

Medicines Australia Code of Conduct Quarterly Report July - September 2009

Medicines Australia Code of Conduct

The quarterly report of decisions 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 - September 2009. Complaints finalised during this period were in relation to materials or activities conducted under Edition 15 of the Code.

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

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How do I obtain a copy of the Code?

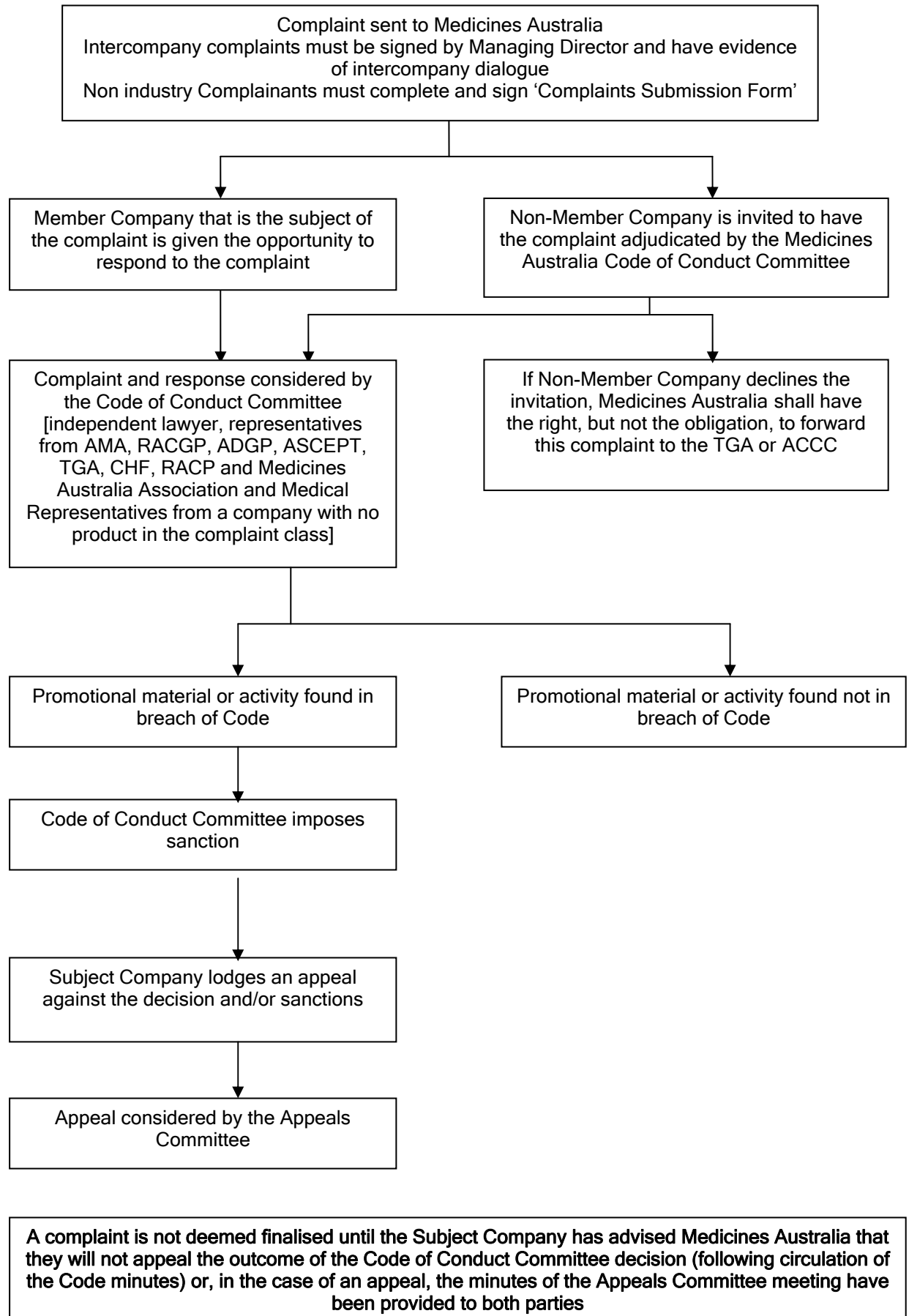
Hard copies of Edition 15 of the Code are available from Medicines Australia.

