Medicines Australia Code of Conduct Quarterly Report July - September 2012

Medicines Australia Code of Conduct

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

The Medicines Australia Code of Conduct was introduced in 1960 and is currently operating under Edition 16 (Effective 1 January 2010).

This report covers all complaints finalised between July-September 2012. Complaints finalised during this period were in relation to materials or activities conducted under Edition 16 of the Code.

Quarterly Reports preceding this Report are available from the Medicines Australia website http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/

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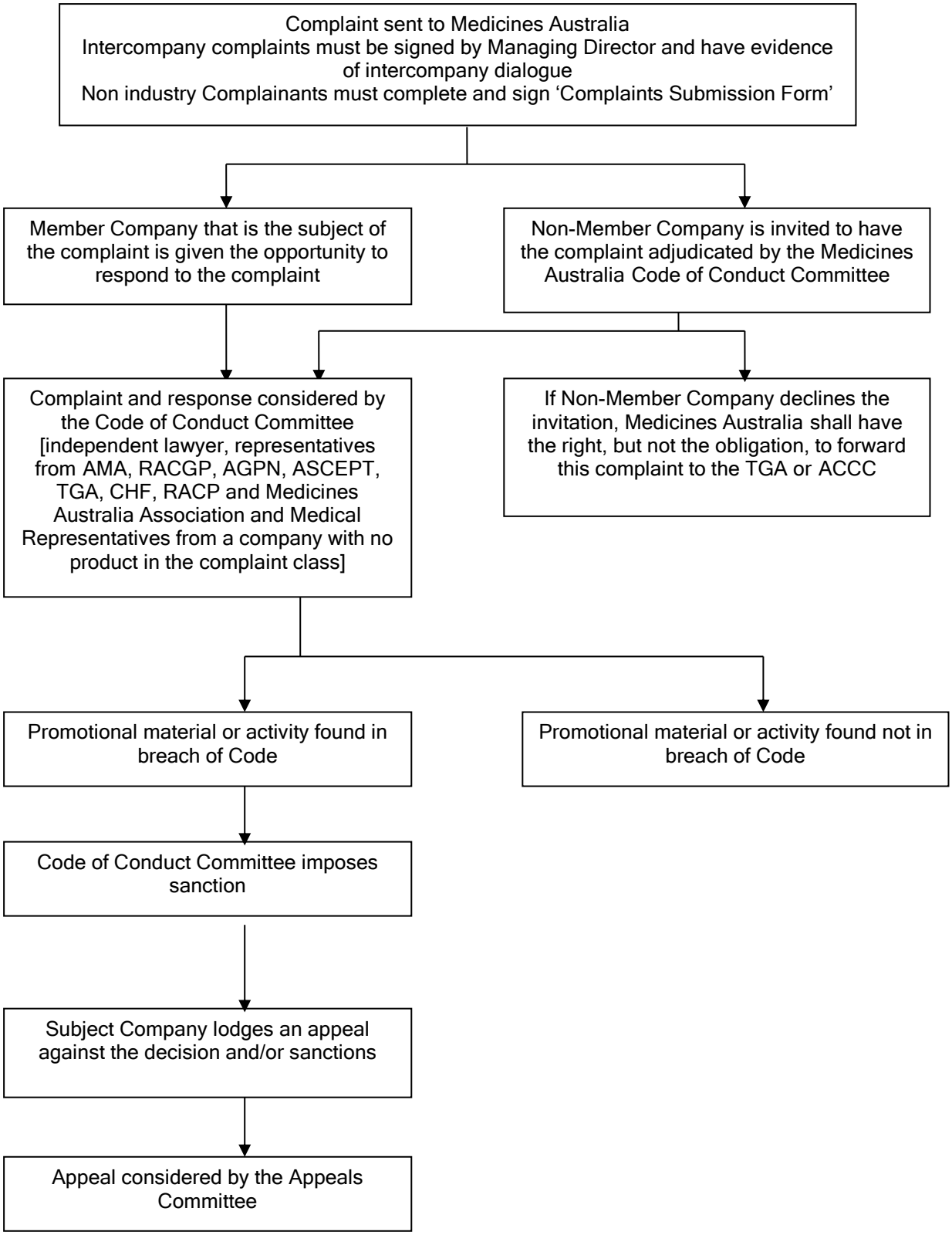
How do I obtain a copy of the Code?

