

Medicines Australia Code of Conduct Quarterly Report July - September 2007

Medicines Australia Code of Conduct

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

The Medicines Australia Code of Conduct was introduced in 1960 and is currently operating under Edition 15 (Effective 6 December 2006).

This report covers all complaints finalised between July and September 2007. Complaints finalised during this period were in relation to materials or activities conducted under Editions 14 and 15 of the Code.

Quarterly Report 1: January - March 2007 and
Quarterly Report 2: April - June 2007 were incorporated into the Code of Conduct Annual Report 2007

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How do I obtain a copy of the Code?

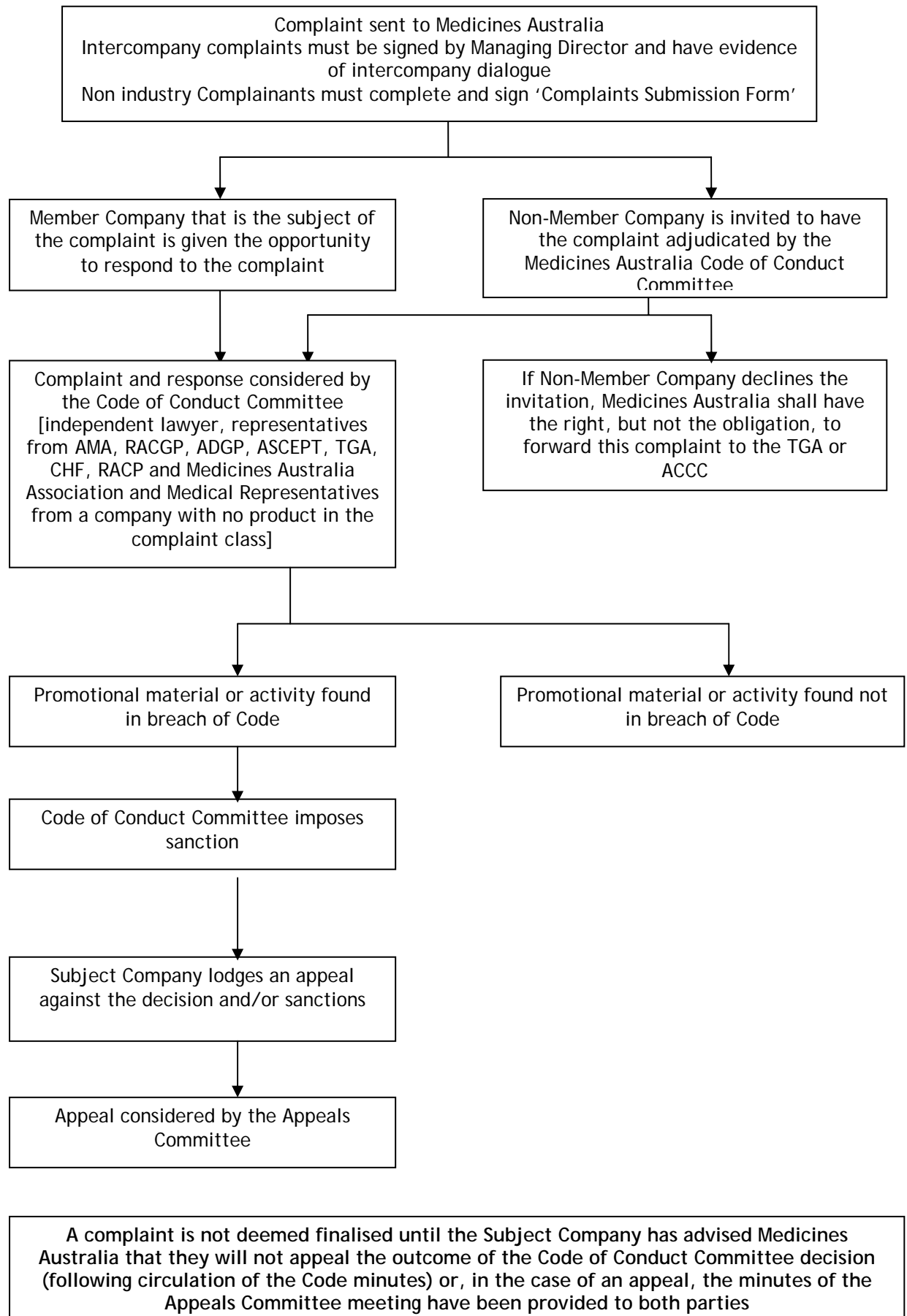
Hard copies of Edition 15 of the Code are available from Medicines Australia.