The Code of Conduct and the Guidelines that accompany the Code are available from the website (<http://www.medicinesaustralia.com.au/pages/page16.asp>).

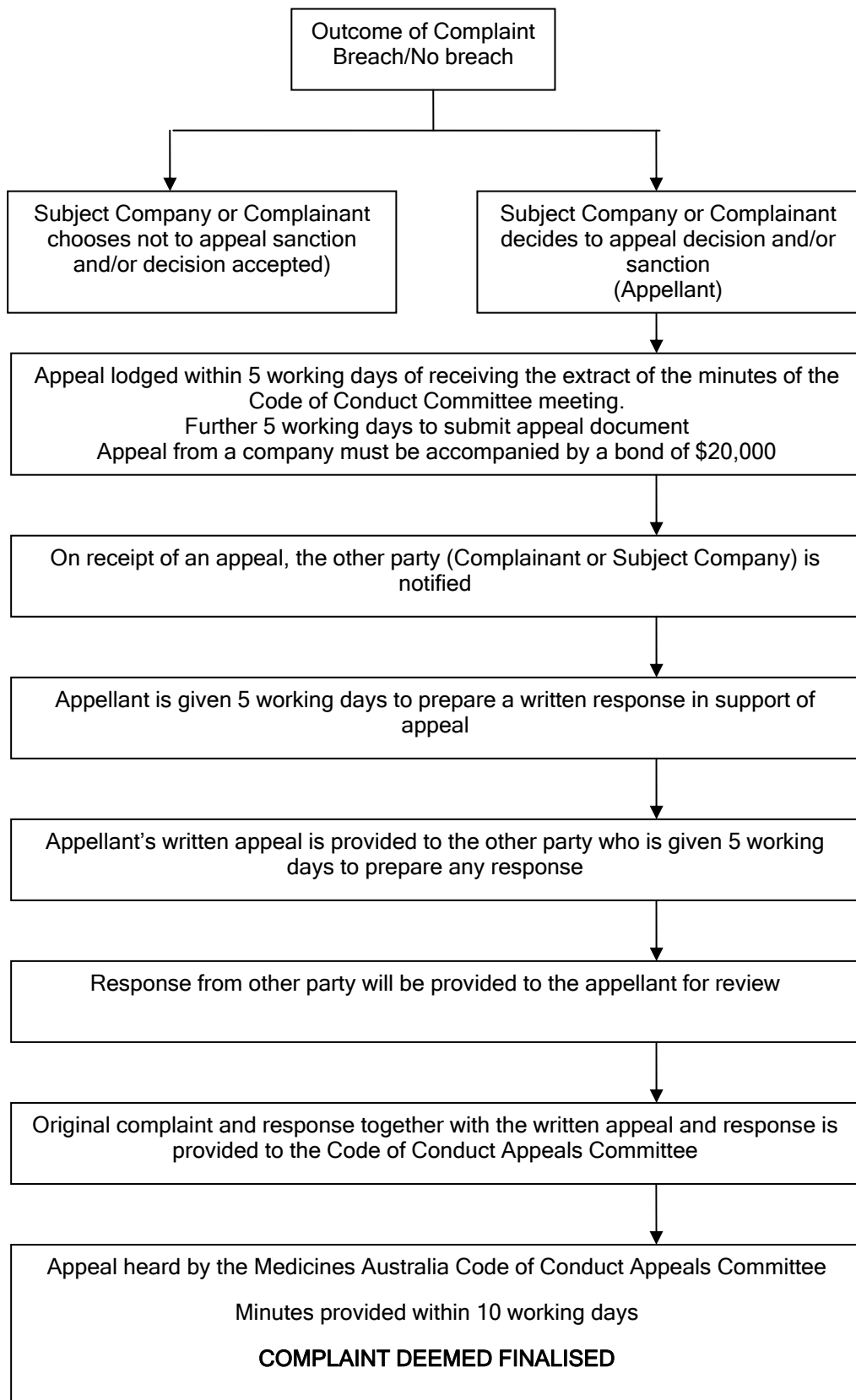
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Medicines Australia Code of Conduct Complaints Handling Process