Copies of Edition 16 of the Code (effective from 1 January 2010) are available from Medicines Australia. An order form is available from http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-currentedition/

The Code of Conduct and the Guidelines that accompany the Code are available from the website (http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/)

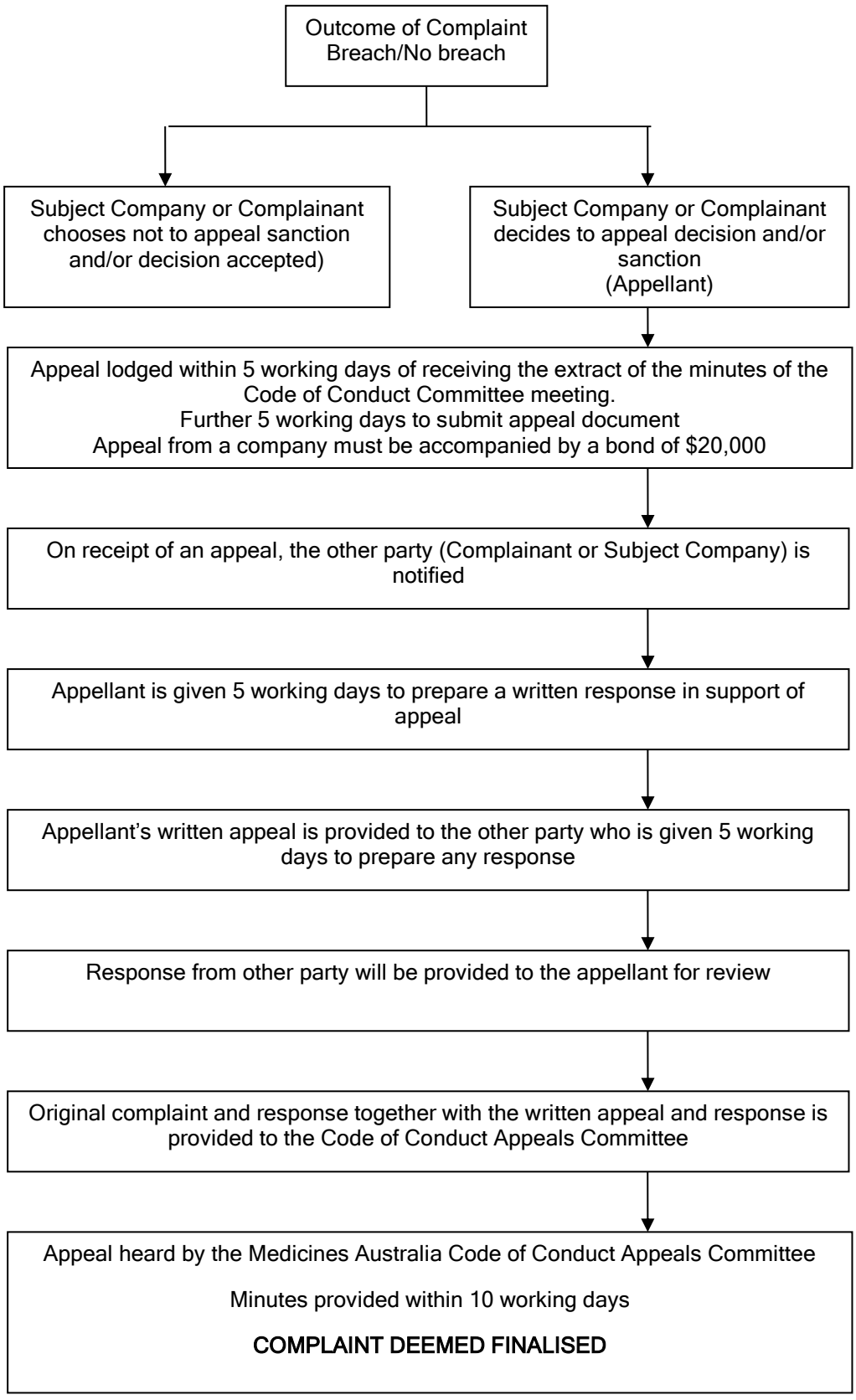
Contents

Medicines Australia Code of Conduct Complaints Handling Process



A complaint is not deemed finalised until the Subject Company has advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Code minutes) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties

Medicines Australia Code of Conduct Appeals Committee Procedures



Committees and Secretariat

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

Committee Member Biographies

Brief biographies for all Code, Appeals and Monitoring Committee members are available on the Medicines Australia website http://medicinesaustralia.com.au/code-ofconduct/committee-membership/

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)
- Medicines Australia Association Representatives (maximum 3)
- Medicines Australia Medical/Scientific Directors (maximum 2)

Observers (No voting rights)

- Therapeutic Goods Administration (TGA)
- Medicines Australia member companies' employees (maximum 2)
- Observer nominated by Medicines Australia (maximum 1)

Advisors (No voting rights)

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

Appeals Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of six trade practices lawyers

Representatives nominated by:

- The College and/or Society associated with the therapeutic class of the product subject to appeal
- The target audience to which the activity was directed eg: AMA, RACGP, AGPN
- Consumers Health Forum of Australia (CHF)
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Medicines Australia Association Representatives (maximum 2)
- Medicines Australia Medical/Scientific Director (maximum 1)

Advisors (No voting rights)

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

Sanctions that can be imposed by the Code of Conduct Committee

Sanctions

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

Withdrawal of material or activity

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

Corrective letter

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

Corrective advertisement

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

Fines (applicable under Edition 15 of the Code)

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

Fine (applicable under Edition 16 of the Code)

Breach	Fine
Technical breach Minor breach	Maximum of $100,000
Moderate	Maximum of $150,000
Severe breach	Maximum of $200,000
Severe breach where activities completed Repeat of previous breach	Maximum of $250,000
Cumulative fine for multiple breaches	Maximum $300,000

Guidelines for determining Code sanctions can be found at page 114 of the Code of Conduct Guidelines (for Edition 16) on the Medicines Australia website at http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/

Table of finalised complaints July – September 2012

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1084	Pfizer Australia	Lipitor Advertisement	Lipitor	Ken Harvey	Breach of Section 12.3	Pay a fine of $50,000
1085	Merck Sharp and Dohme (MSD)	What Contraceptive Are You website and Zoely Promotional Materials	Zoely	Bayer Australia	Breach of Sections 1.1, 1.3 and 1.7	Pay a fine of $75,000
1086	Abbott Australasia	Lipidil Promotional Materials	Lipidil	Merck Sharp and Dohme (MSD)	Breach of Sections 1.3 and 1.7	Pay a fine of $100,000

Lipitor Advertisement - 1084

Subject Company: Pfizer Australia

Complainant: Dr Ken Harvey

Product: Lipitor

Complaint
Dr Harvey alleged that advertisements placed in general media publications directly promoted Lipitor to the general public and therefore were in breach of Section 12.3 of the Code of Conduct.

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

- 12.3 Promotion to the general public

Response
Pfizer responded that it had released the Community Service Announcements (CSAs) after receiving an unprecedented number of calls from consumers regarding the availability of Lipitor. The decision to publish the announcements was not taken lightly and Pfizer acknowledged that it was an unusual and inevitably controversial action.

Pfizer noted that its primary responsibility in releasing in the CSAs was to address the misinformation and to allow patients to make a proper, informed treatment choice.

Code Committee decision
The Committee determined by majority decision that the activity was in breach of Section 12.3 of the Code of Conduct.

<u>Sanction</u>

- Cease using the claim that was found in breach of the Code in any activities directed at the general public
- Pay a fine of $50,000

Consideration of the complaint
The Committee considered that the central question concerning this complaint was whether the published communication to the general public was promoting Pfizer's product Lipitor.

