was clearly the central message conveyed. In reaching its conclusions, the Appeals Committee did not intend to infer that the statement in

paragraph 3 of the letter would not have been misleading even if it had been qualified by a reference to the precautions in the PI.

The onus was on Pfizer to provide the highest level of evidence that there were no safety risks. It would have been judicious to make a less sweeping statement than *"the cardiovascular safety profile of Celebrex has been extensively studied"* when the referenced studies had not been powered to measure cardiovascular risk.

The Appeals Committee considered that, given the emerging evidence and uncertain environment for prescribers and patients, Pfizer should have been more careful and not overstated the evidence as they had.

## Sanction

The Appeals Committee was of the view that it should be considered a severe breach and by a majority agreed that the fine should remain at \$25,000.

In relation to the requirement for a corrective letter, the Appeals Committee concluded that whilst it may be theoretically possible to produce a corrective letter that is not confusing to prescribers, in light of the time elapsed since the letter was issued, that Pfizer had sent other communications to doctors in the interim, and the subsequent changes to the PI, it would be futile to require a corrective letter and that this requirement should be withdrawn. However, the Committee cautioned Pfizer that any communications to health professionals regarding the cardiovascular safety of Celebrex must not be misleading. Any future statement addressed to healthcare professionals should fully and correctly communicate information available to the company at the time and be accurate and balanced, particularly in the charged environment surrounding the safety of COX-2 medicines

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## Metvix (784)

*Promotional materials to healthcare professionals*

### Complaint

A complaint was received from the 3M Pharmaceuticals (3M) alleging that Galderma Australia Pty Limited (Galderma) was in breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Medicines Australia Code of Conduct. 3M argued that the piece was inaccurate, misleading and not supported by the body of evidence.

### Response

A response was received from Galderma denying that it had breached the Code of Conduct. Galderma was of the view that the statements were not making a medical claim, either implicitly or explicitly.

### Committee ruling

#### Issue 1 *“A face this beautiful doesn’t need a scar”*

The Committee discussed whether this statement implied that Metvix PDT caused no scarring or less scarring than other treatments or possibly the highest potential not to leave a scar. Some members commented that the first impression to a reader was that there would be no sign of treatment at all as evidenced by the face pictured in the promotional piece. Members were of the view that this was not entirely consistent with the referenced literature. These papers refer to the cosmetic outcome being better for Metvix PDT than other treatment modalities, but some hypopigmentation or scar formation was possible (3.7% - 11%). Members agreed that it was misleading to imply that there would be no scarring following any treatment with Metvix PDT.

While acknowledging that a provider must undergo training in the use of Metvix cream with the specifically designed Aktelite® lamp, members were of the view that if the promotional materials were sent to healthcare professionals who had not been trained there maybe the potential for them to be misled to understand that Metvix could be used for all types of actinic keratoses and basal cell carcinomas. Members gave the example of a general practitioner receiving this information and then referring a patient to a skin clinic or general practitioner who offered Metvix

PDT treatment without the knowledge that this treatment was only for use where other treatments are unacceptable or where surgery is considered inappropriate.

The Committee stated that while there maybe very good outcomes from Metvix PDT, the statement gave a misleading impression that Metvix PDT would cause no scarring. By a majority, the Committee found the statement in breach of Section 1.3 of the Code.

#### Issue 2 *“Clinical Trials in Australia and overseas have found Metvix PDT is the treatment option patients prefer”*

The Committee noted that not all treatment options had been tested in the referenced studies and therefore this statement was too broad and therefore misleading. The Committee unanimously determined the claim to be in breach of Section 1.3 of the Code.

Members commented that any comparative claim required the highest level of evidence. As already noted, this was an incomplete comparison that did not encompass all available treatments and all indications, the Committee unanimously determined it was in breach of Section 1.7 of the Code. The claim was also found to be a hanging comparator.

#### Issue 3 *“precisely directed treatment”*

The Committee noted the two uses of abbreviations for PDT: ‘photodynamic therapy’ and ‘precisely directed treatment’.

Members commented that PDT (photodynamic therapy) was a well recognised therapy. The majority of members were of the view that the alternate definition was a play on words with each meaning being clearly stated on the promotional item. The Committee remarked that this was a marketing device with no damage or misleading inferences. Some members commented that the term ‘precisely directed treatment’ should be regarded as a promotional claim as it implies that the treatment is more precise than other treatments and is more targeted to the tumour cells than healthy skin. As there was information in the referenced papers that supported the mechanism of action of Metvix to enable targeted treatment of certain types of actinic keratoses and BCCs, members concluded that the statement was not in breach of Section 1.3 of the Code.

As Galderma had used a number of references and not relied solely on data on file, the Committee determined that there was no breach of Section 1.2.2 of the Code.

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## Sanction

The Code of Conduct Committee resolved that Galderma should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its current form.

## Tritace (785)

*Medical Representative Behaviour*

### Complaint

A complaint was received from a healthcare professional alleging that the sanofi-aventis Group was in breach of the Code. The healthcare professional alleged that a representative had stated that funding for research at the hospital was very dependent on the prescribing of Tritace. Medicines Australia had requested the sanofi-aventis Group (sanofi-aventis) to respond to the complaint under Sections 4.2, 4.3, 4.4, all provisions of Section 7 and Section 10.5.

### Response

A response was received from sanofi-aventis advising that they had investigated the matter thoroughly and could find no evidence that a conversation with unethical intentions had occurred.

### Committee Ruling

The Committee noted that the sanofi-aventis medical representative had provided a statutory declaration denying she had implied that research funding to the hospital was dependent on prescriptions of Tritace, as alleged by the healthcare professional. Two other sanofi-aventis representatives who had attended the meeting at the hospital also provided statutory declarations stating that they did not recall the medical representative making any statement implying that research funding was dependent on prescriptions of Tritace.

Members noted that it had only limited information from the healthcare professional regarding the alleged statements and did not have information from either the healthcare professional or the medical representative about what exactly was said that resulted in the complaint being submitted.

The Committee concluded that it had insufficient information and evidence to find sanofi-aventis in breach of the Code. However, the Committee would be very concerned if the alleged activity by the medical representative had taken place and considered that, although no breach was found in this instance, it was appropriate to have submitted the complaint to the Committee.

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Companies should be advised to ensure that any statement made by a company representative could not be misinterpreted.

Members discussed the delay between the alleged activity and submission of the complaint, and recognised this may have been due to the healthcare professional waiting for a response from sanofi-aventis to his original telephone call, and taking time to determine where his complaint should be directed. The Committee wished to encourage the prompt reporting of any activity that might be in breach of the Code and to encourage companies to respond promptly to any complaints made directly to them.

## Tazac (787)

*Promotional material for healthcare professionals*

### Complaint

A complaint was received from a healthcare professional alleging that Aspen Pharmacare Australia Pty Limited (Aspen) was in breach of the Code in relation to promotion of Tazac. The healthcare professional alleged that statements in the promotional material were outside the indications and others were misleading. Medicines Australia had requested Aspen to respond to the complaint in relation to Sections 1.2.2, 1.3, 1.3.1 and 1.7.

### Response

A response was received from Aspen denying that it had breached the Code of Conduct. Aspen maintained that the information was to inform physicians of the mode of action for Tazac and that claims were not misleading or an unfair comparison to a competitor product.

### Committee Ruling

The Committee agreed with the complainant that the statement “promotes gastric emptying” was promoting an unapproved use of Tazac. There is no mention of promotion of gastric emptying in the Tazac Product Information. Whilst the approved indications for Tazac are included on the back of the detail aid, there was no qualification on the front page that promotion of gastric emptying is not an approved use of Tazac. Members discussed whether promotion of gastric emptying was simply useful information for prescribers, but considered that this was likely to be used as a point of differentiation from other drugs in the class.

The Committee concluded that the claim was in breach of Section 1.3.1 of the Code.

#### Pro-kinetic activity comparable to that of Cisapride

The Committee noted that there were no human data to show that the pro-kinetic activity of Tazac was equivalent to cisapride, only animal data. The failure to identify that the claim was based on animal data and had not been proven in humans was considered to be misleading and therefore in breach of Section 1.3 of the Code. Further as the claim was promoting an unapproved use of Tazac

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it was found in breach of Section 1.3.1 of the Code.

The Committee found no breaches of Sections 1.7 or 1.2.2 of the Code.

## Sanction

The Committee resolved that Aspen should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form.

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

## Pariet (788)

*Promotional material for healthcare professionals*

## Complaint

A complaint was received from AstraZeneca Pty Ltd (AstraZeneca) alleging that Janssen-Cilag Pty Ltd (Janssen-Cilag) was in breach of Sections 1.2, 1.3, and 1.7 of the Code in relation to promotion of Pariet. AstraZeneca alleged that several of the claims included major comparative statements that lacked sufficient substantiating data, and that other claims were false and misleading.

## Response

A response was received from Janssen-Cilag denying that it had breached the Code of Conduct. Janssen-Cilag maintained that all statements were clearly referenced and that there was an inconsistency between complaints raised by AstraZeneca in intercompany dialogue and those forwarded to the Code of Conduct Committee.

## Committee Ruling

**Claim 1 Overall implication of superiority of Pariet to Nexium in relief of night-time heartburn and extrapolation of superiority in night-time symptom relief from night-time acid control data.**

Members noted that whilst most evidence suggested that there was a correlation between lowering acidity and symptom relief, the acid reduction was a surrogate measure and cannot be directly applied as evidence for clinical benefit. The Committee considered that collectively the statements in the promotional item and letter and the graphs in the promotional item gave the misleading impression of superiority of Pariet over Nexium, which was misplaced. The sequence of statements was apparently designed to lead a reader to the conclusion that Pariet was superior to Nexium in the relief of symptoms which was misleading and disparaging to Nexium. The Committee found the statements and graphs to be in breach of Sections 1.3 and 1.7 of the Code but not in breach of Section 1.2 from the overall perspective.

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**Claim 2 “Pariet 20mg - better acid control on the first night vs Nexium (esomeprazole) 20mg and 40mg” and “Acid control on night one (healthy volunteers)” graphs**

The Committee considered that the data presented in the graphs did not accurately reflect what was happening in the two treatment groups in the supporting study, where there was a difference between the groups on day zero at baseline before treatment. Further, acid suppression doesn't necessarily accurately reflect symptom control in GORD. In addition, in the comparison between Pariet 20mg and Nexium 40mg in the graph based on another study did not include a representation of the standard deviations. From the abstract of this study there was evidence that the standard deviations were quite large, indicating large variability between patients. The Committee considered that it was preferable that information on standard deviations or error bars be included in graphics to allow a reader to interpret the data.

Members considered that Janssen-Cilag had selected favourable acid control data on night one for Pariet as a surrogate for heartburn control. In fact there was no difference between treatments during the daytime. Members considered that the graphs and associated claims presented highly selected data and were therefore misleading. The Committee concluded that the claims and graphs were in breach of Section 1.3 and 1.7 of the Code as they were misleading, presented highly selective data and made an unfair comparison with Nexium. The claims and graphs were also found in breach of Section 1.2 as they were based on an abstract with respect to the data on Nexium 40mg dose which was inadequate to substantiate the claim of better acid control on night one.