Medicines Australia Code of Conduct Appeals Committee Procedures



Committees and Secretariat

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

Committee Member Biographies

Brief biographies for all Code, Appeals and Monitoring Committee members are available on the Medicines Australia website <http://www.medicinesaustralia.com.au/pages/page96.asp>

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of six trade practices lawyers
- *Representatives nominated by:*
- Australian General Practice Network (AGPN)
- Australian Medical Association (AMA)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Consumers Health Forum of Australia (CHF)
- Royal Australasian College of Physicians (RACP)
- Royal Australian College of General Practitioners (RACGP)
- Therapeutic Goods Administration (TGA)
- Medicines Australia Association Representatives (maximum 3)
- Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- Medicines Australia member companies' employees (maximum 2)
- Observer nominated by Medicines Australia (maximum 1)

Advisors (No voting rights)

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

Appeals Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of six trade practices lawyers
- *Representatives nominated by:*
- The College and/or Society associated with the therapeutic class of the product subject to appeal
- The target audience to which the activity was directed eg: AMA, RACGP, AGPN
- Consumers Health Forum of Australia (CHF)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Medicines Australia Association Representatives (maximum 2)
- Medicines Australia Medical/Scientific Director (maximum 1)

Advisors (No voting rights)

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

Sanctions 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

Guidelines for determining Code sanctions can be found on the Medicines Australia website at <http://www.medicinesaustralia.com.au/pages/page16.asp>

Table of finalised complaints July - September 2009

No.	Subject Company	Material Activity	Product	Complainant	Outcomes	Sanction
1016	CSL	Information to the general public	HPV Vaccine	Member of the general public	No breach 9.4, 9.5.7 & 10.8 Breach 9.5.4	<ul style="list-style-type: none"> • Ensure address is on future materials • Fine - \$1,000
1017	Genzyme	Promotional Material	Renagel	Shire	Breach 9.4 & 9.5 No breach 1.2.1	<ul style="list-style-type: none"> • Withdraw • Fine - \$25,000 • Corrective letter
1018	CSL	Starter Packs	Various	John Hunter Hospital	Breach 4.5 & 5.1.2	<ul style="list-style-type: none"> • Fine - \$1,000
1022	Pfizer	Promotional Material	Lipitor	Healthcare Professional	No breach 1.1, 1.2.2, 1.3, 1.7	

HPV Vaccine 1016

Subject Company: CSL

Complainant: Member of the general public

Product: HPV Vaccine

Complaint

The complainant was of the view that the advertising campaign, directed at women aged 12 - 26 years, encouraging them to be vaccinated with the cervical cancer vaccine before the Government-funded catch-up program ended on 30 June 2009 contravened State and Commonwealth laws and breached the Code of Conduct. While no brand name was used in the commercial, the name 'cervical cancer vaccine' had been used. Given that at the time only one brand of HPV vaccine was available on the National Immunisation Program catch-up program, this was equivalent to encouraging members of the general public to seek a prescription for a specific prescription only medicine.

Sections of the Code

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

- 9.4 Promotion to the General Public
- 9.5.4 Patient Education
- 9.5.7 Patient Education
- 9.10 Discredit to and reduction of confidence in the Industry

Response

CSL responded that the key objective of the Government funded immunisation program is long term control of disease. High levels of vaccine coverage are critical to the success of immunisation programs. CSL implemented a multi-faceted disease education and program awareness campaign, of which radio and television announcements were one component. A secondary message throughout the campaign is the importance of completing all three vaccine doses and of continuing with regular pap smears.

CSL disagreed that the radio and television advertisements will encourage a consumer to seek a specific product. The brand of vaccine used in immunisation programs is determined by State Health Departments through a tender process. Therefore the option of selecting a specific

brand of vaccine is not given to the consumer or the healthcare professional.

Vaccine programs rely on consumer participation for successful implementation. Vaccine experts have commented in local and international conferences that activities conducted by CSL to inform and educate participants have been a contributing factor to the success of the program.