The Code of Conduct and the Guidelines that accompany the Code are available from the website.

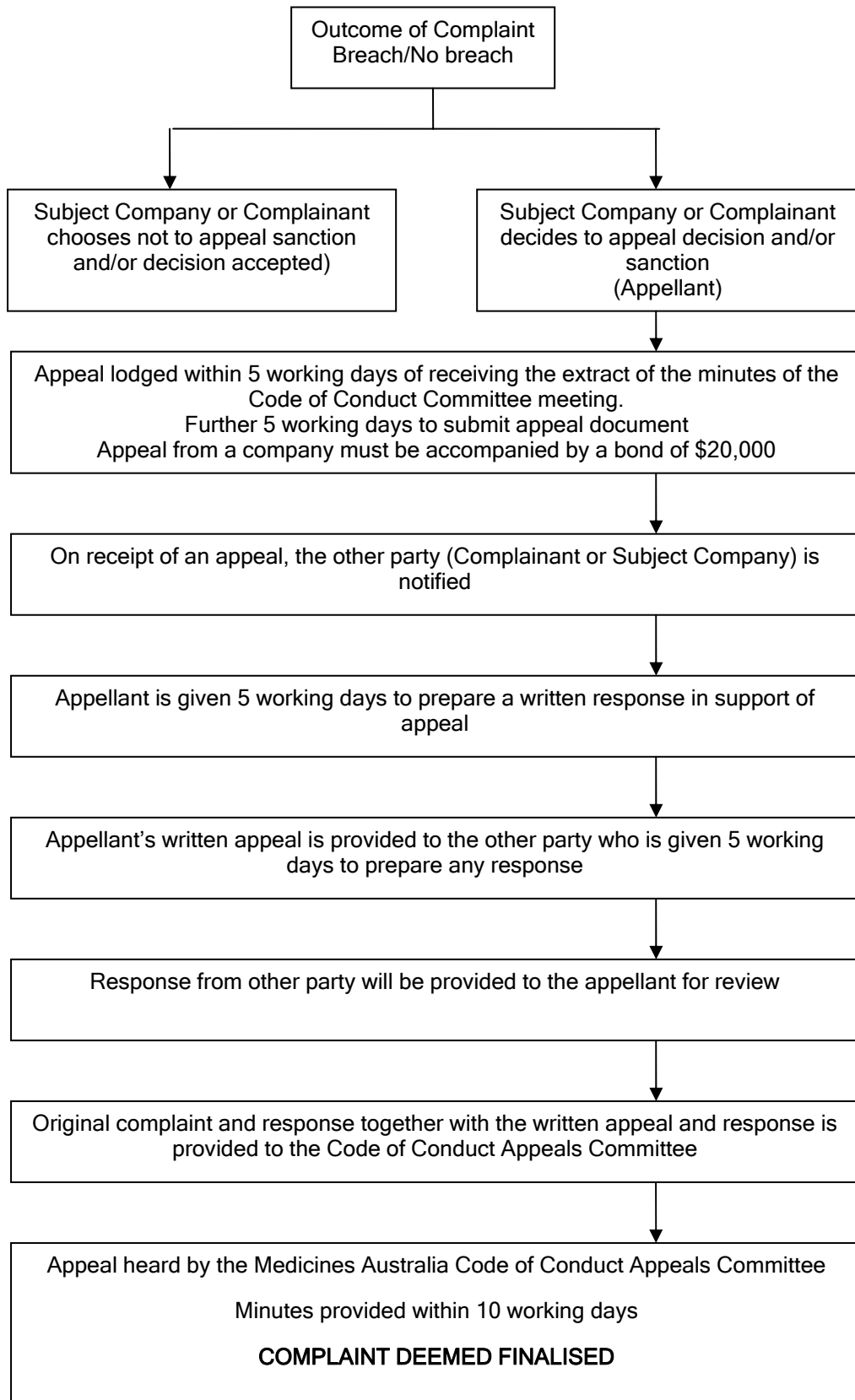
Contents

	Page
Medicines Australia Code of Conduct Complaints Handling Process	3
Medicines Australia Appeals Committee Procedures	4
Code of Conduct and Appeals Committees	5
Sanctions which can be imposed by the Code of Conduct Committee	6
Finalised Complaints:	7
AstraZeneca Heartburn Campaign 870	8
Tykerb 871	9
Seretide 873	10
Norspan 874	13
Penthrox 875	15
Olmotec 876	16

Medicines Australia Code of Conduct Complaints Handling Process



Medicines Australia Code of Conduct Appeals Committee Procedures



Medicines Australia Code of Conduct and Appeals Committees

Complaints listed in this report were considered by the following Committees:

Code of Conduct Committee

Full Members	Observers (No voting rights)
Independent lawyer (Chair)	Two employees of Medicines Australia Member Companies *
One representative nominated by the following organisations:	An observer interested in the Code process
Australian Divisions of General Practice (ADGP)	
Australian Medical Association (AMA)	
Australian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)	
Consumers' Health Forum of Australia	
Royal Australasian College of Physicians (RACP)	
Royal Australian College of General Practitioners (RACGP)	Advisors (No voting rights)
Therapeutic Goods Administration (TGA)	Code of Conduct Secretary
3 Medicines Australia Association Representatives *	Medicines Australia officer responsible for Scientific and Technical Affairs
2 Medicines Australia Medical/Scientific Directors *	Medicines Australia Chief Executive Officer or delegate

Code of Conduct Appeals Committee

Full Members	Advisors (no voting rights)
Independent lawyer (Chair)	Code of Conduct Secretary
Representative from the target audience to which the promotional activity has been directed e.g. RACGP, AMA, ADGP	Medicines Australia Chief Executive Officer or delegate
Representative from 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	
Representative from the Consumers' Health Forum of Australia	
2 Medicines Australia Association Representatives *	
Medicines Australia member company Medical/Scientific Director *	

* Medicines Australia representatives on either Committee must not have a conflict of interest with the therapeutic class of the materials being reviewed.

Sanctions which can be imposed by the Code of Conduct Committee

Sanctions

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

Withdrawal of material or activity

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

Corrective letter

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

Corrective advertisement

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

Fine

Breach

Technical breach
Minor breach
Moderate
Severe breach

Fine

Maximum of \$100,000

Severe breach where activities have ceased
Breach repetitions
Repeat of previous breach

Maximum of \$200,000

Table of finalised complaints July - September 2007

No.	Subject Company	Material Activity	Product	Complainant	Outcomes*	Sanction
870	AstraZeneca	Information to the general public	N/A	CHOICE	No breach found	
871	GlaxoSmithKline	Media release	Tykerb	Roche	No breach	
873	GlaxoSmithKline	Promotional material	Seretide	AstraZeneca	Breach 1.1, 1.2.2, 1.3, 1.7	<ul style="list-style-type: none"> • Withdraw • Corrective letter • Fine - \$50,000
874	Mundipharma	Information and promotional material	Norspan	HCP (GP)	No breach	
875	Device Technologies	Device News and Device Technologies website	Penthrox	TGA	Breach 1.3, 3.3.1, 3.4.2, 9.6, 9.6.3	<ul style="list-style-type: none"> • Withdraw • Corrective letter
876	Schering Plough	Promotional material	Olmotec	AstraZeneca	Breach 1.1, 1.3	<ul style="list-style-type: none"> • Withdraw • Corrective Letter • Corrective Advertisement • Amend Minimum PI and consider amending CMI

AstraZeneca Heartburn Campaign 870

Subject Company: AstraZeneca

Complainant: CHOICE

Product: N/A

Complaint:

The complainant stated that information about 'heartburn' available to the general public encouraged consumers to visit the AstraZeneca website www.heartburn.com.au. While the website does not name a drug it does mention several classes of drugs for heartburn which can only be prescribed by a doctor, including H2-receptor antagonists and proton pump inhibitors as well as antacids. The complainant maintained that this was a form of direct to consumer advertising and therefore in breach of the Code.

Sections of the Code:

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

- 9.4 Promotion to the general public

Response:

AstraZeneca denied that the information available to the general public was encouraging a patient to seek a specific prescription only medicine. The website did not name a prescription medicine and mentioned several classes of drug for heartburn which can be prescribed by a doctor. AstraZeneca asserted that the website contained a large amount of helpful information about heartburn, its management and treatment as well as links to helpful websites such as the Gastroenterological Society of Australia's website.

Code Committee determination:

In a unanimous decision the Code Committee found no breach of Section 9.4 of the Code.

Consideration of the complaint:

The Committee noted that Section 9.4 states:

Prescription products may be promoted only to healthcare 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.

It was also noted that the Code requires pharmaceutical companies to identify within disease state awareness material (both electronic and print) that the information is prepared by an identified company. It would be considered to be misleading if a company did not make this information available to a reader or viewer.

The Committee reviewed the information available on the www.heartburn.com.au website which was referred to on the poster that gave rise to the complaint. Members were of the view that the information on the website was informative and balanced. It was noted that the site included information on lifestyle issues and dietary tips before any reference to medications and recommended that readers discuss their condition with their doctor, which was appropriate. Members were also of the view that it is legitimate to make reference to all the therapeutic classes, both non-prescription and prescription, which are used to treat the condition. The website did not include the name of any particular medicine and did not compare or recommend any specific treatment.