The Committee discussed whether the activity could be considered an advertisement promoting a particular prescription medicine as alleged by the complainant, or an educational activity as argued by the subject company. The Committee accepted that the piece did contain some element of educational information that was relevant to the target audience. The Committee referred to the Glossary in the Code of Conduct (Edition 16, page 158) which defines 'promote' in the context of an advertisement as "all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products". The Committee also reviewed the definition of an 'advertisement', which adopts the definition from the Therapeutic Goods Act 1989 (Cwth), meaning "any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods". It was noted that this definition should be interpreted from the perspective of how a reader of the information would interpret the communication. The Committee agreed by majority that the intent of the communication subject to complaint was to encourage patients who have been prescribed Lipitor to continue to ask for the Lipitor brand of atorvastatin. This is consistent with the definition of an 'advertisement'. A minority of

Committee members disagreed with this opinion. These members considered that the activity was intended to educate patients in response to misinformation about the availability of Lipitor and therefore it was not an advertisement as described by the Code.

Having agreed by majority that the communication issued by Pfizer concerning Lipitor was an advertisement, the Committee then debated at length whether the statement *"A message to the more than 1 million patients prescribed Lipitor®"* was promotional. The Committee referred to the definition of 'promotion, promotional and promotional claim' in the Glossary of the Code of Conduct (Edition 16, page 158). It noted that a statement is promotional if it "conveys the positive attributes of a product which extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product". Some Committee Members considered that the heading statement was intended to create an action by patients who are taking Lipitor to continue to ask for that product. Committee Members considered that in the face of generic competitors entering the market, Pfizer's communication to consumers was intended to encourage patients to ask for the Lipitor brand rather than another brand of atorvastatin. Some members of the Committee also considered that the reference to the "more than 1 million patients prescribed Lipitor" may also be interpreted as suggesting to patients who are not taking Lipitor that it is preferred by a large number of patients and perhaps they should ask for it. The Committee considered that the communication went further than simply telling patients that the suggestion that Lipitor had been discontinued or was not available was incorrect. The Committee agreed by majority decision that the heading statement was promotional and therefore was in breach of the Section 12.3 of the Code of Conduct.

The Committee noted that generic atorvastatin products were recently listed on the PBS. Evidence supplied by Pfizer in support of its rationale for the communication noted that there had been a significant increase in the number of calls to the Pfizer Medical Information department questioning the unavailability of Lipitor. Pfizer reported that the number of calls was 3 times greater than previously received on a regular monthly basis relating to Lipitor. Of these calls, 25% of patients had presented a prescription for Lipitor to a pharmacist and were given false information including that the product was no longer available or had been discontinued; Lipitor had changed its name to Atorvastatin-Pfizer; or that there are supply issues from the manufacturer and there is no stock available. Pfizer had also provided photographic evidence of community pharmacies' displays advising customers that Lipitor was no longer available, had changed packaging to an alternative brand or that another product was the "new" Lipitor. In its response, Pfizer argued that the unprecedented actions of community pharmacies in supplying false and misleading information to patients ultimately led it to issue the advertisement.

The Committee agreed that the activities of some community pharmacies shown in the response were egregious; however it did not agree, by majority, that this justified

undertaking the activity subject to this complaint directed to the general public. The Committee noted that the prohibition on promotion of prescription medicines to the general public reflects the Therapeutic Goods Legislation, which is absolute and does not allow for any justification for this conduct, whether in response to an unprecedented situation or not. The Committee, however, agreed that Pfizer had a right to correct the misinformation being communicated about its product, but any communication to the general public should not have included a promotional claim. The Committee was very concerned at the conduct of some community pharmacists in incorrectly informing patients about the lack of availability of Lipitor and representing other products as replacing Lipitor, however there were alternative solutions available to Pfizer to correct this misinformation.

Sanction
The Committee reviewed the definitions of severe, moderate and minor breaches of the Code. It agreed by majority decision that the activity constituted a minor breach of the Code of Conduct because the conduct did not have any safety implications for patients and would not have a major effect on how the medical profession will prescribe the product.