**Claim 3 “In study 1 Pariet remained superior for holding pH4 vs Nexium on night 5” and “... Pariet remained superior for holding pH4 vs. Nexium 20mg on night 5.”**

Members noted that the statement below the graphs in the promotional item reported a difference that was not statistically significant, which was misleading. The Committee noted that Janssen-Cilag and AstraZeneca had apparently resolved this matter through inter-company dialogue as Janssen-Cilag had conceded that there was defect with the data representation. The Committee expressed its disappointment that this matter had been brought forward as a formal complaint when it had evidently been resolved. The Committee found a minor breach of Section 1.3.

**Claim 4 “78% of patients achieved night-time heartburn relief on day one with Pariet.”**

Members agreed with the complainant that this statement lacked qualification regarding whether heartburn relief was 'satisfactory' or 'complete'. Further the study on which the claim was based was an un-blinded, open label, uncontrolled post-marketing surveillance study which was evidence of inadequate quality to support the strength of the claim. The Committee found that the statement was in breach of Section 1.3 of the Code because it was inadequately qualified and therefore misleading and Section 1.2.2 due to the inadequacy of the study to support the claim.

**Claim 5 “97% of patients were free from heartburn relapse after 1 year”.**

Members considered that the figure of 97% did not accurately reflect the study results. The abstract was published in 1999 and quoted the figure of 97%. However, the full published paper quoted the figure of 92% for the higher dose of rabeprazole and 84% for the lower dose. Members considered it was misleading to quote the figure from the abstract rather than from the published paper. Further, as argued by AstraZeneca, these figures relate to the 52 week time point and do not necessarily reflect the patients being symptom-free for the full period. From the published paper it would seem that approximately 72% of patients remained symptom free for the full year. Members considered that the claim, without appropriate qualification, implied that 97% of patients would be symptom-free for the whole year and was therefore misleading. The Committee found the claim to be in breach of Section 1.3 of the Code but found no breach of Section 1.2 as the published paper was of sufficient quality and detail to be used as substantiating data.

Members noted once again that it appeared that this aspect of the complaint had been resolved through intercompany dialogue, through Janssen-Cilag undertaking to qualify the claim.

**Claim 6 “Pariet 20mg shows superior heartburn relief compared with double dose omeprazole”**

Members noted that the claim of superiority of Pariet over omeprazole was based on a subgroup analysis of the study, for which the primary outcome measure was to look at all severities of heartburn. In the subgroup analysis Pariet was superior only in the more severe heartburn group. In addition the authors had stated in the discussion section that “This finding should not be over-interpreted, as the difference between the treatments on day 4 was the pre-specified

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primary endpoint, and earlier differences between the treatments were considered to be secondary.”

The Committee noted that Janssen-Cilag had accepted AstraZeneca’s view of this claim and agreed to clarify it if the claim was used again. The Committee determined that the claim was in breach of Section 1.3 of the Code because it lacked appropriate qualification and was therefore misleading and in breach of Section 1.7 because it made an unfair comparison with Nexium. No breach of Section 1.2 was found.

#### **Claim 7 Pariet 20mg - superior in treating heartburn compared to omeprazole 40mg” and accompanying graph.**

As noted with respect to Claim 6, Claim 7 was a selective representation of the data from the study - the data presented were only for patients with severe or very severe heartburn and only during the first three days of treatment. The graph was adapted from the paper and provided the data for days one to three rather than the full seven days presented in the paper. On day 4 the two drugs were equivalent, however the footnote in the graph states that by day seven there was no difference between the two drugs, which is incorrect. In addition, there was no information provided to a reader that the primary outcome of the study was across patients of all severities of heartburn in which context there was no significant difference between the two drugs.

The Committee concluded that the claim and associated graph were misleading and therefore in breach of Section 1.3 of the Code and made an unfair comparison with Nexium and in breach of Section 1.7. No breach of Section 1.2 was found because although the data had been inappropriately transferred into the promotional item, the study was appropriate.

#### **Claim 8 “... using rabeprazole (PARIET) as initial treatment in GERD may avoid the need for dose titration”.**

The Committee noted that the claim was a direct quotation from the paper and debated whether it had been taken out of context and was therefore misleading. Members considered that the statement was purely speculative and there were no data in the paper to support it. In addition, members noted that only part of the sentence had been quoted, omitting the preceding qualifying part.

However, the Committee concluded that the statement was generally meaningless and tautologous - the counter statement that using rabeprazole may not avoid dose titration could

also apply. No breach of Sections 1.3, 1.7 or 1.2 was found.

#### **Claim 9 Picture of the Pariet parrot jumping over Losec 20mg and Losec 40mg inferring superiority of Pariet over Losec 20mg and Losec 40mg.**

Members agreed that the graphic gave a misleading impression of superiority of Pariet over Losec 20mg and 40mg. The claims of superiority of Pariet in the promotional item, as noted above, were considered to be inappropriate generalisations from a sub-group analysis of a surrogate measure.

Members determined that the graphic was in breach of Sections 1.3 and 1.7 of the Code. No breach of Section 1.2 was found.

## **Sanction**

The Committee resolved that Janssen-Cilag should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. The claims and graphic found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

The Committee further resolved that Janssen-Cilag should be required to send a corrective letter to healthcare professionals.

In addition the Committee resolved that Janssen-Cilag should be required to pay a fine of \$25,000.

## **Appeal**

An appeal was lodged by Janssen-Cilag against the findings of the Code of Conduct Committee. Janssen-Cilag stated that they accepted the rulings in relation to Claims 1, 2, 7 and 9 however disagreed with the number of findings of the Code of Conduct Committee specifically in relation to the overall nature and severity of the sanction. Janssen-Cilag contended that several of the complaints had been resolved during intercompany dialogue and should not have been submitted to the Code of Conduct Committee.

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## Appeals Committee ruling

The Appeals Committee did not uphold the appeal by Janssen-Cilag in relation to the breaches of Sections 1.2.2 and 1.3 as determined by the Code by the Code of Conduct Committee.

In confirming the findings of the Code of Conduct Committee in relation to Sections 1.2.2 and 1.3 of the Code, members provided the following comments.

Members agreed that it was acceptable to use open labelled trials or post-marketing studies to support a claim if they were appropriately qualified and appropriate to support the claim. It would be preferable that this type of study was also supported by a published study. If only level II or III evidence is available it must be qualified to ensure that a healthcare professional is made aware of the level of evidence when assessing the veracity of the claim.

The Committee noted that it was up to Janssen-Cilag as to whether they could use the study in future promotional materials. When used in this case as the sole reference and without qualification it was considered to be in breach, however if presented in an appropriate context the same conclusion may not be reached.

In relation to the issue that some aspects of this complaint should not have been submitted to the Code of Conduct Committee because they were thought to have been resolved in intercompany dialogue, members were of the view that where a complaint comes before the Committee it should be considered and this was not procedurally incorrect. However, for matters that have been resolved during intercompany dialogue, it may not be appropriate to impose sanctions with respect to those matters.

Members were of the view that there was one matter which was agreed by both companies had been resolved at the intercompany dialogue level (Claim 3) and should not have been included in the submission to Medicines Australia.

to the other aspects of the complaint the sanctions overall were appropriate. The fine of \$25,000 was reduced to \$24,000.

Members considered that the requirement for a corrective letter should remain.

## Sanction

It was agreed that it was appropriate that the material found in breach should be withdrawn and not used in a manner that conveys the same or similar meaning.

The Committee acknowledged that intercompany dialogue had occurred and one aspect of the complaint should not have proceeded to the Code of Conduct Committee. However in consideration of all the breaches found in relation

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## Somac (789)

*Promotional material for healthcare professionals*

### Complaint

A complaint was received from AstraZeneca Pty Ltd (AstraZeneca) alleging that Pfizer Australia Pty Ltd (Pfizer) was in breach of Sections 1.2.2, 1.3 and 1.7 of Code in relation to promotion of Somac. AstraZeneca alleged that the claims were major and would have significant commercial impact in general practice.

### Response

A response was received from Pfizer denying that it had breached the Code of Conduct. Pfizer maintained that the study was of sufficient quality to support a major claim and the claims were consistent with the body of evidence.

### Committee ruling

#### Equivalent healing rates esomeprazole 40mg and Somac 40mg

Members considered that the supporting study was of inadequate design and had a number of methodological flaws and therefore it was inappropriate on which to base the major claims of equivalence between Somac 40mg and esomeprazole 40mg, which is inconsistent with the body of evidence. Members considered that it was misleading to base the strong claim of equivalence between Somac and esomeprazole based on a single paper with evident methodological problems.

The Committee determined that the graph and the table were in breach of Section 1.3 and Section 1.2.2 of the Code. No breach of Section 1.7 was found.

#### Relief of typical GORD symptoms

Members considered the methodological issues used in the paper, noting that the methodology is the same for both esomeprazole and pantoprazole. Therefore it considered that the argument by the complainant AstraZeneca was not sustainable. No breach of Sections 1.3 or 1.7 was found.

Symptom relief - "Our results show that pantoprazole (40mg o.d.) and esomeprazole (40mg o.d.) are equally effective in relieving GERD-related symptoms.

The Committee considered that in the referenced study the results were fairly similar across all the patients and different drugs. Therefore, it was not possible to distinguish between the drugs in that context. The Committee concluded that there was no breach of Sections 1.3 or 1.2.2.

### Sanction

The Committee resolved that Pfizer should take immediate action for the prompt withdrawal of the promotional material found in breach and should permit no further appearance of it in its present form. The claims and graph found in breach should not be used again in their present form or in a manner that conveys the same or similar meaning.

In addition, the Committee resolved that Pfizer should be required to pay a fine of \$15,000.

### Appeal

An appeal was lodged by Pfizer against the findings of the Code of Conduct Committee. Pfizer contended that the Code of Conduct Committee's decision ranged beyond the actual complaint before it, and its conclusion that breaches had occurred were not in accordance with the outcomes of the review.

### Appeals Committee ruling

The Appeals Committee did not uphold the appeal by Pfizer in relation to the breaches of Sections 1.2.2 and 1.3 as determined by the Code by the Code of Conduct Committee.

In confirming the findings of the Code of Conduct Committee in relation to Sections 1.2.2 and 1.3 of the Code, members provided the following comments.

- From the current body of evidence, there appears to be little established differences between the various PPI products. Larger head to head studies could provide further clarification.
- The Appeals Committee agreed that one referenced paper was of inadequate design and had a number of methodological flaws and therefore it was inappropriate on which to base the major claims of equivalence between

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Somac 40mg and esomeprazole 40mg. The Appeals Committee was not satisfied that the Code of Conduct Committee had erred in finding that the paper was inadequate to support the claims.