The Committee was of the view that a patient would not link this website with any specific medicine. If a patient asked their doctor for the medicine that is supplied by AstraZeneca as the provider of the website, it would be the role of the healthcare professional to firstly assess whether the patient did have reflux, secondly whether they required any medication and if this was considered necessary which treatment was most appropriate for the particular patient.

Healthcare professional members of the Committee noted that there is a hierarchical treatment approach for reflux patients which was discussed appropriately in the materials.

The Committee did caution that it may not be possible for a pharmaceutical company to conduct a disease awareness campaign where there was only one available treatment for the medical condition where the campaign's message was to recommend

to readers to 'talk to your doctor' or 'ask your doctor' as this could lead to a patient effectively asking for a prescription for a specific medicine.

In a unanimous decision the Committee found no breach of Section 9.4 of the Code in relation to the 'heartburn' information supplied by AstraZeneca.

Tykerb 871

Complainant: Roche Pharmaceuticals (Roche)

Subject Company: GlaxoSmithKline Australia (GSKA)

Product: Tykerb

Sections of the Code:

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

- 12.1.1 Sanctions

Complaint:

Roche alleged a repeat breach of the Code in relation to complaint Tykerb (867) and a breach of Section 12.1.1. Roche stated that GSK had again provided material to a public media outlet and had therefore failed to comply with the sanction imposed by the Code Committee.

Response:

GSKA stated that it had not issued any media releases since the ruling made by the Code of Conduct Committee on 16 April 2007 in relation to Tykerb (867).

4 media articles on Tykerb were published/broadcast in Adelaide on 7 May 2007. A GSKA spokesperson had provided information in response to a specific request by the *Adelaide Advertiser's* health writer. GSKA had no knowledge of, and did not provide any materials to, the other broadcaster/publishers.

Code Committee determination:

The Committee found no breach of Section 12.1.1 of the Code.

Consideration of the complaint:

The Committee noted GSKA's statement that it had not issued any media releases following the ruling of the Code of Conduct Committee at the 16 April 2007 meeting.

GSKA response to *Adelaide Advertiser*

The Committee reviewed the written materials tendered by GSKA that had been provided to the *Adelaide Advertiser* health writer. Members were of the view that it was acceptable for GSKA to respond to a request from health writer and did not

consider the materials provided by GSKA to be in breach of the Code.

In relation to the information on the Tykerb Expanded Access Program, it was noted that the program was authorised under the TGA Clinical Trial Notification (CTN) Scheme and had been subject to approval by the relevant ethics committees. However members noted that information provided to the media by GSKA would not have been part of any ethics approval process. Members also commented that the drive for patient recruitment through the media could also have been initiated by the trial centres keen for additional patients. This was not considered to be a negative aspect; however companies must be careful when providing information about clinical trials to the general public. Members did not raise any issues with the provided text for the recorded 1800-number automated message.

Radio and Television Broadcasts (3)

The Committee was of the view that there was no evidence that GSKA had been responsible for or provided any information to the journalists responsible for these media stories.

Members commented that there is no evidence that GSKA is continuing to promote Tykerb and expected that GSKA had also instructed the PR agency working on their behalf not to engage in any further such activities.

By a unanimous decision, the Committee did not find a breach of Section 12.1.1 of the Code.

Seretide 873

Subject Company: GlaxoSmithKline Australia (GSKA)

Complainant: AstraZeneca

Product: Seretide

Complaint:

The complainant alleged that the Seretide detail aid contained several claims that are not consistent with the body of evidence and the key findings of the referenced study stand in direct contrast to the claims.

Issue 1: Excel Study - alleged manipulation of data by GSK

Claim 1

"However, there was a significant difference in the rate of moderate to severe exacerbations over time, in favour of Seretide, in the last two months (p=0.006)"

Claim 2

"New evidence: the benefits of Seretide's long lasting control" and graph entitled "Number of Moderate to Severe Exacerbations"

Claim 3

"57% lower rate of moderate to severe exacerbations with Seretide"

Claim 4

"Seretide is "...significantly superior to [Symbicort] in reducing the rate of moderate/severe exacerbations with regular, stable dose treatment"

together with the "EXCEL Claims"

Sections of the Code:

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

- 1.3 Nature and Availability of Claims
- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 1.7 Comparative Statements

Issue 2 Asthma control relating to inspiratory flow rate

Claim 1

"Accuhaler - for long lasting control in an award winning device"

Claim 2

Graph titled "Inspiratory flow rate" with the claim "Accuhaler is the only asthma dry powder inhaler to deliver consistent dosing even at low inspiratory flow rates" with transparent overlay information on Symbicort Turbuhaler.