Code Committee decision

- In a majority decisions the Committee did not find a breach of Section 9.4 of the Code.
- In a majority decision the Committee found a technical breach of Section 9.5.4 of the Code.
- In a majority decision the Committee did not find a breach of Section 9.5.7 of the Code.
- In a unanimous decision the Committee did not find a breach of Section 10.8 of the Code.

Sanction

- Pay a fine of \$1,000.
- Ensure that any future educational messages broadcast on radio or television includes the address or locality of the registered office of the company.

Consideration of the complaint

The Committee noted that the complainant had been unable to be specific about the dates, times and broadcaster of the television and radio advertisements subject to complaint except for one radio announcement on 1 June 2009 on an Adelaide FM radio station. The complainant had been provided with three publicly sourced examples, however CSL was not provided with these examples prior to its response to the complaint being lodged. CSL had supplied a radio announcement transcript from 1 June 2009 on Adelaide FM radio and text of the television announcement that had screened in May to June 2009 which CSL confirmed were components of a campaign it had implemented. The Committee relied on these advertisements supplied by CSL in its consideration of the complaint.

The majority of members were of the view that as the HPV Vaccination Program is listed on the National Immunisation

Program (NIP) Schedule and funded under the Immunise Australia Program it was in the public interest for women to be aware of the existence of the vaccine and that three vaccinations are required to complete the course. It was also noted that there was support from Government and other key stakeholders for the immunisation program. Members also noted that the decision on which HPV vaccine is administered as part of the NIP is determined through a State tender process and is not selected by the individual general practitioner.

The Committee considered the complainant's submission that CSL used the term 'HPV Vaccine' in the communications to the general public. The complainant had asserted that whilst the brand name was not used, a prescription-only medicine had been identified. Members of the Committee commented that there had been no reference to the brand name (Gardasil) or the Australian Approved Name (Quadrivalent Human Papillomavirus Vaccine); only that girls and women within the specified age group can access cervical cancer vaccination through the free NIP. A majority of the Committee considered that the campaign was encouraging women to see their doctor to be immunised against cervical cancer and to receive the complete course but was not encouraging members of the general public to seek a prescription for a specific prescription only medicine. The Committee considered that the argument concerning whether a doctor actually writes a prescription for the vaccination was not relevant to its consideration of the complaint.

A minority of members took an alternative view, that the campaign was creating a demand for a specific prescription-only medicine. These members considered that whilst the advertisements do not identify a specific prescription medicine by generic name or brand name, there was only one brand of HPV vaccine that was available free of charge through the NIP for the 'catch-up' program. These members considered that the communication campaign was equivalent to encouraging women to seek a particular prescription-only medicine.

In a majority decision the Committee did not find a breach of Sections 9.4 or 9.5.7 of the Code.

In a unanimous decision the Committee did not find a breach of Section 9.10 of the Code.

In a unanimous decision the Committee found a technical breach of Section 9.5.4 of the Code because the locality of the sponsor was not included in the radio announcement.

During its discussion of the complaint the Committee particularly noted that whilst it was aware of the public health benefits of vaccination, this or any other disease communication campaign must be judged against the requirements of the Code and not on its public health benefit or the public interest.

Sanctions

Having found a technical breach of Section 9.5.7 of the Code, the Committee determined that CSL should:

- Pay a fine of \$1,000.
- Ensure that any future educational messages broadcast on radio include the address or locality of the registered office of the company.

Renagel 1017

Subject Company: Genzyme Australasia (Genzyme)

Complainant: Shire Australia (Shire)

Product: Renagel

Complaint

Shire alleged that two items produced by Genzyme - a leave behind for healthcare professionals and a non-branded phosphate binder patient education leaflet - were in breach of the Code.

Shire asserted that the leave behind was an irresponsible representation of the available data, was misleading, failed to substantiate the claim with appropriate evidence and made an unbalanced comparison of the various phosphate binders used in hyperphosphataemia in chronic renal failure. It was further asserted that the patient education piece was promotional and made disparaging comparative statements towards metal phosphate binders and was direct-to-consumer advertising.