- General practitioners would not have all the evidence to evaluate the claims which were based on very technical arguments which are generally not accessible to most GPs. General practitioners could be influenced by these claims that give the impression that Somac was superior to Nexium, which cannot be adequately substantiated.
- The Code of Conduct Committee was not wrong to disregard another referenced paper in making its decision; in consideration that the paper had not been published at the time the advertisements were issued.
- There was no evidence that the Code of Conduct Committee placed undue reliance on the issue not subject to complaint by AstraZeneca in making its decision but agreed that where a Committee discusses any aspect not subject to complaint there should be a statement in the minutes acknowledging this and stating that it was not to be taken into consideration when determining whether a breach had occurred and any resulting sanctions. It was perfectly legitimate for the Code of Conduct Committee to note some issues relating to material before it.
- The Appeals Committee did not make any comment on the reasoning for finding a breach of Sections 1.3 in relation to “equivalent healing rates” based on the paper but no breach of Section 1.3 in relation to the claim “relief of typical GORD symptoms”.

## Sanction

The Appeals Committee agreed with the requirement that the promotional material in question be withdrawn from use and not used again in the same or similar format or in a manner that conveys the same meaning.

In relation to the proposed fine of \$15,000, the Committee resolved that this was appropriate and should remain.

## Avandia (790)

*Promotional material for healthcare professionals*

### Complaint

A complaint was received from Servier Laboratories (Australia) Pty Ltd (Servier) alleging that GlaxoSmithKline Australia Pty Ltd (GSK) was in breach of Sections 1.1, 1.2.2, 1.3, 1.3.1 and 1.7 of the Code in relation to a slide presentation to healthcare professionals on the use of Avandia. Servier’s complaint pertained to the promotion of misleading efficacy data and the implication of an effect of Avandia on the progression of Type 2 diabetes.

### Response

A response was received from GSK denying that it had breached the Code of Conduct. GSK contended that the intercompany dialogue minutes provided by Servier were not consensus documents and that the complaint was a misrepresentation of the educational initiatives. GSK maintained that the data and the way in which it was represented were neither inaccurate nor misleading.

### Committee Ruling

#### Efficacy data presentation

Members considered whether the reduction in glycosylated haemoglobin of 1.5% claimed in the slide presentation, which was referenced to a poster presentation, was reflective of the body of evidence and the Avandia Product Information. Members noted that the reference was not a published, peer-reviewed study, and the authors were both employees of GlaxoSmithKline, which may introduce potential conflicting interests. Members further noted that the data from the study regarding a 1.5% reduction in HbA1c sustained for 30 months was derived from extension studies of the four studies included in the review. The subjects in the extension studies were most likely to be responders rather than non responders, thereby skewing the results towards a greater reduction in glycosylated haemoglobin. The Committee considered that it should have been disclosed in the slide presentation that the efficacy result was from the population that responded to rosiglitazone and may not be representative of the general population. Members considered that the study result of a reduction of 1.5% in HbA1c appeared not to be

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representative of the other evidence. Without knowing which studies had been included in this paper it was impossible to know whether or not they also appeared in the summary graph. The Committee considered that the 1.5% reduction claimed in the slide presentation was greater than the results reported in the PI.

The Committee determined that the data presented was not representative of the body of evidence and therefore was unbalanced and misleading and in breach of Sections 1.1 and 1.3 of the Code. The Committee also determined that the study, which was a poster presentation, did not include sufficient information and detail for a reader to evaluate the validity of the claims and therefore its use to support the claim was in breach of Section 1.2.2 of the Code.

### Implied effect on disease progression

Members discussed the statements that “the glitazones target the underlying cause of type 2 diabetes rather than treating only the symptom (hyperglycaemia)” and that “Avandia improves beta cell function”. Members considered that it was not correct to refer to insulin resistance and decline in beta-cell function as the ‘causes’ of type 2 diabetes. Rather these are the pathogenic mechanisms. The actual causes of type 2 diabetes include genetic propensity and obesity.

Members noted that the Avandia PI states that studies to show that Avandia preserved (rather than improved) beta cell function had been conducted in rodent models and not in humans. The study refers to some human data based on estimates of beta cell function. Members considered that these data indicate that adding Avandia to metformin or a sulphonylurea may delay the rate of deterioration of beta cell function.

Members considered that these claims were not correct and went further than the referenced data would support. The Committee concluded that the statements were in breach of Sections 1.1 and 1.3 as they were not correct and were therefore misleading; in breach of Section 1.3.1 because they were inconsistent with Product Information and claimed actions of Avandia that went beyond that approved by the TGA; and in breach of Section 1.2.2 because the claims were based on the referenced paper which, as discussed in relation to the efficacy claims, provides insufficient detail for a reader to evaluate the validity of the claims and is a poster presentation which has not been subject to peer-review.

Members debated whether the claims were also in breach of Section 1.7 because the UKPDS data were presented earlier in the slide

presentation and therefore there may have been an implicit comparison with other drugs. However, the Committee concluded that no breach of Section 1.7 should be found because there was no direct comparison where the claims were presented. In discussing this complaint the matter of the statement that “*no clinically relevant drug interactions have been observed with rosiglitazone*” was discussed. Whilst this statement was consistent with the PI, it was noted that there were several recent papers suggesting there are potentially significant drug interactions between rosiglitazone and trimethoprim, ketoconazole, gemfibrozil and rifampicin and suggested that the PI may need to be updated.

## Sanction

The Committee resolved that GSK should take immediate action for the prompt withdrawal of the slide presentation found in breach and should permit no further appearance of it in its present form. The statements found in breach of the Code should not be used again in their present form or in a manner that conveys the same or similar meaning.

The Committee further resolved that GSK should be required to pay a fine of \$15,000.

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## Diamicron MR (791)

*Promotional material for healthcare professionals*

### Complaint

A complaint was received from GlaxoSmithKline Australia Pty Ltd (GSK) alleging that Servier Laboratories Australia Pty Ltd (Servier) was in breach of Sections 1.1, 1.3 and 3.3.1.2 of the Code in relation to promotion of Diamicron MR. GSK alleged a statement that patients in whom “Intolerance with previous agent with respect to hypoglycaemia” was implying that patients who have experienced hypoglycaemia with other sulphonylureas are suitable candidates to initiate Diamicron therapy and this was false and misleading.

### Response

A response was received from Servier denying that it had breached the Code of Conduct, except for a technical breach of Section 3.3.1.2. Servier maintained that the Abridged PI was included on the piece and that Servier had communicated information about hypoglycaemia to healthcare professionals.

### Committee Ruling

The Committee noted that Servier had conceded that a technical error had occurred by its failure to include the Australian Approved Name adjacent to the most prominent presentation of the brand name. A breach of Section 3.3.1.2 was found.

The Committee further noted that Servier had already undertaken to cease using the Diamicron MR promotional card and had sent a corrective letter to general practitioners who would have been exposed to the card.

The Committee reviewed the promotional card and considered that the statement regarding “intolerance with previous agent with respect to hypoglycaemia” was insufficiently explanatory in consideration that hypoglycaemia can occur with any sulphonylurea, although it may occur less frequently with gliclazide. The statement implies that Diamicron MR doesn’t cause hypoglycaemia, which is not correct and may mislead prescribers.

The Committee concluded that the promotional item was in breach of Sections 1.1 and 1.3 of the Code.

### Sanction

The Committee was concerned not to undermine the intercompany dialogue process through which Servier had given undertakings to cease use of the Diamicron MR card, destroy all copies and send a corrective letter to doctors. However, it did consider the breaches of the Code should be taken seriously.

The Committee resolved that Servier should take immediate action for the prompt withdrawal of the Diamicron MR card that had been found in breach and should permit no further appearance of it in its present form. The statements found in breach of the Code should not be used again in their present form or in a manner that conveys the same or similar meaning.

In consideration that Servier had already sent a corrective letter to doctors, which the Committee would have required, it accepted that appropriate correction had been undertaken.

The Committee resolved that Servier should be required to pay a fine of \$5,000 as they considered that the promotional item should have been reviewed more carefully by Servier prior to distribution.

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## Diamicron (791)

*Allegation of a breach of Section 12.3 of the Code by GlaxoSmithKline (GSK)*

### Complaint

In its response to complaint Diamicron (791), Servier Laboratories Australia Pty Ltd (Servier) had alleged that GlaxoSmithKline's (GSK) complaint was frivolous, with no patient safety issue and that intercompany dialogue had already resulted in action by Servier which addressed the issues and GSK was in breach of Section 12.3 'Abuse of the Code'. Medicines Australia had invited GSK to respond to the allegation of abuse of the Code.

### Response and Committee Ruling

GSK had responded that Servier had created the deliberate and false impression that it had ceased to use the item deemed to be in breach and had issued a corrective letter to all doctors who had been exposed to the item. GSK maintained that Servier had never confirmed that the corrective letter had been sent. However, Servier had provided evidence to the Code of Conduct Committee in support of the corrective letter having been sent.

The Committee was of the view that intercompany dialogue between GSK and Servier could have been developed further and GSK could have requested confirmation that the corrective letter had been sent.

The Committee was unanimously of the view no breach of Section 12.3 of the Code should be found.

## Symbicort (792)

*Advisory Board Meetings*

### Complaint

A complaint was received from GlaxoSmithKline Australia Pty Ltd (GSK) alleging that AstraZeneca Pty Ltd (AstraZeneca) was in breach of Sections 1.1, 1.3 and 1.3.1, 1.6, 4.9 and 10.5 of the Code regarding a series of meetings in relation to Symbicort. GSK alleged that the Advisory Board meetings were promotional in nature and did not constitute a genuine Advisory Board.

### Response

A response was received from AstraZeneca denying that it had breached the Code of Conduct. AstraZeneca refuted the allegation and asserted that the meetings were authentic Advisory Board meetings with no promotional intent.

### Committee Ruling

The Committee noted that it was evident that the use of corticosteroid/beta-agonist combination inhalers as a single therapy for both prevention of asthma and acute exacerbations was an emerging area, however this indication was not currently approved for use in Australia for Symbicort.

Members considered that the title of the meeting "The Dawn of a New Era in Asthma Management" promised something that is already happening; something that is agreed, whereas, any new indication for Symbicort as a single therapy for asthma has not been approved in Australia. The Committee considered that the repeated use of the tagline "The dawn of a new era in asthma management" in the letter of invitation was not consistent with the usual format for Advisory Board meetings and was more indicative of promotional forums.

Members considered that the "State Advisory Board" meetings were using the Advisory Board title to disguise early promotion of a new, unapproved use of Symbicort. Members considered that the meetings were not real Advisory Board meetings but were clearly promoting an unapproved indication. The Committee considered the meetings appeared to be a mechanism for priming key opinion leaders with information about a possible new indication

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for Symbicort. This was a disturbing marketing concept. Although the new indication for Symbicort had been approved in two countries, as stated in the AstraZeneca response to the complaint, it had not been approved in Australia and there was no guarantee that it would be.

The Committee noted that no terms of reference for the State Advisory Boards had been provided by AstraZeneca. Members considered that it was usual practice for there to be defined terms of reference for true Advisory Boards.

Members considered that usually a company would convene a single national Advisory Board to advise it on a particular product or issue. The members of an Advisory Board are limited to approximately ten key specialists, who are worked hard to provide advice to the company. It was considered unnecessary to establish groups of people in each State.