The Committee agreed by majority decision that Pfizer should:

- Cease using the claim "*A message to the more than 1 million patients prescribed Lipitor"* in any activities directed at the general public
- Pay a fine of $50,000

The Committee agreed by unanimous decision that corrective action was not appropriate in this instance as it would have the potential to compound the offence of promoting the product to consumers.

When determining the sanction, the Committee considered the extremely widespread distribution of the advertisement, being in a wide variety of print media as well as radio segments across a range of stations. It also considered the inability for corrective action and that the activity was determined to be promotion of a prescription medicine to the general public. However, this view was balanced by the single statement being found in breach and the conduct of community pharmacies that had precipitated the activity.

What Contraceptive Are You website and Zoely Promotional Materials - 1085

Subject Company: Merck Sharp and Dohme (MSD)

Complainant: Bayer Australia

Product: Zoely

Complaint
Bayer alleged that several of Merck Sharp & Dohme's (MSD) activities relating to its product Zoely were in breach of the Code of Conduct. The complaint described seven separate issues that were allegedly in breach of the Code – six relating to Zoely promotional materials and one relating to MSD's Consumer Website. However, Bayer also advised that three of the seven issues had been resolved during inter-company dialogue.

Sections of the Code
The activities remaining unresolved following intercompany dialogue were alleged to be in breach of the following Sections of Edition 16 of the Code:

- 1.1 Responsibility
- 1.3 False or misleading claims
- 1.7 Comparative Statements
- 12.1 General Principles
- 12.3 Promotion to the general public
- 12.8 Use of the internet

Response
MSD confirmed in its response that three of the alleged breaches outlined in the complaint had been resolved during intercompany dialogue and therefore were not addressed in the response. MSD requested that the Committee make a determination on the four outstanding issues.

Code Committee decision
The Committee determined:

- Issue 1 – WCAY Youtube: majority decision no breach of Sections 12.1, 12.3 and 12.8
- Issue 2 – claim "short, light, and often less painful...": unanimous decision breach of Sections 1.1, 1.3 and 1.7
- Issue 3 – claim "hormones similar to her own...": majority decision no breach of Sections 1.1 and 1.3
- Issue 4 – claim "made for her...": unanimous decision no breach of Sections 1.1 and 1.3

Sanction
The Committee agreed by unanimous decision that this was a moderate breach of the Code and imposed the following sanctions:

- Distribute a corrective letter to all general practitioners who had the promotional material detailed to them by a MSD sales representative
- The claims found in breach must not be used in the same or similar form in any future materials
- Pay a fine of $75,000

Consideration of the complaint
Mr Daniel noted that the complaint contained several issues that had been resolved during intercompany dialogue, and that there were four remaining issues that required the Committee's consideration.

Issue 1: Use of www.youtube.com (YouTube) to host educational videos

The Committee discussed the use of YouTube as a medium for interacting with the general public to provide educational information. The complaint related to the appearance of suggested links that appear alongside the content created and published by MSD on YouTube. Bayer had alleged that these links were to content that did not comply with the Code and which was promotion to the general public of a prescription medicine. The Committee acknowledged that in accordance with the terms for YouTube hosting a video, a series of 'Suggested Clips' will be displayed on the same page as the video. The selection of these suggested clips is automated through YouTube and is based on key words defined by the video creator when uploading a video. The selection of suggested clips is randomised (for example, all clips that have a key word "contraception" will be grouped together), and the suggested clips may change each time the original video is viewed. The Committee understood that the video creator has no control over the suggested clips that may be displayed alongside their video.

The Committee agreed that the principles and provisions of the Code

still apply and the fact that this activity occurred in the social media does not exclude it from compliance with the Code. A minority of the Committee were of the opinion that as a company does not have full control over the information that will appear on the same page as its created content, the use of sites such as YouTube should not be allowed. The Committee agreed unanimously, that the content displayed alongside the MSD video, but not created by MSD, could lead to the promotion of a prescription product to the general public.

The Committee agreed that Social Media is an expanding area and recommended caution in using an avenue for which a company does not have total control over content associated with its activity.