Sections of the Code

Shire alleged that the leave behind for healthcare professionals was in breach of the following Sections of the Code:

- 1.1 Responsibility
- 1.2.1 Provision of substantiating data
- 1.3 False or misleading claims

Shire alleged that the patient education leaflet was in breach of the following Sections of the Code:

- 9.4 Promotion to the General Public
- 9.5 Patient Education
- 1.2.1 Provision of substantiating data

Response

Genzyme denied that either the leave behind or the patient education leaflet were in breach of the Code. It asserted that the claim “bind without buildup” was a factual statement consistent with the approved Product Information and was not misleading or comparative.

Genzyme also rejected the allegation that the patient education leaflet was promotional to patients and denied any breach of the Code of Conduct or the principles underlying it.

Code Committee decision

Leave Behind

In a majority decision no breach of Sections 1.1, 1.2.1, 1.3 of the Code.

Patient Education leaflet

In a unanimous decision a breach of Sections 9.4 and 9.5 (specifically 9.5.1, 9.5.4, 9.5.6 and 9.5.7) of the Code. No breach of Section 1.2.1.

Sanction

- Withdraw the patient education leaflet found in breach (The Code Committee acknowledged that Genzyme had agreed to withdraw the materials in the intercompany dialogue)
- Pay a fine of \$25,000
- Send a corrective letter to all renal physicians and clinical nurse consultants in charge of renal and dialysis units informing them of the Code of Conduct Committee decision and requesting that they destroy the patient education material found in breach or return it to Genzyme. This letter should be sent to all renal physicians and units who had been provided the patient education material found in breach.

Consideration of the complaint

The Committee was informed that Genzyme had requested advice from the Code Secretariat about the inclusion of Appendix J (a separate item of patient education) in the complaint documentation when this item was not subject to complaint or discussed in the intercompany dialogue. The Secretariat had obtained clarification from Shire. Shire had advised that this item was an example of good patient education provided by Genzyme. Shire commented that this had been raised with Genzyme during intercompany dialogue. The Committee determined that Appendix J was irrelevant to its consideration of the complaint and would not form part of its consideration of this complaint.

Leave Behind

The Committee reviewed the pharmacodynamics section of the Renagel Product Information (PI) which states that Renagel contains sevelamer a non-absorbed phosphate binding poly (allylamine hydrochloride) polymer, free of metal and calcium.

While noting that the recipients of this leave behind are a small, highly specialised group of physicians, some members were of the view that the audience is irrelevant. The Code does not differentiate between audiences when considering if a claim is misleading.

Members commented that the leave behind did not identify the salts that are actually used in phosphate binding (for example, calcium carbonate or lanthanum carbonate); it only stated the name and symbols for the ions calcium, magnesium, aluminum and lanthanum, which therefore makes the information incomplete. Some members were of the view that by grouping these phosphate binders together this was an implied comparison with Renagel, suggesting that lanthanum has the same 'buildup' as magnesium, calcium and aluminium phosphate binders. Members also considered that the reference by Chertow et al to support the 'bind without buildup' claim was irrelevant to the claim because it only compared sevelamer with calcium carbonate, not other phosphate binders.

From the information supplied members noted that issues with specific metal-based phosphate binders, including:

- Aluminum based phosphate binders - central nervous system effects and unmasking of Alzheimer's disease
- Calcium based phosphate binders - calcium has been shown to build up in the vasculature of renal patients causing calcification in coronary arteries

The Committee noted that Shire had stated that none of these effects had been found with lanthanum carbonate.

A minority of the Committee considered that by grouping magnesium, aluminum and calcium together with lanthanum the leave behind could be interpreted to imply that lanthanum may cause similar clinical consequences to those experienced with magnesium-, calcium- and aluminium-based phosphate binders, which could not be substantiated.

However, a majority of members were of the view that whilst the material demonstrated a lack of attention to detail, was incomplete and far from best practice, it was not in breach of the Code because the claims 'bind without buildup' and

'Renagel... a non-absorbed phosphate binding polymer, free of metal' were factual and consistent with the PI and were not misleading. The Committee concluded that the leave behind only compared sevelamer with the other phosphate binders with respect to whether they are metals and whether they resulted in a 'buildup' in the body, which could be substantiated from the Product Information documents for Renagel and Fosrenol (lanthanum carbonate). The leave behind did not claim that this buildup caused any clinical effects.