Members noted that if AstraZeneca had not used the Advisory Board title it would have been prevented from discussing the unapproved indication with doctors. Members concluded that description of the meetings as “State Advisory Boards” was to enable the promotion of an unapproved use of Symbicort to specialists.

The Committee unanimously determined that a severe breach of Sections 1.1, 1.3 and 1.3.1 of the Code should be found as it had promoted an unapproved use of Symbicort to specialist doctors through the series of State meetings.

The Committee also unanimously determined that the conduct of the “State Advisory Board” meetings would bring the industry into disrepute and therefore found AstraZeneca in breach of Section 10.5 of the Code.

No breach of Section 1.6 was found because the term “new” was not used directly in relation to the product being new or having a new indication. No breach of Section 4.9 was found because Section 4 did not apply to the activities subject to the complaint.

## Sanction

The Committee resolved that AstraZeneca should take immediate action for the prompt cessation of the Symbicort State Advisory Board meetings, and that no further meetings should be held similar to those described in the complaint and found in breach.

The Committee further resolved that AstraZeneca should send a corrective letter to all specialists who attended the State Advisory Board meetings

informing them that it had been found in severe breach of the Code of Conduct.

The Committee further resolved that AstraZeneca should be required to pay a fine of \$100,000.

## Appeal

An appeal was lodged by AstraZeneca against the findings of the Code of Conduct Committee. AstraZeneca contended that the Advisory Board meetings were not promoting unapproved indications for Symbicort and that the Code of Conduct Committee could not give advice in favour or against any particular structure for Advisory Boards.

## Appeals Committee ruling

The Appeals Committee did not uphold the appeal by AstraZeneca in relation to the breaches of Sections 1.1, 1.3 and 1.3.1 as determined by the Code of Conduct Committee. Members agreed that there were no patient safety implications from these breaches and amended the finding to these being moderate breaches of the Code.

The appeal in relation to the finding of a breach of Section 10.5 of the Code was upheld by the Appeals Committee. In confirming the findings of the Code of Conduct Committee in relation to Sections 1.1, 1.3 and 1.3.1 of the Code, members provided the following comments:

### Invitation

- There was insufficient control exercised by AstraZeneca in the wording and presentation of the invitation, which could only be construed by recipients as an invitation to a promotional meeting.
- The tagline “Dawn of a new era” juxtaposed with some of the wording may mislead a prescriber to believe that there was already a new indication approved for Symbicort. In addition, the brand name Symbicort was used in association with an unapproved use.
- Members of the Committee noted that the definition of ‘promotion’ provided by AstraZeneca differed from that in the glossary of the Code.

Members considered that the meetings held by AstraZeneca were promotional as defined by the Code.

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## Number of meetings

- The multiplicity of meetings provided more than a suspicion of a promotional activity to “prime” key opinion leaders for use of Symbicort as a single inhaler therapy, who in turn influence GP prescribing.
- The Committee was not convinced that it is necessary to hold Advisory Board meetings in every state, nor, particularly, to hold two meetings in the same city
- Members commented that this type of activity could open the floodgates for inappropriate activities by pharmaceutical companies - there could be national, state, regional meetings which would be inappropriate and expose the industry to criticism. Committee members commented that AstraZeneca was exploiting a loophole and this went against the spirit of the Code.

## Meetings

- Members were of the view that there was a more compelling argument that the series of meetings had a promotional purpose given the number of participants with respect to the total number of respiratory physicians in Australia.
- Members commented that the series of meetings could influence physicians down the track and was seen as a priming activity by the company.
- The meetings had the potential to affect prescribing.
- The Committee did not agree that there was any potential for patient harm given the learned audience.
- The minutes provided to members of the Appeals Committee were very brief, given AstraZeneca’s claim that these were in-depth advisory meetings of several hours duration - members were of the view that if the meetings had been a more genuine means of seeking advice the minutes would have included much greater detail and discussion. There was no evidence in the minutes provided that there was a significant diversity of prescribing practice in different states that warranted holding meetings in each state, or more than one meeting in one state.
- The Committee members commented that there appeared to be reluctance on the part of AstraZeneca to enter into meaningful intercompany dialogue with GSK regarding the content and nature of the meetings.

While aware that Advisory Boards are not sufficiently defined in the Code, members were of the view that the Code of Conduct and Appeals Committees were delivering a message to companies that the use of quasi-advisory boards for promotional purposes was not acceptable.

In summary members commented that the content of the invitation was careless and signalled a lack of rigour in AstraZeneca procedures for issuing invitations and convening or conducting advisory board meetings.

## Sanction

The Appeals Committee agreed that the requirement for a corrective letter to all attendees of the Symbicort Advisory Board meetings was not appropriate in the circumstances.

The Appeals Committee agreed that the fine of \$100,000 imposed by the Code of Conduct Committee should be reduced to \$25,000.

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# Actonel (793)

*Promotional material for healthcare professionals*

## Complaint

A complaint was received from Merck Sharp & Dohme (Australia) Pty Ltd (MSDA) alleging that the sanofi-aventis Group (sanofi-aventis) was in breach of Sections 1.1, 1.2.2 and 1.3 of the Code in relation to promotion of Actonel. MSDA alleged that the detail aid misrepresented the efficacy of risedronate by using data of inadequate strength.

## Response

A response was received from sanofi-aventis denying that it had breached the Code of Conduct. Sanofi-aventis maintained that the referenced studies were adequate and of sufficient quality to support the claims.

## Committee ruling

Members considered that the referenced study, which was a retrospective analysis of an observational database, contained a number of methodological flaws. It was considered to be an inadequate reference to support the claims that Actonel provides anti-fracture protection in six months. Further, members considered that the graphical representation of the data “Incidence of non-vertebral fractures at six months” was misleading because it gave the impression that Actonel was significantly better than Fosamax in providing fracture protection at six months, whilst this difference was not statistically significant. Members considered that the inclusion of the comparison against nasal calcitonin, which is not available in Australia, was irrelevant.

Members were of the view that the poster abstract was also an inadequate reference on which to base claims regarding Actonel as it provides insufficient information to allow a reader to adequately evaluate the validity of the claims.

Another referenced study was a retrospective, pooled analysis of the data from four separate studies and a fourth study was also a retrospective analysis of two separate studies.

Members considered that the data provided by these four studies was extremely inadequate on which to base strong claims of fast-acting fracture protection and protection maintained for up to seven years.

The Committee reviewed the detail aid and discussed how the claims were presented sequentially in a manner intended to build up a case for Actonel from fast acting, starting within six months, and up to seven years protection. Members considered that the overall effect of the detail aid was misleading and that the sum of all aspects of the presentation was more significant than taking each part separately. Members considered that the claims for Actonel and its superiority to Fosamax were based on very inadequate data presented in a manner intended to make the evidence appear more substantial than it is.

The Committee unanimously resolved that the presentation was in breach of Sections 1.1, 1.2.2 and 1.3 because it was not balanced, was misleading and was based on evidence of inadequate quality to support the claims. The Committee also found the presentation in breach of Section 1.7 of the Code because it made an unfair comparison with Fosamax that was unable to be adequately substantiated.

## Sanction

The Committee resolved that sanofi-aventis should take immediate action for the prompt withdrawal of the Actonel detail aid that had been found in breach and should permit no further appearance of it in its present form. Any other promotional materials containing the same claims and/or graphs should also be withdrawn and not used again.

The Committee further resolved that sanofi-aventis should be required to send a corrective letter to healthcare professionals. In addition, the Committee resolved that sanofi-aventis should be required to pay a fine of \$50,000.

## Appeal

An appeal was lodged by the sanofi-aventis Group in relation to the findings of the Code of Conduct Committee. The sanofi-aventis Group argued that the reference used to support the fracture protection claims for Actonel was appropriate and that the claims in the detail aid were not unbalanced or misleading.

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## Appeals Committee ruling

The Appeals Committee did not uphold the appeal by sanofi-aventis in relation to the breaches of Sections 1.1, 1.2.2, 1.3 and 1.7 as determined by the Code by the Code of Conduct Committee.

In confirming the findings of the Code of Conduct Committee in relation to Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code, members provided the following comments:

- The peer review process can be highly variable. Just because a paper has been peer reviewed, does not mean that its quality or validity cannot be challenged.
- The adjustments from crude risk should have been revealed by the statistician in the referenced paper.
- The referenced paper shows there was no significant difference between Actonel and Fosamax at 6 months - only in comparison to nasal calcitonin, which is equivalent to placebo. The inclusion of nasal calcitonin in the graphical comparison was to make it appear that Actonel is significantly different to Fosamax.
- The "Study Overview" box states only the total number of subjects in the study, not the number in each group, which would have assisted readers to evaluate the reliability of a single point estimate.
- Readers cannot determine how the statistical adjustments were done.
- The referenced paper is difficult to understand, particularly 'crude' and adjusted' risk. GPs would find it hard to make sense of the referenced paper. The onus is on a company to ensure that promotional claims are clear.
- It was agreed that there is a place for the type of analysis undertaken by the authors, but this must be used appropriately and in association with other published studies. Sanofi-aventis had presented the data in a way that can't adequately be supported.
- The poster abstract was the sole supporting data to support the claim of onset within six to eighteen months. The other referenced paper on the same page doesn't refer to onset of
- Effect at six months.

### Moderate Breach Section 1.2.2

The data may support statements in relation to Actonel, but not with respect to any comparison with Fosamax. The poster abstract should not be used as the sole supporting data to support a claim. The appeal against a breach of Section 1.2.2 was not upheld.

### Moderate Breach Section 1.3

The Appeals Committee agreed that the graphics and claims comparing Actonel and Fosamax were misleading. One reference supports early onset of action for Actonel, but not a comparison with Fosamax. Committee agreed that there was no complaint from MSD in relation to the use of the 7 year data therefore this aspect of the appeal was upheld.

### Moderate Breach Section 1.7

The comparison to Fosamax cannot be substantiated and was misleading.

### Moderate Breach Section 1.1

A company has a responsibility to ensure that all materials are correct, accurate and balanced. In light of the material being found to be misleading and that it made a comparison that could not be substantiated, the appeal against a breach of Section 1.1 of the Code was not upheld.

## Sanction

Having considered this appeal and given reasons why the appeal should not be upheld, the Appeals committee then reviewed the proposed sanction to ensure it was appropriate to the breaches found.

The Appeals Committee agreed that the material found in breach should be withdrawn and not used again or in a manner which conveyed the same or a similar meaning.

The Appeals Committee agreed that a corrective letter should be sent to all GPs who had been detailed using this material, highlighting the aspects found in breach of the Code. Sanofi-aventis should confirm to Medicines Australia that they can identify the GPs who were detailed with the item (estimated at 1200). The corrective letter should be approved by the Chairman and members of the Code of Conduct Committee and published within one month of receipt of these minutes. Confirmation of the mailing of this corrective letter should be provided by way of a letter from the mailing house - including how many letters (no names) and the date sent.