Sections of the Code:

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

- 1.1 Nature and Availability of Claims
- 1.2.2 Level of Substantiating Data
- 1.3 False or Misleading Claims
- 1.7 Comparative Statements

Response:

GSKA stated that the sales aid subject to complaint was not in breach of the Code as it has relied on the appropriate body of evidence and correctly presented the data contained in the relevant peer reviewed publications.

Code Committee determination:

The Code Committee unanimously found breaches of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code in relation to all claims under both Issues 1 and 2 of the complaint.

Sanctions

- Take immediate action for the prompt withdrawal of the Detail Aid and permit that no further appearance of the item in its current form or in a manner that conveys the same or similar meaning.
- Corrective letter to all general practitioners and respiratory physicians who had been detailed with the item found in breach.
- Fine of \$50,000

Consideration of the complaint:

Issue 1: Excel Study - alleged manipulation of data by GSK

Claim 1

"However, there was a significant difference in the rate of moderate to severe

exacerbations over time, in favour of Seretide, in the last two months (p=0.006)"

Claim 2

"New evidence: the benefits of Seretide's long lasting control" and graph entitled "Number of Moderate to Severe Exacerbations"

Claim 3

"57% lower rate of moderate to severe exacerbations with Seretide"

Claim 4

"Seretide is "...significantly superior to [Symbicort] in reducing the rate of moderate/severe exacerbations with regular, stable dose treatment"

together with the "EXCEL Claims"

Members of the Committee were of the view that the graph adapted from the R. Dahl et al Study (the Excel study) depicting the number of moderate to severe exacerbations placed undue emphasis on this subgroup of the study without adequately explaining the primary endpoints which found that *"the mean rate of all exacerbations over 24 weeks was similar in both treatment groups [salmeterol/fluticasone propionate combination (SFC) and formoterol/budesonide combination (FBC)]"*. It was not sufficiently clear to a reader that the number of moderate to severe exacerbations related to 10% of subjects treated with Seretide and 11% of subjects treated with Symbicort who had moderate to severe exacerbations throughout the study period. The lower rate of moderate to severe exacerbations with Seretide was obtained from a post hoc subgroup analysis and was not a pre-determined study endpoint. The Committee noted that the summary of the study in the published reference described the further post hoc analyses that were conducted. The Committee noted that the primary endpoint was not stated in the tabulation describing the Excel study on the page opposite the graph; only in the text under the table.

The Committee considered the clinical relevance of the numerical imbalance between the treatment groups with respect to the number of moderate or severe exacerbations in the Excel study. Whilst the

difference was just statistically significant in the final eight weeks of the study, the Committee questioned the clinical relevance. The Committee considered that the numerical difference observed in the study should have been regarded as hypothesis generating rather than a sound basis for making a major claim of superiority of Seretide over Symbicort. The Committee considered that the referenced data was inadequate as the basis for the claims.

The Committee also expressed concern at the conflation in the promotional material of the statistical data represented in Table 2 and Figure 3 in the Dahl et al paper, which gave the adjusted mean rate of exacerbations per year, with the representation of Figure 2 of the Dahl paper which was the cumulative number of exacerbations. The figure of 57% reduction in the rate of exacerbations was not derived from the cumulative number of moderate/severe exacerbations but rather from the adjusted mean rate per year for moderate/severe exacerbations.

Members also commented that as this material was being detailed to general practitioners the definitions of moderate and severe as used in the study should have been stated in the promotional material as the study definitions were not necessarily the same interpretations as Australian practitioners would use.

Members were of the view that by substituting the word 'is' into the claim in place of the study outcome statement which used 'was' makes a generalisation of the study data which is not appropriate. (Use of "Seretide is "...significantly superior..." instead of the stated conclusion "SFC was found...")

The Committee concluded unanimously that the claims and associated graphical representation of data from the Excel study on pages 7 and 8 of the detail aid were unbalanced, misleading and made an unfair comparison with Symbicort. The data were inadequate, being a post-hoc secondary analysis of a sub-group of questionable clinical significance, on which to basis a major comparative claim. Lack of qualifiers makes this table and claim misleading and

was in breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code.

Issue 2 Asthma control relating to inspiratory flow rate

Claim 1

"Accuhaler - for long lasting control in an award winning device"

Claim 2

Graph titled "Inspiratory flow rate" with the claim "Accuhaler is the only asthma dry powder inhaler to deliver consistent dosing even at low inspiratory flow rates" with transparent overlay information on Symbicort Turbuhaler.