Members noted that Genzyme had stated that this was a one-off mailer and would not be printed again and no more copies would be distributed. Genzyme had also given an undertaking that any future materials which linked lanthanum with calcium, magnesium and aluminum would make it clear that there is a difference between lanthanum and other metal phosphate binders and include a qualifying statement for lanthanum regarding the clinical significance of its accumulation based on the Fosrenol PI.

By a majority decision the Code Committee determined that the leave behind for Renagel did not breach sections 1.1, 1.2.1 or 1.3 of the Code.

Patient Education leaflet

Members were very concerned by the alarmist nature of the images and text in the patient education leaflet. The images and text implied that the patient should be very concerned about taking certain phosphate binding medicines containing calcium or metal. The images initially suggest lack of control and chaos. On pages 6 and 7, where phosphate binders are discussed, the images and text suggest that accumulation from taking a phosphate binder results in another uncontrollable problem. When the reader reaches the last page the image is of a tidy room, with everything in order, together with the statement "Genzyme Australia strongly recommends speaking to your healthcare professional for further information about your treatment", which suggests that the Genzyme product can solve the problem.

While noting the response from Genzyme that the patient education item was intended to be used by the physician with the patient, the text did not give this

impression. It directly encouraged the patient to talk to their health professional, which would not be necessary if the item was intended to be used by a health professional in a consultation. The Committee also noted the assertion from Shire that this item could be found in renal physician waiting rooms and treatment rooms of dialysis units.

The Committee was particularly concerned by the statements on page 6 of the patient education leaflet "Some phosphate binders can accumulate in your body over time. So while they clean up phosphorus, they may create other complications with your heart, bones, brain or other tissue." and on page 7 "Some phosphate binders contain calcium or metal that may be left behind. This calcium and metal can accumulate and may create complications." These references to differences between the side effects of phosphate binders were comparative; such comparisons are not appropriate in materials for the general public or patients. These statements would encourage a patient to be concerned about their treatment and to seek an alternative treatment. The leaflet promotes fear, confusion and alarm for patients.

The Committee was concerned that the leaflet would confuse the patient. It first explains the concept of accumulation as meaning accumulation of phosphorus and then discusses accumulation of calcium and metal as a result of taking a medicine to bind phosphate.

Members were also concerned by the use of the Genzyme company name on every page of the item. It noted that the name appeared four times on the last page and the Genzyme website was given on the last page, which may add to the encouragement to a patient to seek the Genzyme product. The Committee commented that the comparative statements on pages 6 and 7 and the statement on page 8 "Genzyme Australia strongly recommends speaking to your healthcare professional for further information about your treatment" suggests to a patient that there may be a problem with their treatment and they should ask about the Genzyme treatment. The Committee considered that the leaflet was promotional and was in breach of Section 9.4 of the Code. The use of 'strongly recommends' particularly implies

that there is a problem that needs to be addressed and suggests to a patient that they need to see their doctor urgently.

In a unanimous decision the Committee found the patient education leaflet to be in breach of Sections 9.4 and 9.5 of the Code. Members were of the view that the item was not balanced (9.5.1), the name of the supplier was prominent as it appeared on every page of the document (9.5.4), the tone of the message (text and images) may cause alarm or misunderstanding (9.5.6) and the leaflet was not written in a manner which was balanced and could raise unfounded hopes of successful treatment (9.5.7). Members considered that the patient leaflet was not educational but may encourage a patient to seek a prescription for a specific prescription-only medicine and was therefore in breach of Section 9.4.

The Committee considered the allegation that the leaflet may also breach Section 1.2.1 of the Code. The Committee noted that this section relates to the provision of substantiating data. There had been no evidence presented that Genzyme had failed to respond to a request for substantiating data. No breach of Section 1.2.1 was found.