The Committee was of the view that as no advertisement had been placed in any journals, the requirement for a corrective advertisement should be removed from the list of sanctions.

In consideration that there was no likelihood of risk to patient safety, the Committee agreed that the fine of \$50,000 should be reduced to \$25,000.

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## Betaferon (794)

*Company sponsored DVD*

### Complaint

A complaint was received from Biogen Idec Australia Pty Ltd (Biogen Idec) alleging that Schering Pty Ltd (Schering) was in breach of Sections 6.4, 9.5 or 9.8 of the Code in relation to a talk at a MS Awareness Day. Biogen Idec alleged that information provided by the speaker and subsequently circulated to healthcare professionals, MS patients and carers was promotional and should not have been provided to members of the general public.

### Response

A response was received from Schering Pty Ltd denying that it had breached the Code of Conduct. Schering maintained that it was acting as an arm's length sponsor of the Victorian MS Society MS Awareness Day. All materials and comments by the speaker were independent of Schering.

### Committee Ruling

The Committee discussed the information provided in the letters of complaint and response and the content of the DVD recording of the presentation by the invited speaker. It was noted that the DVD had also been distributed by Schering at the MS Australia Scientific Meeting held in November 2004.

Members were of the view that the sponsorship of the MS Society meeting at which the speaker gave the presentation in itself was not in breach of the Code.

Committee members questioned what arrangements had been made between the MS Society and Schering in relation to the sponsorship. While companies should know what their sponsorship is used for, there is also the issue of third party independence in determining the scientific program content and speakers for their meeting. In this case the speaker was a Clinical Professor of Neurology and founder of a Multiple Sclerosis Centre in the US. Schering maintained that he had no association with the company and was reporting his personal, independent opinions regarding the MS therapeutic area's clinical trials (including complementary and alternative medicines).

Members discussed the provision of the recorded DVD of the speaker's presentation and its distribution at the November 2004 MS Society Scientific Meeting where the DVD was distributed to healthcare professionals. The Committee unanimously determined that no breach of Sections 6.4, 9.5 or 9.8 should be found as Schering was entitled to sponsor the original meeting at which the professor's presentation was made and was also entitled to distribute the DVD to health professionals at the MS Society Scientific Meeting in November 2004.

The Committee discussed Schering's argument that Biogen Idec should be required to justify that it had not abused the Code in bringing the complaint against Schering. The Committee determined that although no breach of the Code had been found, Biogen Idec was justified in seeking explanations of the situation. Further, had Schering responded to the original correspondence from Biogen Idec in the recommended 10 day period, the complaint may not have proceeded to the Committee. The Committee unanimously determined that there was no case of abuse of the Code to be answered by Biogen Idec.

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## Zocor (795)

*Promotional material for healthcare professionals*

The Committee unanimously found no breach of Sections 1.1 or 1.3 of the Code as the reference to “only 17” was sufficiently prominent and the inclusion of the explanatory note to the number needed to treat above the abridged prescribing information.

### Complaint

A complaint was received from a healthcare professional alleging that Merck Sharp & Dohme (Australia) Pty Ltd (MSDA) was in breach of the Code as the photo in the advertisement showed only 12 women while the advertisement stated that the number of women needed to treat to prevent an adverse event is 17. Medicines Australia had requested that MSDA respond to the complaint under Sections 1.1 and 1.3 of the Code.

### Response

A response was received from MSDA denying that it had breached the Code of Conduct. MSDA maintained that advertisement was not visually deceptive and that the message of the number needed to treat of 17 was clearly identified throughout the advertisement.

### Committee Ruling

The majority of Committee members expressed the view that most busy healthcare professionals would probably not count the actual number of people in the photo. The majority of members did not consider the portrayal of 12 women to be misleading as it was sufficiently clear in the text of the advertisement that the number needed to treat was 17, including the prominent boxed, reverse highlighted text “only 17” and the repetition of “...you only need to treat 17 patients...” immediately below the picture.

A minority of members considered that it was unfortunate that MSDA had not been consistent with the number of people in the photo and the claim relating to number needed to treat. However, considering the advertisement in its entirety, the Committee unanimously concluded that it was not misleading. The Committee noted that the number 17 was used twice in the advertisement and that it included a statement above the abridged prescribing information “The picture above contains 12 people and is not intended to represent the number of people needed to treat.” Members also commented that there was no assumption that all the women in the photo were diabetic, but displaying people who may be at risk.

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# Epilim 786 and 797

Promotional material for healthcare professionals

## Complaint

A complaint was received from a healthcare professional claiming that promotional material for Epilim was deceptive. A letter was also received from the Therapeutic Goods Administration (TGA) advising that they had received complaints from a medical practitioner and a pharmacist concerning an advertisement for Epilim. The complaint from both the original complainant and the TGA related to the same advertisement and raised the same issues. Medicines Australia had requested the sanofi-aventis Group (sanofi-aventis) respond to the complaint under Sections 1.2.2, 1.3 and 1.7 of the Code.

## Response

A response was received from sanofi-aventis stating that while they did not agree with the objections and comments in the complaint, they were prepared to amend any further versions of the mailer to take into account the comments of the complainants.

## Committee Ruling

### Graph showing bioavailability variance of generic drugs

The Committee discussed the meaning of 'variance' and agreed that the definition provided by the healthcare professional complainant of "Statistical term meaning a measure of the average distance between each set of data points and their mean value; equal to the sum of the squares of the deviation from the mean value" was correct. That is, the term 'variance' means 'discrepancy'. The term 'variance' also means 'discrepancy' in common English. It was not clear which meaning was intended.

Members agreed that the referenced FDA source was guidance for pharmaceutical companies in the US using 'mean plasma control' which was not the same as measures used by the TGA in Australia which are 'area under the curve' and time to reach maximum plasma concentration. It was also noted that the graph used in the Epilim mailer was an adaptation from that used in the referenced paper published in *Clinical Therapeutics* in 1986. The graph was based on

the 75/75 rule; at least 75% of subjects in a crossover bioequivalence study have bioequivalence parameters that do not differ from the brand name drug by more than 25%. Members commented that the graph in the Epilim mailer used +25% (125%) and -20% (80%).

Members of the Committee were of the view that the graph in the mailer was not appropriate as it was not in an Australian context and was not adequately explained or presented. The Committee questioned the meaning of the x-axis label "percentage of volunteers" and considered that without further explanation the graph was uninterruptible and meaningless. The Committee considered that the graph was in part adapted from FDA Guidance and applied as though it was the TGA's requirements. While the graph was adapted from FDA guidance, a generic drug will not necessarily have this extent of variance from the originator brand and therefore it was misleading to imply that this was the variance for a generic brand of sodium valproate. The variance of a generic brand of sodium valproate may be much tighter. Committee members stated that it would have been more appropriate to use a heading that indicated that the graph reflected the FDA Guidelines for Bioavailability and Bioequivalence Studies for Orally Administered Drug Products.

Members acknowledged that in the case of products with a narrow therapeutic window it may not be advisable to switch a patient stabilised on a particular product to another brand; however it was not appropriate to imply that generic products should not be used. Committee members noted that PB Schedule listed different brands of sodium valproate with a bioequivalence indicator.

The Committee unanimously determined that the graph was in breach of Sections 1.2.2 and 1.3 of the Code as the graph was misleading and did not adequately reflect the referenced source.

### Case History

The Committee was concerned that the case history, which inferred that it was an actual case in NSW through use of the NSW driver's license image and patient's initials, was not based on an actual case in Australia and was therefore misleading. The case history was referenced to an editorial in *Human Psychopharmacology* 1987. Sanofi-aventis stated that the case history was an international case adapted to Australia and was not an actual Australian case. Members noted that the published case report had included a paragraph which stated "On examination, the substituted tablets were found to be from a different country of origin, and although they were said to contain the same amount of sodium

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*valproate as his Epilim, clearly lacked the same bioavailability.*”Members considered that it was very misleading to imply that this variance between Australian approved sodium valproate products might occur, as the case was taken from a different regulatory environment from Australia where thorough steps are taken to avoid such occurrences.

Members of the Committee commented that the attempt to Australianise the case was particularly serious as Australian healthcare professionals may think that this had occurred in Australia with Australian approved generic products.

The Committee unanimously determined that the case history was in breach of Sections 1.2.2 and 1.3 of the Code as it was not relevant to the Australian environment, was not sufficiently substantiated by reference to an Australian approved generic product or products and was misleading by omission.

As there was no specific comparator mentioned, no breach of Section 1.7 of the Code was found.

## Sanction

The Committee resolved that sanofi-aventis should take immediate action for the prompt withdrawal of the mailer and should permit no further appearance of it in its current form. Any other promotional materials containing the same graphics and case history should also be withdrawn and not used again. The Committee noted that sanofi-aventis had stated in their response that they were prepared to amend any future materials.

The Committee further resolved that sanofi-aventis should be required to pay a fine of \$50,000.

## Television advertising to the general public (798)

*Information to the general public via television*

### Complaint

A letter from the Australian Broadcasting Authority (ABA) had been forwarded to Medicines Australia by the Complaints Resolution Panel as it had determined that the products subject to complaint did not fall within its jurisdiction and that the matter should be referred to the Medicines Australia Code of Conduct Committee. The ABA referral was in relation to a complaint from a healthcare professional alleging that several companies were promoting their products to members of the general public via television news or current affairs. Medicines Australia had asked Roche Products Pty Ltd (Roche), Abbott Australasia Pty Ltd (Abbott) and Merck Sharp & Dohme (Australia) Pty Ltd (MSDA) to respond to the complaint in relation to Sections 9.2, 9.3, 9.4 and 9.5 of the Code.

### Response

Letters of response were received from Roche, Abbott and MSD each denying that they had breached the Code of Conduct.

### Committee Ruling

Members of the Committee commented that it was the responsibility of companies to ensure that any material provided to media outlets was not promotional and was current, accurate and balanced. This also applied to materials supplied by agencies working on behalf of pharmaceutical companies. Members commented that as a company may not always be informed of what was going to be broadcast, it was critical that any information provided was of the highest standard. The Committee acknowledged that this may leave a company vulnerable, but a company must ensure that its material is written in a manner which is balanced in terms of contraindications, precautions and adverse reactions. In particular, individual case studies of personal experience with a product are less likely to be balanced.

The Committee considered that it was the responsibility of a company to do their best to ensure that the provisions of the Code are complied with and any materials that are provided to media are balanced and

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not promotional. It was insufficient defense to say that a company does not know what the media will do with the material or how they will interact with the patient contacts.

Members acknowledged the lengthy process that had occurred with the ABA and Complaints Resolution Panel prior to the complaint being received by Medicines Australia. This complaint was lodged with the ABA prior to Xenical being rescheduled to S3 (pharmacist-only medicine).

## Roche

Members commented on the ethics of nominating patients to speak to the media. While noting Roche's response that patients contact Roche to report positive experience with the weight loss product and give permission for their names to be provided to the media, members commented that this type of testimonial may be used by the media to discuss positive outcomes from a particular treatment and if the company provided the names of the patients, a link can be formed back to the company. Members also commented that even if a company provides accurate and balanced information in a written format to a media outlet, the provision of patient names to the media who could subsequently interview these people resulting in promotion of a particular prescription medicine was cause for concern.