The Committee based its decision on the content displayed alongside the MSD video, that had been supplied by Bayer in its complaint documentation. The Committee noted that based on the materials before them, the Suggested Clips were not promotional or complementary to MSDs educational content and the users who had uploaded those clips did not have any association with to MSD. The Committee determined by majority decision that MSD's activity had not breached Sections 12.1, 12.3 and 12.8 of the Code. The Committee did note, however, that a different set of Suggested Clips displayed in association with MSD's video may have led to a different decision. The Committee cautioned that companies should carefully consider what content may be displayed in association with the company's content published through the social media and whether the association between the company's content and other content could result in promotion to the general public.

Issue 2: Use of claim *"Short light and often less painful bleeds..."*

The Committee noted that the claim was used in two contexts, each with slightly different wording. The claim *"Short, light and often less painful withdrawal bleeds"* was contained in a promotional piece to doctors whereas the claim *"Short, light and often less painful withdrawal bleeds compared to ethinyloestradiol and drospirenone"* was included in two promotional pieces to pharmacists.

The Committee noted that MSD had acknowledged that the claim was in breach of the Code. The Committee unanimously agreed that the claim in both its forms, to doctors and pharmacists, could not be adequately substantiated and was a hanging comparator and were in breach of Sections 1.1, 1.3 and 1.7 of the Code of Conduct. The Committee did not agree with MSD's assertion that this was not a serious breach of the Code. It noted that any claims which are found to be false and that may influence the prescribing habits of healthcare professionals are not minor breaches of the Code.

Issue 3: Use of claim *"Hormones similar to her own"*

The Committee discussed the claim and the definition of "similar" as provided in MSD's response. A minority of the Committee considered that the statement was incorrect and misleading because the use of the word "hormone" is potentially misleading as nomegestrol acetate is a synthetic steroid rather than a hormone and is not "similar" in all facets to a naturally occurring hormone. It was noted that the Product Information states that nomegestrol is

"structurally similar" to naturally occurring progesterone.

The majority of the Committee agreed that in the context of the promotional piece the statement is pharmacologically correct and the inclusion of the word "structurally" is not needed. These members of the Committee considered that the claim was not incorrect or misleading. Therefore, the Committee agreed by majority decision that the claim *"Hormones similar to her own"* was not in breach Sections 1.1 and 1.3 of the Code.

Issue 4: Use of claim *"Hormones made for her"*

The Committee agreed unanimously that the statement *"Hormones made for her"* would not lead a healthcare professional to believe that Zoely was made for a particular subset of women or a particular woman. The Committee agreed that the claim could be supported by the Approved Product Information. Further, the Committee agreed that the use of a generic image of a female in the promotional piece does not indicate that the product can only be used in the same demographic of that individual. The Committee noted that the intended audience would have the knowledge to discern that the image was a representation for promotional purposes only, and would have the skill and expertise to prescribe accordingly.

The Committee agreed by unanimous decision that the statement *"Hormones made for her"* was not in breach Sections 1.1 and 1.3 of the Code.

Sanction

The Committee reviewed the definitions of severe, moderate and minor breaches of the Code. It agreed by unanimous decision that the activity constituted a moderate breach of the Code of Conduct because the conduct did not have any safety implications for patients and but may have an effect on how the medical profession will prescribe the product.

The Committee agreed by unanimous decision that MSD must:

- cease using the claims:
  - *"Short, light and often less painful withdrawal bleeds"*; and
  - *"Short, light and often less painful withdrawal bleeds compared to ethinyloestradiol and drospirenone"*

  and not use these claims again in the same or similar form
- send a corrective letter to all general practitioners who were detailed by a sales representative using the promotional material containing the claim found in breach of the Code.
- pay a fine of $75,000

Lipidil Promotional Materials - 1086

Subject Company: Abbott Australasia

Complainant: Merck Sharp and Dohme (MSD)

Product: Lipidil

Complaint

MSD alleged that a number of claims made in Lipidil promotional materials were in breach of the Code of Conduct. Specifically MSD's complaint referred to the following Lipidil claims:

- Lipidil has cardio-protective effects that are not supported by the

scientific literature and the current Lipidil Product Information (PI).
- Lipidil has LDL-C reductions not reflective of the scientific literature.
- The use of a surrogate marker "sdLDL-C" to imply clinical outcome benefits that are not proven for Lipidil.
- The use of a tagline that biases prescribing because it is an emotional appeal to doctors.