Sanctions

Having found a breach of Sections 9.4 and 9.5 of the Code, the Committee determined that Genzyme should:

- Withdraw the patient education leaflet found in breach. (The Committee noted that Genzyme had agreed to withdraw the item in the intercompany dialogue.)
- Send a corrective letter to all renal physicians and clinical nurse consultants in charge of renal and dialysis units informing them of the Code of Conduct Committee decision and requesting that they destroy the patient education leaflet found in breach or return it to Genzyme. This letter should be sent to all renal physicians and units who had been provided with the patient education material found in breach.
- Pay a fine of \$25,000, by a majority decision. Members noted that this fine was lower than might otherwise have been applied because Genzyme had already agreed to withdraw the item and not use it again.

CSL Starter Packs 1018

Subject Company: CSL

Complainant: John Hunter Hospital (JHH)

Product: Various

Complaint

The Director of Pharmacy at John Hunter Hospital alleged that a CSL representative had provided product samples to the Dermatology Clinic at John Hunter Hospital. The Director stated that this was in breach of the John Hunter Hospital *Protocol for Liaison with Pharmaceutical Company Representatives* which requires all medicine samples to be left with the Pharmacy Department and not left in clinical areas or with Medical Officers. The Director of Pharmacy asserted that CSL's explanation that the representative was new to the role and was not aware of the hospital policy was not an adequate reason for non-compliance. All company representatives visiting the Hospital should read and comply with the Hospital's policies and procedures.

Sections of the Code

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

- 4.5 Company Representatives
- 5.1.2 Product Starter Packs

Response

CSL responded that the complaint had arisen due to a miscommunication and misunderstanding between CSL and John Hunter Hospital. CSL asserted that during a meeting at John Hunter Hospital to discuss clinical papers, which was attended by a CSL company representative, dermatology registrars and three nurses, the representative announced that starter packs were available for three CSL dermatological products. One of the nurses present had explained that the starter packs would have to be taken to the Pharmacy Department. The representative said she would take the starter packs to Pharmacy, but the nurse insisted on doing so herself. CSL has confirmed that the starter packs arrived at Pharmacy at John Hunter Hospital the very same day.

CSL stated that significant effort had been made to contact the Director of Pharmacy, but apart from one phone call, CSL was unable to speak with him directly. CSL

considered the complaint had arisen due to a miscommunication between CSL and John Hunter Hospital, and a misunderstanding of the circumstances relating to the delivery of the starter packs to the Pharmacy. CSL asserted there had been no breach of the hospital policy or Sections 4.5 and 5.1.2 of the Code.

Code Committee decision

- In a majority decision the Committee found a minor breach of Sections 4.5 and 5.1.2 of the Code.

Sanction

- Pay a fine of \$1,000
- Provide education to all company representatives of the importance of adherence to hospital policies.

Consideration of the complaint

The Committee noted the chronological sequence of events relating to this complaint. Members were of the view that there had been miscommunication and misunderstanding between CSL and the JHH.

Members accepted that the representative was apparently aware of the hospital policy which required starter packs to be delivered directly to the hospital pharmacy, and it was the intention to deliver the starter packs to pharmacy. However, on CSL's admission, the representative had provided them to a nurse on the undertaking that she would deliver them to the hospital pharmacy. The CSL representative had no surety that the starter packs would be delivered to the pharmacy and there was no evidence provided that the nurse had signed for receipt of the starter packs. It was noted that the starter packs evidently were provided to the Pharmacy on the same day by the nurse, which had prompted the Director of Pharmacy to contact CSL that day.

The Committee by a majority decision found a minor breach of Sections 4.5 and 5.1.2 of the Code because the representative had not complied with hospital policy. However members acknowledged that the representative had intended to adhere to hospital policy but a staff member of the hospital had contributed to the failure of the representative to fully adhere to the policy.

Members recommended that the hospital provide information to its staff in relation to the hospital's policy for the delivery of starter packs and that CSL reinforce to its representatives adherence to hospital policies and the Code and that these responsibilities may not be carried out by another person on a representative's behalf.

Sanctions

Having found a minor breach of Sections 4.5 and 5.1.2 of the Code, the Committee determined that CSL should:

- Pay a fine of \$1,000
- Provide education to all company representatives of the importance of adherence to hospital policies.