Members of the Committee expressed concern that one reference was a 1998 abstract (in-house company information) that had never been published providing the Seretide Accuhaler data and this was used to make comparisons with data generated in 2004 for Symbicort. Whilst noting the qualifying statement that the graphs were adapted from two separate *in vitro* studies, members were of the view that the comparison on a single graph was inappropriate as the evidence for Seretide was of inadequate quality, being an abstract of an unpublished in-house study, on which to base a comparative claim. Also, the clinical relevance of the *in vitro* data has not been established. The claim for 'long-lasting control' was not relevant to the data presented in the graph, which only related to dose delivered at different inspiratory flow rates. Members concluded that the graph was misleading, unbalanced, and the substantiating data was selective and inadequate. It made an unfair comparison with Symbicort Turbuhaler.

Members also commented that because the Accuhaler device is 'award winning' as a technological achievement, this does not constitute an endorsement of the clinical outcome of its use with a medicine.

The Committee found a breach of Sections 1.1, 1.2.2, 1.3 and 1.7 of the Code in relation to Claims 1 and 2 under Issue 2.

Members were of the view that this was a moderate breach and whilst there was no

potential for patient harm there was the potential for having an effect on how the medical profession will prescribe the product.

The Committee also commented that GSKA should take more care when preparing detail aids or leave behind materials for healthcare professionals. Poor quality information does not enhance the image of the industry and whilst there was no allegation of a breach of Section 10.8 members were concerned that the level of information and education in this item could reduce confidence in the industry.

Sanctions

Having found several breaches of the Code, the Committee considered an appropriate sanction.

The Committee determined that GSKA should:

- Take immediate action for the prompt withdrawal of the Detail Aid found in breach of the Code and advise medical representatives that no further appearance of any item in its current form or in a manner that conveys the same or similar meaning is permitted.
- Send a corrective letter to all general practitioners and respiratory physicians who had been detailed with the item found in breach. The letter should communicate to recipients that the promotional material for Seretide had been found in breach of the Code.
- On the basis of the primary endpoints in the Excel study no significant difference had been found between Symbicort Turbuhaler and Seretide Accuhaler.
- Claims for superiority of Seretide over Symbicort had been found in breach of the Code because they could not be adequately substantiated.
- The promotional material had included claims regarding dose delivery at different inspiratory flow rates that were based on selective data that could not be substantiated.
- Pay a fine of \$50,000. In imposing this fine the Committee stated that it had taken into account the requirement for a corrective letter as well.

Norspan 874

Subject Company: Mundipharma

Complainant: Healthcare professional

Product: Norspan

Complaint:

The complainant expressed concern at the marketing of Norspan by Mundipharma to general practitioners. It was alleged that at an education evening hosted by Mundipharma the case study used gave misleading advice to GPs and the company was misrepresenting the true indications of Norspan and other opioid products. The Complainant also alleged that insufficient attention had been given to the risks and management of long-term dependency, side effects and problems of withdrawing from the medication.

Sections of the Code:

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

- 1.1 Nature and availability of claims
- 1.3 False and misleading claims
- 1.3.1 Unapproved products and indications

Response:

Mundipharma maintained that all information and medical claims presented to doctors in the Continuing Medical Education (CME) meeting were balanced, accurate and fully supported by the Norspan Product Information. Further, the material presented at the CME meeting was consistent with the approved indication for Norspan.

Code Committee determination:

In a majority decision the Code Committee found no breach of Sections 1.1, 1.3 or 1.3.1 of the Code.

Consideration of the complaint:

The Committee commented that healthcare professionals will consider the evidence for using a particular medicine from a range of sources. This will include the Product Information (PI), published studies and information provided at an educational event. The Committee also noted that the meeting in question was an educational activity accredited by the Royal Australian College of General Practitioners (RACGP)

and the Australian College of Rural and Remote Medicine (ACRRM) - Total CPD points: 4 (Group 2). The Committee noted the attendees' comments in the evaluation questionnaires that they had benefited from attending the meeting with 93% considering the presentation to be sufficiently evidence based.

Members also commented that it is the responsibility of a treating doctor to use a medicine in accordance with the PI and to make decisions on each patient's specific needs. Members noted that the case study referred to by the complainant was consistent with subjects included in the pivotal Phase III study reported in the Norspan PI.