Sections of the Code
These claims were alleged to be in breach of the following Sections of Edition 16 of the Code:
- Section 1.1 Responsibility
- Section 1.2.2 Level of substantiating data
- Section 1.3 False or misleading claims
- Section 1.3.1 Unapproved products or indications
- Section 1.7 Comparative statements
- Section 4.2 Medical Literature and Reprints
- Section 18 Discredit to and reduction of confidence in the industry

Response
Abbott disagreed that the materials were in breach of the Code. Abbott strongly argued that the materials in question promoted the use of Lipidil within its approved indications, and were adequately supported by data which are in line with the current body of evidence and are consistent with the approved PI.

Code of Conduct Committee decision
The Committee determined:
- Issue 1: Claims of cardiovascular outcome benefits: unanimous decision breach of Sections 1.1 and 1.3. Majority decision breach of Section 1.3.1. Unanimous decision no breach of Section 18.
- Issue 2: "21% reduction...": unanimous decision breach of Sections 1.3 and 1.7
- Issue 3: Implied benefits: unanimous decision breach of Section 1.3
- Issue 4: "be lipidiligent": unanimous decision no breach of Section 1.1

Sanction
The Committee agreed by unanimous decision that this was a moderate breach of the Code and imposed the following sanctions:
- The claims found in breach must not be used in the same or similar form in any future materials
- No corrective action required

The Committee also agreed by majority decision to impose a fine of $100,000.

Consideration of the complaint
Issue 1: Claims of cardiovascular outcome benefits
The Committee noted that this issue centred on Abbott's use of three claims in a number of materials, specifically:

- *"Lipidil significantly reduced total CVD events"*
- *"...addition of fibrate therapy may further reduce CVD risk inpatients with type 2 diabetes mellitus in whom hypertrigliceridaemia and low HDL-C persist despite effective LDL treatment with statins"*
- *"High CV Risk → add statin? → add Lipidil? → Low CV Risk"*

The Committee noted that these claims were based on post-hoc sub-group analyses of two studies, the FIELD and ACCORD studies, in which the primary endpoint had not reached statistical significance. The Committee

noted that the Lipidil Product Information states: *"at the present time, no results of long-term controlled clinical trials are available to demonstrate the efficacy of fenofibrate in the primary or secondary prevention of atherosclerotic complications"*. The Committee noted in Abbott's response to the complaint that the data used to support the claims was not available at the time of TGA approval of the Product Information, but Abbott had argued that the claims were consistent with the approved indications for Lipidil.

The Committee accepted that while there was a signal in both the FIELD and ACCORD studies that fenofibrate may reduce cardiovascular risk in patients with high triglycerides and low HDL-C, no randomised, controlled clinical trials had been done to support the claims. Furthermore, the Committee noted that study used to substantiate the claim *"...addition of fibrate therapy may further reduce CVD risk inpatients with type 2 diabetes mellitus in whom hypertrigliceridaemia and low HDL-C persist despite effective LDL treatment with statins"* (Elam M *et al.*, 2011) had stated in the conclusions that the "ACCORD-Lipid supports the hypothesis that intensive combination therapy with a statin plus a fibrate may reduce CVD risk in T2DM (Type 2 diabetes mellitus) patients with significant dyslipidemia (both hypertrigliceridemia and low HDL-C). A randomised trial conducted in patients with these lipid abnormalities is needed in order to provide definitive proof for this hypothesis. Pending the design and completion of such a trial, practitioners should use available evidence to guide decision making regarding the use of combination lipid therapy in patients at high risk of CVD."

The Committee noted that the FDA Endocrinologic and Metabolic Drugs Advisory Committee had reviewed the ACCORD data and had reached a similar conclusion to that of the Elam study noted above – further investigation is required to substantiate the hypothesis. Furthermore, the Code Committee noted that the evidence as described in the ACCORD and FIELD studies showed a highly variable outcome for patients on combined statin/fibrate therapy.