Lipitor 1022

Subject Company: Pfizer Australia (Pfizer)

Complainant: Healthcare professional

Product: Lipitor

Complaint

The complainant had stated that the vast majority of research on statins has shown that they are of little or no benefit to women. Although a small cardiovascular benefit is seen in women with pre-existing cardiovascular (CV) disease, there is no overall mortality benefit with treatment, and for those without CV disease, statins have not proven to reduce CV disease. Even though some trials have suggested CV benefits, the majority of research has not.

The healthcare professional suggested that Lipitor is unlikely to protect older women but may cost them money and put them at risk of the well documented side effects.

The complainant alleged that the Pfizer advertisement is misleading, and not based on conclusive evidence, and should be removed from the media.

Sections of the Code

Pfizer was asked to respond to the complaint under the following sections of the Code:

- 1.1 Responsibility
- 1.2.2 Level of substantiating data
- 1.3 False and misleading claim
- 1.7 Comparative statements

Response

Pfizer responded that it did not accept that the advertisement is misleading, out of step with existing policies and guidelines and was not in breach of the Code of Conduct.

Pfizer also asserted that the advertisement was fully supported by the Product Information, consistent with the TGA approved indications for Lipitor, within the PBS listing for lipid-lowering drugs, aligned with independent guidance on lipid management in men and women and supported by clinical trial data.

Code Committee decision

- In a majority decision the Committee found no breach of Section 1.3 of the Code.
- In a unanimous decision the Committee found no breach of Sections 1.1, 1.2.2 and 1.7 of the Code.

Consideration of the complaint

The Committee noted that the three advertisements subject to complaint were included in one issue of an on-line newsletter for healthcare professionals. The Committee reviewed the three advertisements and noted that they included different levels of information:

- first advertisement does not include any reference to the indications, but does include a direct link to the Product Information and PBS listing;
- second advertisement includes the PBS listing and a statement to review the Approved Product Information in the Primary Advertisement in this publication; and
- third advertisement is the Primary advertisement which includes a statement of the approved indications, the Minimum Product Information and PBS listing.

The Code permits a company to refer from a short advertisement to a Primary advertisement and provide a direct link to the Product Information when the advertising is in an electronic format.

In considering the complainant's allegation that there was no evidence to support the benefit to women of statins in CV disease, members reviewed the Lipitor Product Information and noted that there was no distinction between male and female patients in the approved indications. In the clinical studies provided by Pfizer, which included thousands of subjects, women had been included in the study population, although at lower numbers than men (in one study women were 19% of the study population). All patients in the trials were hypertensive or hypercholesterolemic or had a CV event - that is they had CV risk factors. Members noted the American Heart Association "Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women" which include data on women in high, intermediate and low risk groups. The Committee concluded that there is evidence that statins are of benefit to both men and women in the

prevention of CV disease where a person has CV risk factors.

The Committee discussed whether the advertisements could be interpreted to infer that all older women need cardioprotection with Lipitor, regardless of whether they had risk factors. Members commented that a healthcare professional will assess whether a patient, male or female, meets the approved indications and PBS criteria for treatment with a statin. The advertisements are directed at healthcare professionals who are familiar with prescribing statins.

One member was of the view that because the advertisements do not make it clear that the 'grandma' depicted has CV risk factors or meets the criteria for treatment with a lipid-lowering drug, they are potentially misleading.

The majority of members considered that the advertisements were not inferring that all older women need Lipitor regardless of risk factors.

Some members were of the view that the first and second advertisements in particular could be clearer and avoid any risk of misinterpretation of the cardioprotection claim if it was clearly stated in the advertisement that 'grandma' must have CV risk factors to be prescribed Lipitor.

In a majority decision the Committee found no breach of Section 1.3 of the Code as the advertisements provided sufficient reference to the Product Information and PBS listing information, which identify the criteria for prescribing Lipitor, or had included this information within the advertisement.

The Committee accepted that there is no distinction between male and female patients in the approved indications for Lipitor or in the PBS listing criteria for lipid-lowering drugs. Other independently published guidelines do not differentiate between men and women in the treatment criteria for statins. In a unanimous decision the Committee found no breach of Sections 1.1, 1.2.2 and 1.7 of the Code.