The majority of members were of the view that the presentation used at the CME meeting provided sufficient scientific evidence and information to enable a prescriber to make an informed decision. Members also noted that Mundipharma's response stated that issues such as weight management and diet were part of the management plan. The presenter, who had provided a letter to Mundipharma summarising the content of his presentation, had emphasised to the audience that opioids are not first line therapy for patients and that a "trial of opiates should be instituted to determine a patient's response, particularly in improvement of function before committing to long term use" and that "ongoing monitoring if response to the opiates in both pain relief and improvement of function, is paramount."

However, a few members were of the view that the moderator's handbook and power point presentation were not totally balanced. The potential side effects for Norspan were not emphasised whereas there was considerable attention given to the side effects of non-steroidal anti-inflammatory drugs (NSAIDs) and there was no recommendation to institute weight loss measures for the case study subject who was obese. However, the Committee noted that these issues had not been specifically raised by the complainant and Mundipharma had not had the opportunity to respond to them.

The Committee noted that the adverse effects in patients who had been prescribed Norspan reported by the complainant were all listed in the Product Information, which had been included in the reading material for participants in the CME meeting. It was also noted that one report of side effects provided by the complainant noted that the patient had been commenced on 10 microgram Norspan patches whereas the recommended starting dose is 5 micrograms.

By a majority decision the Committee concluded that there was no breach of Sections 1.1, 1.3 and 1.3.1 of the Code. Whilst some members of the Committee had some concerns that the slide presentation and printed material were not completely balanced, the correspondence from the presenter, which had reported the points he had emphasised in his presentation, was one of the factors that mitigated the Committee's concerns in this particular instance.

Penthrox 875

Subject Company: Device Technologies

Complainant: Therapeutic Goods Administration

Product: Penthrox

Complaint:

The complainant alleged that an article in "Device News" March 2007, published by Device Technologies, promoted the "analgesic" methoxyflurane rather than the device which it purports to promote and there was no reference to the side effects from methoxyflurane and no Product Information had been included. The complainant further stated that when the website was consulted, which required no password and therefore was freely accessible to the public, there was no CMI available and the article was promotional in tone and promoted unapproved indications. The complainant alleged that the behaviour is likely to bring the industry into discredit.

Sections of the Code:

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

- 1.3 False or Misleading Claims
- 3.3.1 Printed Promotional Material
- 3.4.2 Mailings
- 9.6 Use of the Internet
- 9.6.3 Use of the Internet
- 10.8 Discredit to, and reduction of confidence in the Industry

Response:

Device Technologies acknowledged the validity of a number of aspects of the complaint and advised that it had taken immediate corrective actions to ensure compliance with the Code by removing all internet advertising for Penthrox. As the majority of products supplied by Device Technologies are medical devices they were not as familiar with requirements for advertising a medicine or the Medicines Australia Code. Device Technologies maintained that the intention of the article was to promote the device, but acknowledged that the content may have been poorly constructed leading to possible misinterpretation. However there was no intention to bring discredit to the industry.

Code Committee determination:

In a unanimous decision the Committee found a breach of Sections 1.3, 3.3.1, 3.4.2, 9.6 and 9.6.3 of the Code.

No breach of Section 10.8 of the Code was found.

Sanctions

- Withdraw material found in breach from the website
- Corrective letter to all recipients of the newsletter and to place this corrective letter on the website where the newsletter appears

Consideration of the complaint:

The Committee noted that this complaint was in relation to an article promoting a prescription medicine and the medicine delivery device. Members were of the view that a company that markets any therapeutic good should be aware of the Therapeutic Goods Advertising Code and applicable industry Codes of Conduct/Practice. However the Committee noted that Device Technologies had immediately undertaken corrective action on being advised of the complaint. The company had implemented new policies in relation to approval processes within the organisation and in providing training to all staff in the area of compliance with advertising requirements.

Members were of the view that the article was in breach of Sections 1.3, 3.3.1, 3.4.2, 9.6 and 9.6.3 of the Code as it contained promotional statements in relation to a prescription medicine that could be accessed by members of the general public on the internet and was not balanced in terms of communicating the precautions, side effects, interactions with other medicines etc. Members were particularly concerned that the article claimed that the medicine has no known side effects and provides safe and effective pain relief whereas the medicine is a potent inhalational anaesthetic with well known risks. The Product Information includes a number of precautions and contraindications and also a warning to health workers who are regularly exposed to patients using Penthrox inhalers.

Sanctions

Having found a number of breaches of the Code the Committee considered an appropriate sanction.

Although this medicine is only available in restricted circumstances, the information provided to health practitioners should be corrected. The Committee determined that Device Technologies must distribute a corrective letter that highlights the side effect section of the Product Information to all recipients of the Device News (March 2007) and in addition that Device Technologies should publish this corrective letter on the website where the newsletters can be found. The content of this corrective letter must be approved by the Committee prior to publication and distribution.