The Committee agreed by unanimous decision that the claims of cardiovascular outcome benefits with Lipidil were in breach of Section 1.1 and 1.3 of the Code. The Committee agreed by majority decision that the claims were also in breach of Section 1.3.1 of the Code because the claims went beyond the approved indications stated in the PI.

The Committee noted that MSD had also alleged a breach of Section 18 – discredit to and reduction in confidence in the industry. However, as this Section of the Code relates to the relationship between industry and Health Consumer Organisations and patients, the Committee unanimously determined that the complaint had not been made out.

Issue 2: Claim *"21% reduction in LDL-C"*

The Committee noted that the claim is used in a graph which was adapted from a study conducted by Grundy SM et al, 2005 (SAFARI trial). The Committee noted that the SAFARI trial showed that combination therapy resulted in a 31.2% change from baseline, and that simvastatin alone resulted in a 25.8% change. The combination therapy therefore showed an absolute reduction of 5.4% more

than simvastatin alone. The claim of 21% greater is a relative reduction.

The Committee noted that the ACCORD trial showed no difference in the LDL-C reduction between Lipidil and placebo with patients who were on simvastatin therapy. Additionally, the Committee noted additional studies, summarised in McKeage and Keating (2011) which showed variable results in the reduction of LDL-C by fenofibrate. The Committee considered that the use of the Grundy (2005) study was selective and did not reflect the body of the literature.

The Committee unanimously agreed that the claim *"21% reduction in LDL-C"* was false and misleading, and that Abbott had been selective in its representation of the literature. The Committee agreed unanimously that this claim was in breach of Sections 1.3 and 1.7 of the Code. The Committee acknowledged that Abbott had agreed in intercompany dialogue to revise the claim.

Issue 3: Imply clinical outcome benefits from Lipidil's effect on sdLDL-C

The Committee noted that it is well established that fenofibrate can reduce small dense LDL-C (sdLDL-C), however it is not universally accepted that reduction in sdLDL-C levels will result in reduced CVD risk. The Committee also noted that the FIELD and ACCORD studies did not significantly reduce cardiovascular risk for patients on Lipidil.

The Committee agreed unanimously that the implied benefits from Lipidil's effects on sdLDL-C were misleading and were in breach of Section 1.3 of the Code.

The Committee also noted that the pack shots contained in items HL10154 08/10 and HL10188 12/10 included a Solvay logo on the Lipidil pack. The Committee recommended that these images are updated to reflect the current Lipidil packaging.

Issue 4: Use of the tagline *"Be Lipidiligent"*

The Committee agreed unanimously that the tagline *"Be Lipidiligent"* was not overly emotive, nor would doctors be influenced to prescribe Lipidil as a result of this tagline. The Committee agreed that doctors would not be persuaded that to not prescribe Lipidil would be negligent as alleged by MSD.

The Committee agreed unanimously that there was no breach of Section 1.3 of the Code.

Sanction

The Committee reviewed the definitions of severe, moderate and minor breaches of the Code. It agreed by majority decision that the claims found in breach constituted a moderate breach of the Code of Conduct because the conduct did not have any safety implications for patients and but may have an effect on how the medical profession will prescribe the product.

The Committee agreed that as these pieces were distributed to both specialists and general practitioners, the wider audience extended the impact of the breach.

The Committee agreed by unanimous decision that Abbott must:

- withdraw the materials found in breach in their current format
- cease using the claims:
  - *"Lipidil significantly reduced total CVD events"*
  - *"...addition of fibrate therapy may further reduce CVD risk inpatients with type 2 diabetes mellitus in whom*

hypertrigliceridaemia and low HDL-C persist despite effective LDL treatment with statins"

- *"High CV Risk → add statin? → add Lipidil? → Low CV Risk"*
- *"21% reduction in LDL-C"*

And not use the claims again in the same or similar form

- cease the use of the surrogate marker sdLDL-C to imply clinical outcome benefits that are not yet proven for Lipidil
- pay a fine of $100,000