In reviewing the material provided by the PR agency acting for Roche to Channel 7, members of the Committee were concerned that the information in Attachment 2 "*Healthcare Professionals and Weight Loss*" was not balanced and went beyond purely educational information.

The Committee discussed whether the provision of the package of information by the PR Company on behalf of Roche was in compliance with the Code of Conduct. Whilst the information provided was probably correct and factual, members were of the view that the information provided to Channel 7 was promotional. It was selective and not balanced by appropriate information about precautions, side effects, contraindications etc. Although the approved PI was included in the package of information, Attachment 2, "*Healthcare Professionals and Weight Loss*", was not balanced.

### Section 9.2

The Committee was of the view that the material provided to Channel 7 was not a media release and therefore no breach of Section 9.2 of the Code was found.

### Section 9.3

The Committee discussed at length whether the material was in breach of Section 9.3 of the Code and whether this section applied to the material supplied by Roche. The Committee acknowledged that Roche had provided the written information and patient details in response to a request from Channel 7 and Roche did not have any editorial rights over what information was broadcast. The Committee also acknowledged that it was likely that Roche had been given a short time frame in which to respond to the request for information. By a majority no breach of Section 9.3 of the Code was found.

### Section 9.4

The Committee unanimously found a breach of Section 9.4 of the Code as the material provided to Channel 7, particularly Attachment 2, was not balanced and went beyond a simple non qualitative or quantitative description of the therapeutic category or approved indication. These materials in combination with the provision of contact details for a case study that had positive outcomes from use of the product could be viewed as encouraging the usage of that product.

### Section 9.8

The Committee unanimously found no breach of Section 9.8 of the Code.

## Sanction

Having found a breach of the Code in relation to these materials, Roche or their agencies must not provide this information package again.

The Committee also imposed a fine of \$20,000.

## Abbott

### Section 9.2

As Abbott had not provided a media release to any media outlet, no breach of Section 9.2 of the Code was found.

### Section 9.3

In their response Abbott claimed that they had not initiated any contact with or provided any information to the media outlet other than the name of a general practitioner. No breach of Section 9.3 of the Code was found.

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## Section 9.4

In their response Abbott claimed that they had not initiated any contact with or provided any information to the media outlet other than the name of a general practitioner. No breach of Section 9.4 of the Code was found.

## Section 9.8

As no breach of Sections 9.2, 9.3 or 9.4 was found the Committee found no case to answer in relation to a breach of Section 9.8 of the Code.

## MSDA

### Section 9.2

As MSDA had not provided a media release to any media outlet no breach of Section 9.2 of the Code was found.

### Section 9.3

In their response MSDA claimed that they had not initiated any contact with or provided any information to the media outlet other than the animated graphics showing the method of action of Ezetrol. No breach of Section 9.3 of the Code was found.

### Section 9.4

In their response MSDA claimed that they had not initiated any contact with or provided any information to the media outlet other than the animated graphics showing the method of action of Ezetrol. No breach of Section 9.4 of the Code was found.

### Section 9.8

As no breach of Sections 9.2, 9.3 or 9.4 was found the Committee found no case to answer in relation to a breach of Section 9.8 of the Code.

# Solian (799)

*Promotional material for healthcare professionals*

## Complaint

A complaint was received from Bristol Myers Squibb Australia (BMS) Pty Ltd alleging that the sanofi-aventis Group (sanofi-aventis) was in breach of Sections 1.1, 1.3, 1.5 and 1.7 of the Code in relation to advertising for Solian. BMS stated that good faith had been demonstrated in attempting to resolve the complaint and BMS was concerned that sanofi-aventis had not taken the complaint seriously nor followed through on an agreed action.

## Response

A response was received from sanofi-aventis acknowledging that they had agreed during inter-company dialogue to stop using the claim, but the publication in the *MIMS Bimonthly* October/November 2004 and *MIMS CNS Guidelines* containing the advertisement had been an oversight and not deliberate. Sanofi-aventis advised that they had taken immediate steps to cease the circulation of the CNS Guidelines with only 587 copies being distributed, the remainder being quarantined for destruction.

## Committee Ruling

Members commented that despite the prolonged intercompany dialogue and sanofi-aventis' agreements to cease use of the tagline and claim, they could understand BMS's frustration that sanofi-aventis appeared to be disregarding the process.

### The Way Back

The Committee did not agree that the tagline "The Way Back" implied that Solian was the best option or had special merits that other antipsychotics could not deliver. However, some members of the Committee were of the view that the term did imply that Solian was the only way back compared to other products within the class, especially where the word 'The' was highlighted, and must have a promotional intent. By a majority the Committee found no breach of Sections 1.1, 1.3 or 1.5 of the Code.

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## With Solian you now have an effective atypical antipsychotic that doesn't cause significant weight gain

Members were of the view that in respect of the use of 'now' in this claim there was an implication that Solian was the only product that did not cause significant weight gain; that it offered something other products could not.

The Committee noted that there was no head to head comparison between Solian and other antipsychotics that would show in absolute terms that Solian doesn't cause weight gain and another antipsychotic does. A comparison of the Solian and Abilify PIs may suggest that Solian causes less weight gain. However, in the case of comparative efficacy or safety claims it was not appropriate to base a comparison solely on the PIs and that there must be other substantiating evidence to support such a claim.

The Committee noted that sanofi-aventis had agreed to cease using the claim in its present form and the use of "now".

The Committee found a breach of Sections 1.1, 1.3 and 1.7 of the Code because it was misleading, made an unfair comparison and sanofi-aventis had not demonstrated sufficient responsibility to ensure all claims were balanced and accurate. The Committee did not agree with the complainant that this was a repeat breach as the matter had not previously been before the Code of Conduct Committee.

The Committee noted that sanofi-aventis had agreed in August 2004 to delete the word 'now' from future promotional materials however the wording had continued to appear in publications into 2005. Members agreed that whether inadvertent or intentional, it was unprofessional of sanofi-aventis to allow this to occur. It was further noted that the failure to adhere to an undertaking to a complainant following intercompany dialogue had the potential to bring the complaints process and industry into disrepute.

The Committee also commented that sanofi-aventis had not offered any defense to the alleged breaches, and had only explained that the continued appearances of the claim and tagline had been due to a lapse in their processes, and perhaps had not treated the complaint with due consideration.

Committee members urged companies to enter into intercompany dialogue in an attempt to reach a resolution which was binding on both companies. While agreeing that a subject company may not acknowledge a breach of the Code when acquiescing to the complainant's request for amendment of promotional material, it

should be undertaken in good faith and in the spirit of the Code.

## Sanction

The Committee resolved that sanofi-aventis should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its present form. The statements found in breach of the Code should not be used again in their present form or in a manner that conveys the same or similar meaning.

The Committee further resolved that sanofi-aventis should be required to send a corrective letter to the healthcare professionals who received the MIMS CNS Guidelines (587 copies). If sanofi-aventis was unable to identify precisely who these recipients were, the corrective letter must be sent to the full target audience for the 2500 printed copies of the CNS Guidelines

The Committee also resolved that sanofi-aventis should destroy any remaining copies of MIMS CNS Guidelines held in their warehouse (1913 copies) and that sanofi-aventis should confirm in writing to Medicines Australia that this destruction has been completed.

The Committee also imposed a fine of \$20,000.

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# Fosamax (800)

*Promotional material for healthcare professionals*

## Complaint

A complaint was received from the sanofi-aventis Group (sanofi-aventis) alleging that Merck Sharp & Dohme (Australia) Pty Ltd (MSDA) was in breach of Sections 1.2, 1.2.2, 1.3 and 1.7 of the Code in relation to promotional pieces for Fosamax. Sanofi-aventis alleged that the FACT study results were used in such a way as to imply superior fracture protection for Fosamax.

## Response

A response was received from MSDA denying that it had breached the Code of Conduct. MSDA refuted the suggestion that it had conducted a campaign which aimed to mislead prescribers or provide inaccurate statements.

## Committee Ruling

### Complaint 1

#### **The alleged link between increase in BMD and reduction in fracture risk is controversial**

In considering the complaint the Committee noted that there appeared to be a consistent theme through many of the promotional items in that there was an implication that if greater efficacy in increasing Bone Mineral Density (BMD) is established that this then relates to greater efficacy as a fracture preventative. Having reviewed the references provided by sanofi-aventis and MSDA, members understood that the contribution of BMD to fracture risk was not a precise relationship. While originally it had been found that medicines that increase BMD may reduce fracture risk, in recent years other indicators of bone fragility such as bone turnover and changes to bone architecture have emerged that should be considered when providing information to healthcare professionals on management of osteoporosis.

The Committee commented that there were some anomalies in the data with some medicines good at increasing BMD but with no resulting decrease in fracture risk, while other medicines showed minor efficacy on BMD but had demonstrated good results in decreasing fracture risk. The strength of the link between BMD and reduction of fractures was recently acknowledged to be more complex.

Members advised that a patient with a low BMD was at greater risk of fracture, and if BMD was increased that risk is reduced, but it is not clear how much the risk was reduced. However increasing BMD is only one of the indicators and a direct linear correlation between increasing BMD and decreasing fracture risk had not been established. Members also voiced a concern that a company should not imply a clinical advantage of one medicine over another based on surrogate markers.

Members were of the view that if there was a reasonable connection in the mind of the prescriber that one drug offers greater clinical advantages over a comparator drug, and there was insufficient information or clarification of the actual data on which this comparison was based, this was misleading and in breach of the Code. In the case of alendronate and risedronate, if the claims were restricted to increasing BMD and reducing bone turnover, this would be acceptable. However, where the import of a claim was that there is a clinical advantage as a result of increasing BMD and reducing bone turnover, this was misleading based on surrogate rather than fracture outcomes.

The Committee accepted that there was a strong correlation between low BMD and fracture risk. But it was not clear and subject to scientific conjecture concerning the complex relationship between increasing BMD and fracture risk outcomes. Members commented that in a therapeutic area where there was emerging data, it was extremely important that very clear information is presented to healthcare professionals to allow them the opportunity to make an informed prescribing decision.

In the referenced meta-analysis, an increase in BMD did not always decrease the fracture risk. Therefore the Committee considered that if the claims relying on this meta-analysis infer fracture risk benefit, they require qualification such as 'in the context of bisphosphonates' and 'surrogate measures do not reliably predict clinical outcomes'.

### Mailer A

Members were of the view that the manner in which the claim "To reduce fracture risk, increase BMD" was used in association with the FACT outcomes that Fosamax caused greater increase in BMD and greater reduction in bone turnover would lead a prescriber to believe that there was evidence to show that Fosamax was better than risedronate in preventing fractures. There was an inference of clinical benefit resulting from BMD increase, a surrogate marker. However it was noted by one member of the Committee that

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MSDA had provided the referenced paper (the FACT study) and the PI to doctors folded within the mailer and this offered them the opportunity of reading the study and making an informed decision. The majority of members were not convinced that this was sufficient to overcome the lack of qualification on the mailer that clinical evidence of greater reduction of fractures with Fosamax compared with Actonel had not been demonstrated and that the relationship between increasing BMD and reducing fracture risk was not clear cut and appears to vary between products.