Olmetec 876

Subject Company: Schering-Plough

Complainant: AstraZeneca

Product: Olmetec

Complaint:

The complainant alleged that two important pieces of information were not included in a promotional item for Olmetec. These are the omission of the recommended starting dose for the elderly which is 10mg and that the 10mg tablets are not PBS listed and are not currently available in Australia. AstraZeneca stated that this omission of relevant dosage information is misleading to prescribers and exposes elderly patients to unnecessary safety risk and is therefore a severe breach of the Code.

Sections of the Code:

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

- 1.1 Responsibility
- 1.3 False or Misleading Claims
- 10.8 Discredit to, and reduction of confidence in the Industry

Response:

Schering-Plough rejected the allegations. It stated that information on the 10mg dosage had not been included because this strength is not available in Australia and that a starting dose of 20mg in the elderly does not represent a significant safety risk. The materials included the Minimum PI and the list of precautions including use in the elderly, enabling prescribers to be well informed and avoid safety issues.

Code Committee determination:

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

No breach of Section 10.8 was found.

Sanctions

- Withdraw materials found in breach
- Corrective letter to all healthcare professionals detailed with the item
- Corrective advertisement to be published in the same journals as the advertisement found in breach

- Amend the Minimum Product Information as was proposed in intercompany dialogue
- Consider amending the CMI to more closely reflect the dosage described in the Product Information in relation to the elderly and special populations.

Consideration of the complaint:

The Committee noted that there had been considerable intercompany dialogue and that the two companies had resolved the majority of the issues originally subject to complaint. The Committee congratulated both companies on the manner in which this was undertaken.

Members noted the offers by Schering-Plough to amend the Minimum Product Information and provide the full Product Information to all healthcare professionals being detailed with Olmetec.

In relation to the concern that whilst the 10mg dose in the elderly and people with renal insufficiency was approved in Australia, a 10mg tablet was not currently available, Members noted the advice from Schering-Plough that the inclusion of a statement in the Product Information that 10mg is not currently available in Australia had been accepted by the TGA and Schering-Plough.

The Committee reviewed the Product Information for specific references to the elderly:

Page 8 - "Use in the elderly"; and
Page 13 Dosage and Administration "Special Populations - Elderly" where a lower starting dose of 10mg once daily is recommended.

The Committee also reviewed the Minimum Product Information included on the advertisement and noted that it did not include any reference to a recommended starting dose of 10mg in the elderly. Rather it stated that "The dose of olmesartan medoxomil should not exceed 20mg daily...."

Members were of the view that use of medicines by the elderly is a matter that must be taken seriously and advertised appropriately. The principles of the quality use of medicines require that only medicines that are scored for cutting or breaking can

be recommended for use at a reduced dosage. Olmetec is not scored. Therefore it would not be appropriate for a healthcare professional to tell a patient to cut the 20mg Olmetec tablet in half because the 10mg dose was not available in Australia. It was also noted that many elderly patients may have difficulty cutting a tablet even if it was scored.

Having reviewed the literature and based on the knowledge of the healthcare professionals members, the Committee accepted that as many as 65%-70% of patients with hypertension will be elderly. The Committee considered that the Olmetec promotional material should make it clear to a prescriber that the recommended starting dose for the elderly is 10mg and include clear advice that 10mg is currently not available in Australia.

The Committee was of the view that although it is acceptable for a company to promote a specific dose or formulation to healthcare professionals, the content of any advertisement or leave behind must be consistent with the Product Information and where there is a specific reference to a different starting dose for a particular population such as the elderly this should be included in the Minimum Product Information and on the item. The omission of this information was misleading and unbalanced and was therefore in breach of Sections 1.1 and 1.3 of the Code. The Committee did not consider that the issues would bring the industry into disrepute and noted that Schering-Plough had made significant endeavours to propose amendments that would have corrected the breaches.

Sanctions

Having found the materials in breach of the Code the Committee considered an appropriate sanction.

The Committee determined that Schering-Plough should:

- Withdraw the materials found in breach
- Send a corrective letter to all healthcare professionals detailed with the leave behind
- Publish a corrective advertisement in the same journals as the advertisement found in breach

- Amend the Minimum Product Information as was proposed in intercompany dialogue
- Consider amending the CMI to more closely reflect the dosage described in the Product Information in relation to the elderly and special populations.

The Committee did not impose a fine as there had been considerable attempts to resolve the complaint and amend the information during intercompany dialogue.