By a majority the Committee found the claim “To reduce fracture risk, increase BMD” closely associated with the FACT data to be in breach of Section 1.3 of the Code.

#### **Leave Behind A**

By a majority the Committee found the claim “BMD Fracture Risk” was misleading in the context of juxtaposition with the FACT data and in breach of Section 1.3 of the Code. Members were of the view that by implying Fosamax was better than Actonel at reducing fracture risk without supporting clinical data for fracture risk protection was misleading. Some Committee members commented that if MSDA had restricted its claims based on the data from the FACT study to increasing BMD and reducing bone turnover rather than inferring that fracture risk reduction had been demonstrated, the materials would have offered a more balanced view of the current findings in this field.

#### **Media Release**

No breach of Section 1.3 of the Code was found as members were of the view that the information was sufficiently qualified by the explanation that the study was not powered to examine differences in fracture risk reduction and that the measures were surrogate measures of fracture risk.

#### **Complaint 2**

**Greater increases in BMD are not necessarily associated with greater decreases in fracture risk as demonstrated in the body of evidence**

For the same reasons as described under Complaint 1, by a majority the Committee found that the claim “Hip BMD ↑ of 3% predicts a non-vertebral fracture risk ↓ of 46%” (Mailer A) was in breach of Sections 1.2.2 and 1.3 of the Code because the data are insufficient to support the claims which are therefore misleading.

**Increasing BMD and reducing bone turnover = reduced fracture risk (Leave Behind B)**

The Committee found the complaint not made out as this statement did not appear in Leave Behind B.

**“In this study, Fosamax clearly demonstrated superior efficacy, using surrogate measures of fracture risk”**

The Committee found no breach of the Code because the information was sufficiently qualified by the explanation that the study was not powered to examine differences in fracture risk reduction and that the measures were surrogate measures of fracture risk.

#### **Complaint 3**

**Inadequate evidence to support a comparative graph**

The Committee determined that MSD was not solely relying on data on file as the claim was also referenced to a published paper. Members were of the view that the graph was consistent with, and can be calculated from, the data in the publication. No breach of Sections 1.2.2 or 1.7 of the Code was found.

#### **Complaint 4**

**Irrelevance and selectivity of the results presented (omission of the fracture data)**

The Committee considered that because the FACT study was not powered to examine differences in fracture risk reduction between Fosamax and risedronate, MSDA was not obliged to include this information in any of the promotional items. No breach of 1.2 of the Code was found.

However, the Committee reiterated its earlier findings that the close association between the FACT data and statements about fracture risk reduction as described in Complaints 1 and 2, and the failure to qualify that these claims were based on surrogate markers and not clinical data, Mailer A and Leave behind A were misleading and made an unfair comparison between Fosamax and risedronate and were in breach of Sections 1.3 and 1.7 of the Code.

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## Complaint 5

### Intent to mislead via juxtaposition of fracture risk reduction (or statements regarding fracture risk) with results of the FACT Study

As discussed under previous complaints, the Committee agreed with the complainant that the juxtaposition of the FACT Study data that Fosamax caused a greater increase in BMD and greater reduction in bone turnover with statements about fracture risk reduction imply that Fosamax had a clinical benefit with respect to fracture risk reduction although this has not been established. The lack of qualification that no clinical advantage of Fosamax over Actonel in relation to reduced fracture risk was considered to be misleading.

The Committee confirmed its earlier findings in relation to Mailer A and Leave Behind A, and for the same reasons found that Leave behind B was in breach of the Code as follows:

#### Mailer A

Breach Section 1.3 of the Code

#### Leave Behind A

Breach Section 1.3 of the Code

#### Leave Behind B

Breach Section 1.3 of the Code

#### Media Release

No breach of Section 1.3 as the statements were sufficiently qualified

#### Mailer B

In relation to Mailer B, the Committee determined that the complaint was not made out because the mailer did not refer to the FACT data, which was the basis of the complaint. No breach of Section 1.3 of the Code was found in relation to Mailer B. However the Committee cautioned that where a claim of clinical superiority is made for Fosamax over risedronate that is based on surrogate markers rather than clinical data this would be misleading.

## Complaint 6

### Intent to mislead via the repeated use of the word “superior”

Members discussed the use of superior in the promotional pieces and were of the view that ‘superior’, used in the context of the various statements, was not in breach of Sections 1.3 or 1.7 of the Code.

However members commented that there was definitely an implication in the promotional items elsewhere found in breach that there was a clinical advantage in using Fosamax.

## Sanction

The Committee resolved that MSDA should take immediate action for the prompt withdrawal of the material found in breach and should permit no further appearance of it in its present form. The statements found in breach of the Code should not be used again in their present form or in a manner that conveys the same or similar meaning.

The Committee further resolved that MSDA should be required to send a corrective letter to the healthcare professionals who received the promotional items. The corrective letter should state that Fosamax has not been shown to be superior to Actonel in relation to fracture risk reduction by data available to date and that the claims in the promotional items found in breach were based on surrogate markers. If MSDA was unable to identify precisely who these recipients were, the corrective letter must be sent to all general practitioners.

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# Norvasc (802)

*Promotional materials for healthcare professionals*

## Section 1.3.1

The Committee found no breach of Section 1.3.1 for the reasons outlined in the previous section.

## Complaint

A complaint was received from the Solvay Pharmaceuticals (Solvay) alleging that Pfizer Australia Pty Ltd (Pfizer) was in breach of Sections 1.2.2, 1.3 and 1.3.1 of the Code in relation to advertisements for Norvasc. Solvay alleged that the advertisements were inaccurate, misleading and not supported by the body of evidence or the current approved PI.

## Response

A response was received from Pfizer denying that it had breached the Code of Conduct. Pfizer maintained that the aim of the advertisements was to highlight the importance of treating elevated blood pressure in order to help prevent significant cardiovascular events.

## Committee Ruling

The Committee was of the view that it was widely understood by doctors that prescribing an antihypertensive with the purpose of lowering blood pressure would thereby reduce the risk of stroke and myocardial infarction. Members stated that the association between high blood pressure and stroke is well known. Members also commented that strokes are dramatic by their very nature and therefore did not find the image of the infarcted brain misleading.

### Section 1.2.2

The Committee did not agree that the dramatic visual of an infarcted brain implied the use of Norvasc primarily for the treatment or prevention of stroke and/or myocardial infarction except through the primary indications of blood pressure control and angina. The Committee agreed with the general consensus from both companies that there is no disputing the ability of antihypertensive agents to reduce the risk of stroke and myocardial infarction. The Committee found no breach of Section 1.2.2 of the Code.

### Section 1.3

The Committee found no breach of Section 1.3 for the reasons outlined in the previous section.

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## Monitoring Committee Report

During the 2004/2005 reporting period the Monitoring Committee reviewed promotional materials in the cardiovascular therapeutic class, invitations to company sponsored educational meetings, market research activities and advertisements in electronic prescribing software across all therapeutic classes.

At the meeting to review all advertisements in the *Cardiovascular therapeutic class* (18 advertisements from 10 companies) members of the Committee raised a number of issues for communication to all companies.

- References and qualifying statements must be of sufficient size and clarity to ensure a reader is not misled. Companies must ensure that the materials submitted to the Monitoring Committee were the original size as smaller copied versions do not allow the Committee to review all aspects of advertisements in the form received by healthcare professionals.
- Promotional taglines must comply with all provisions relating to promotional claims.
- False covers on magazines must include a statement of sufficient size and prominence that the cover must be removed prior to placing the magazine in an area where it may be read by a member of the general public.
- Secondary advertisements must include a reference to the location of the Primary advertisement or the location of the PI within the journal.
- Short advertisements must not contain promotional claims.

The review of *invitations to company sponsored educational meetings across all therapeutic classes* (1373 invitations and 30 companies) was undertaken over five Committee meetings. While compliance was again at a high level there were a number of issues raised that were communicated to all companies. In addition to minutes of the meeting this information was provided to companies via the Code Newsletter.

- Companies should provide the Monitoring Committee with the number of attendees and the type (eg GPs, specialists, nurses etc).
- Further to information provided in 2003, the RACGP provided Medicines Australia with the required wording for inclusion on invitations: "Allocated total CPD points 4 (Group 2) in the RACGP QA&CPD Program". The only alternative was "CPD Points have been applied

for" if the Provider was waiting on the adjudication outcome.

- A general comment in relation to evening educational meetings was that the agenda should contain sufficient information relating to the educational content of the meeting and time allocation to provide a healthcare professional with sufficient information on which to make their decision on attending. This was particularly important where there are no CPD points attached to the presentation.
- For weekend meetings, while acknowledging travel time for healthcare professionals should not encroach on workdays, the Committee was of the view that if a weekend meeting was advertised it should be two days duration with educational content on both days
- The Committee considered that the venues selected by companies for educational meetings recognised the professional standing of the audience without being extravagant or inappropriate.

The review of *market research materials* (127 items from 19 companies) was held over three Committee meetings. This was the first time this type of material had been reviewed by the Monitoring Committee. Overall companies were clearly cognisant of the requirements of Section 8.3 of the Code. The Committee made a number of comments that would be of educative value to all companies.

- In relation to any payment made for participating in market research, companies were encouraged to state the actual payment and length of time needed to complete the survey or questionnaire.
- There should be no added incentives such as the use of a competition to encourage healthcare professionals to participate in the market research.
- A donation to a registered charity in lieu of payment would be acceptable on the condition that the donation was commensurate with the time taken to complete any work.
- Companies were also encouraged to provide information on the purpose of the research and what the company was going to do with the data.
- Privacy Statements should always be included on any item of market research with informed consent the preferred option.

The review of all *advertisements in electronic prescribing software* (40 advertisements from 13 companies) raised a number of issues which were communicated to all member and non member companies via a memo and the Code Newsletter. Medicines Australia is working with the provider and companies to ensure greater

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compliance with the requirements for this section of the Code.

- The Committee determined that the generic name in a number of advertisements was either too small or the contrast between the text and background was insufficient to allow easy reading.
- A number of advertisements did not include all information required for Primary advertisements. It was evident there was confusion between the definition of Primary and Short advertisements.

## Provisions of the Code

### Relevant to complaints in the Annual Report

#### Edition 14

#### 1. Nature and Availability of Information and Claims

##### 1.1 Responsibility

It is the responsibility of companies, their employees and their medical/technical advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct\*, fully supported by the Product Information, literature\* or “Data on File”\* or appropriate industry source, where these do not conflict with the Product Information.

Activities of company representatives\* must comply with the Code at all times.

##### 1.2 Substantiating Data

###### 1.2.1 Provision of Substantiating Data

Further to the information supplied or generally available, a company will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

Data in support of a claim, including “data on file” or “in press” must be made available without delay upon reasonable request.

Where this material is not available through standard library services, it must be made available without delay.

###### 1.2.2 Level of Substantiating Data

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

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

##### 1.3 False or Misleading Claims

All information, claims and graphical representations provided to health care professionals and members of the general public must be current, accurate, balanced and must not

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mislead either directly, by implication, or by omission.

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

#### 1.3.1 Unapproved products and indications

Products that have not been approved for registration by the Department of Health and Ageing must not be promoted. However, samples of unapproved products may be displayed and educational material\* made available at International Congresses\* and Australasian Congresses in accordance with Section 6. This restriction also applies to unapproved indications for registered products.

#### 1.4 Good Taste

All promotional and educational material (including graphics and other visual representations) must conform to generally accepted standards of good taste and recognise the professional standing of the recipients.

These materials must not contain anything which would be likely to cause serious or widespread offence taking into consideration prevailing community standards.

#### 1.5 Unqualified Superlatives

Unqualified superlatives must not be used. Claims must not imply that a product or an active ingredient is unique\* or has some special merit, quality or property unless this can be substantiated.

The word "safe" must not be used without qualification.

#### 1.6 New Products

The word "new" must not be used to describe any product, presentation, or therapeutic indication, which has been available and generally promoted for more than 12 months in Australia.

#### 1.7 Comparative Statements

Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. In presenting a comparison, care must be taken to ensure that it properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. "Hanging" comparatives - those which merely claim that a product is better, stronger, more widely prescribed etc must not be used.

"Data on file" when used to substantiate comparative statements must comply with the requirement of Section 1.2.

### 3. Promotional Material

For products that have a "Boxed Warning" included in their Approved Product Information, all promotional material must include the Boxed Warning or include a prominent statement drawing attention to the Boxed Warning.

In addition, all promotional material covered by Section 3.1, 3.2, 3.3 (with the exclusion of 3.3.3), 3.4 and 3.5 must include a clear and prominent statement drawing the attention of the reader to any Pharmaceutical Benefits Scheme (PBS) listing and restrictions or its non availability via the PBS.

#### 3.1.2.2 A Secondary advertisement must contain:

- (a) The brand name of the product
- (b) The Australian Approved Name(s) of the active ingredient(s)
- (c) The name of the supplier and the city, town or locality of the registered office
- (d) A clear and unambiguous statement for prescribers to review the Product Information before prescribing
- (e) A statement to the effect that further information is available on request from the supplier.
- (f) All PBS listings, including any restrictions, as required in the preamble to Section 3

#### 3.1.2.3 A secondary advertisement must also contain either:

- (a) the Full Disclosure Product information (See Section 2.1), the Abridged Disclosure Product Information (See Section 2.2) or the Minimum Product Information for Primary advertisements (see Section 2.3) or
  - (b) the location of the Product Information within the same publication either by reference to the location of the Product Information or a Product Information Index;
- or
- (c) the location of the Primary Advertisement contained within the same publication by reference to the advertisers index.

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### 3.3.1 Printed promotional material

**3.3.1.1** Where an item of printed promotional material is demonstrated, on completion of the presentation, the Product Information must be offered to the individual reviewing the promotional material or, in a group situation, to the audience.

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

- (a) The brand name of the product
- (b) The Australian Approved Name(s) of the active ingredient(s)
- (c) The name of the supplier and the city, town or locality of the registered office
- (d) Full or abridged disclosure Product Information
- (e) All PBS listings, including any restrictions, as required in the preamble to Section 3

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

**3.3.1.4** Where it is impractical to print the Product Information on the body of the promotional material, the promotional material will carry a statement to the effect of the following in a type size of not less than 2 mm.

“Please review Product Information before prescribing. Product Information accompanies this item.”

The item is then to be accompanied by a full or abridged Product Information document.

### 3.9 The Use of the Internet for Pharmaceutical Information

Medicines Australia supports the right of Companies to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and health care professionals.

However, the promotion of products covered by the Code of Conduct to the general public via the Internet would breach Section 9.4 of the Code and various therapeutic goods legislation which stipulate that prescription medicines must not be promoted to the public.

An advertisement is defined as any statement which is intended (directly or indirectly) to promote the use or supply of a medicine. In providing information to members of the general public, companies must ensure that the intent of this action is informational and not promotional. Care needs to be taken by companies to ensure that material published is of the kind that it is reasonable to conclude that no intention of promotion exists.

### 3.9.1 Information available to the General Public

The purpose of this section is to identify how current, accurate and balanced information regarding prescription medicines available in Australia can be provided via this medium to members of the general public. The intent of the provision of this information must be educational and must never be promotional if it can be accessed by members of the general public.

The following information may be provided to members of the general public:

**3.9.1.1** A brief non-promotional summary of the company's products available in Australia.

This information should be current, accurate and balanced and must not be promotional. It must contain information about the product's precautions, adverse reactions, warnings and contraindications and interactions and may contain information about current research or clinical data that would assist members of the general public understand how this product works, its uses and compliance advice.

All information provided to members of the general public about prescription medicines must be in accord with the product's current Approved Product Information.

**3.9.1.2** A copy of the product's Consumer Medicines Information (CMI).

CMIs must appear in their entirety. They must not be amended, abridged or displayed in a promotional manner.

**3.9.1.3** Reference or linkages to other reputable information sources that provide valuable educational material that would enhance a member of the general public's understanding of a disease area.

When making such a reference or linkage a clear screen displaying the following statements must appear before the information can be accessed:

- that the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should

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- refer to the CMI for products to fully understand the terms of a product's registration in Australia
- that the intent of providing this material is informational and not as advice
  - any information provided by this source should be discussed with the reader's health care professional and does not replace their advice

#### **4. Medical Representatives**

**4.2** Companies have a responsibility to maintain high standards of ongoing training for representatives.

**4.3** Medical representatives should possess sufficient medical and technical knowledge to present information on the company's products in an current, accurate and balanced manner and should be conversant of all provisions of this Code.

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

**4.9** Under no circumstances shall representatives pay a fee, in cash or kind, in order to gain access to a healthcare professional.

**6.2.1** Any hospitality provided by Companies either directly or by sponsorship or assistance to the meeting organisers of educational meetings, must be secondary to the educational purpose

#### **6.4. Sponsorship or Involvement in Australasian Congresses**

Companies may assist and make financial contributions to educational meetings organised by third parties and may sponsor the attendance of health care professionals at these meetings, if:

- the primary objective of the meeting is the enhancement of medical knowledge and the quality use of medicines in Australia
- any assistance or sponsorship provided will be used for activities that further that objective, which would not bring discredit upon the industry and are able to successfully withstand public and professional and community scrutiny and
- conform to professional and community standards of ethics and good taste

#### **6.5 Sponsorship of Health Care Professionals**

The selection criteria for sponsorship to allow health care professionals to attend Educational Meetings must be based solely on their interest in the area of medicines being discussed and their ability to communicate any relevant information to Australian health care professionals to enhance the quality use of medicines.

#### **7. Sponsorship**

The Code of Conduct recognises the significant contribution of the pharmaceutical industry to the quality use of medicines in Australia through sponsorship of health care professional organisations and activities involving health care professionals.

The provisions of this Section cover the sponsorship of any activities involving health care professionals by a company, including the attendance at international scientific and educational meetings.

**7.1.2** No sponsorship should be conditional upon any obligation to prescribe a particular product. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing or dispensing practices.

**8.1.7.** Any payment to the medical profession must be commensurate with the work involved and not based upon the number of prescriptions written.

**8.2.2** Companies should not offer any monetary or any other type of reward to healthcare professionals, their families and/or employees for taking part in PFPs.

**8.2.3.** PFP should involve patients being treated for approved indications of the product.

**8.2.4.** Product Familiarisation Programmes should only be initiated in the first 12 months following first supply of the product approved for registration, the approval of new indications\* or substantive changes to the product. PFP should not be carried out for a period exceeding 12 months.

#### **9.2 Product Specific Media Statements**

**9.2.1** The purpose of a media releases is to provide current, accurate and balanced information about medicines available in Australia and therefore must include information about the product's precautions, adverse reactions, warnings, contraindications and interactions. The intent of such media releases must be educational and not to promote particular treatments to the general public.

A media release issued directly, or through conferences for the lay media to announce a new product or major indication approval to the public, will be allowed if the product has been registered for use in Australia and the medical profession has been supplied with the appropriate information.

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The media release may include the product's trade name, the Australian Approved Name of the product, its approved indications, therapeutic class, launch date and a balanced and accurate discussion of the product's method of action.

The media release must indicate any PBS listings and restrictions or a notation if the product is not listed on the PBS. It must also be accompanied by a copy of the product's current Consumer Medicine Information or the direct website of information.

The media release must be in language that reflects current community standards and must not include any material that could be considered promotional or comparisons with other products.

**9.2.2** No other media releases relating to a specific medicine are permitted however it is acceptable to respond to both media inquiries and inquiries from members of the general public.

**9.2.3** Media releases should not be accompanied by any material which encourages or is designed to encourage the use of any prescription medicines. Its purpose should be solely educational and informative.

**9.2.4** Companies are always responsible for all material prepared for the media by the agencies engaged by them.

### **9.3 General Media Articles**

General media articles concerning specific prescription products must not be initiated by companies. However, information on medical conditions is allowed.

Companies should not attempt to encourage the publication of general media articles or their content with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.

### **9.4 Promotion to the General Public**

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

### **9.5 Patient Education**

It is acknowledged that members of the general public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The purpose of such information should be educational and

should encourage patients to seek further information or explanation from the appropriate healthcare professional. In addition, the following criteria should be satisfied:

**9.5.1** The educational material must be current, accurate and balanced.

**9.5.2** The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.

**9.5.3** Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.

**9.5.4** 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.

**9.5.5** The educational material must include a statement directing the patient to seek further information about the condition or treatment from his/her doctor. Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a product.

**9.5.6** The tone of the message must not be presented in a way which unnecessarily causes alarm or misunderstanding in the community.

**9.5.7** On all occasions the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes of successful treatment or stimulating the demand for prescription of a particular product

### **9.6 Patient Aids**

Patient aids which are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific. The content of such material must be designed to assist with patient compliance by providing information which clarifies method of administration, precautions, special instructions and like information. It must not make comparisons or include promotional claims.

### **9.8 Discredit to, and Reduction of, Confidence in, the Industry**

Activities with, or materials provided to members of the general public must never be such as to bring discredit upon, or reduce confidence in the

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pharmaceutical industry. Such activities would be seen as a Severe Breach of the Code of Conduct.

### **10.2 Hospitality**

Any hospitality offered by Companies to health care professionals should be simple, modest, secondary to the educational content and provided in an environment that enhances education and learning. The venue and location at which a company provides hospitality to health care professionals must be conducive to education and learning and must not be chosen for its leisure or recreational facilities.

A Company must not subsidise or pay for the costs of family or companions of attendees at educational meetings.

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

Activities engaged in by Companies with health care professionals or materials provided to health care professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry.

A breach of this requirement is a Severe Breach of the Code of Conduct.