Medicines Australia Code of Conduct Quarterly Report October-December 2011

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 October-December 2011. 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/)

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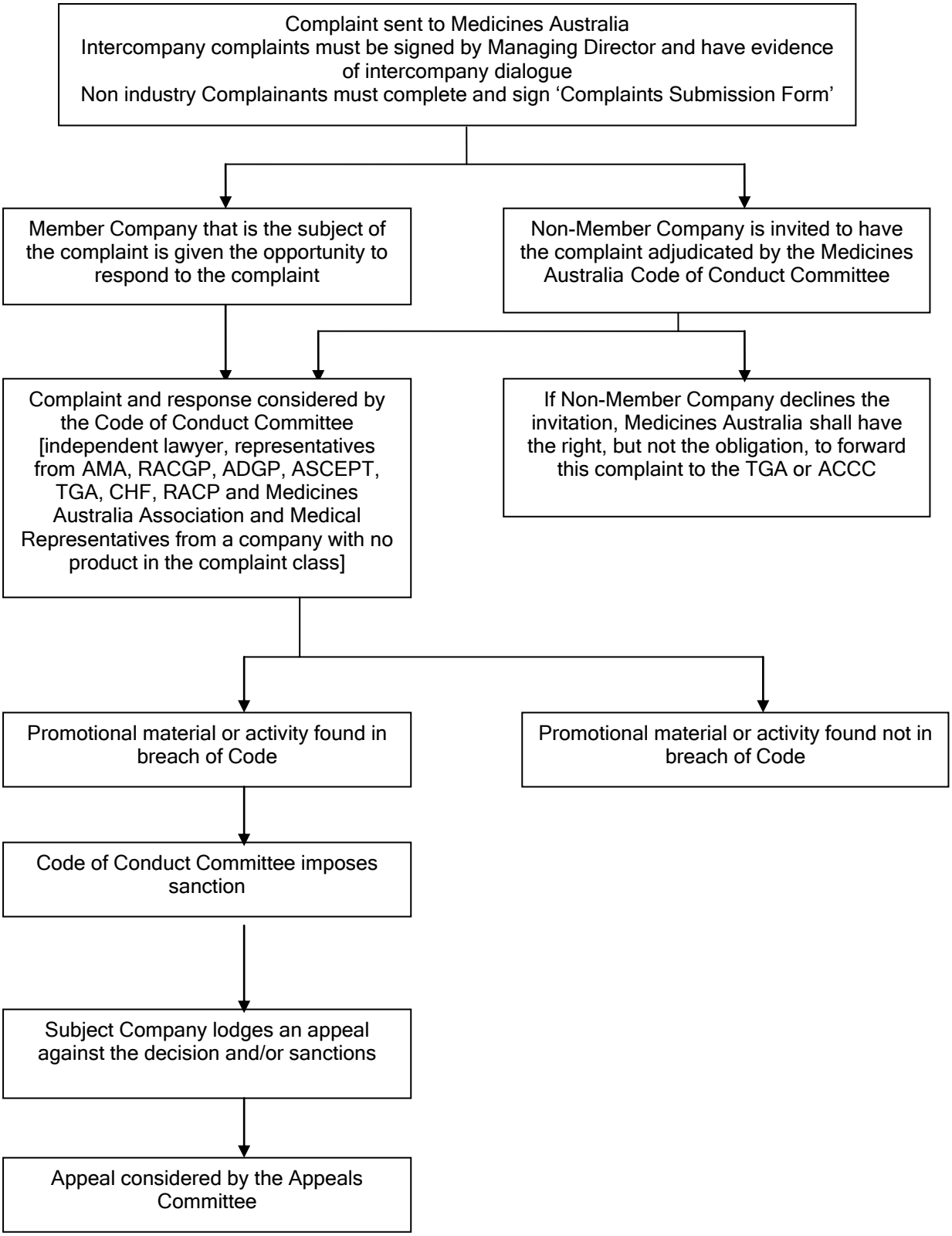
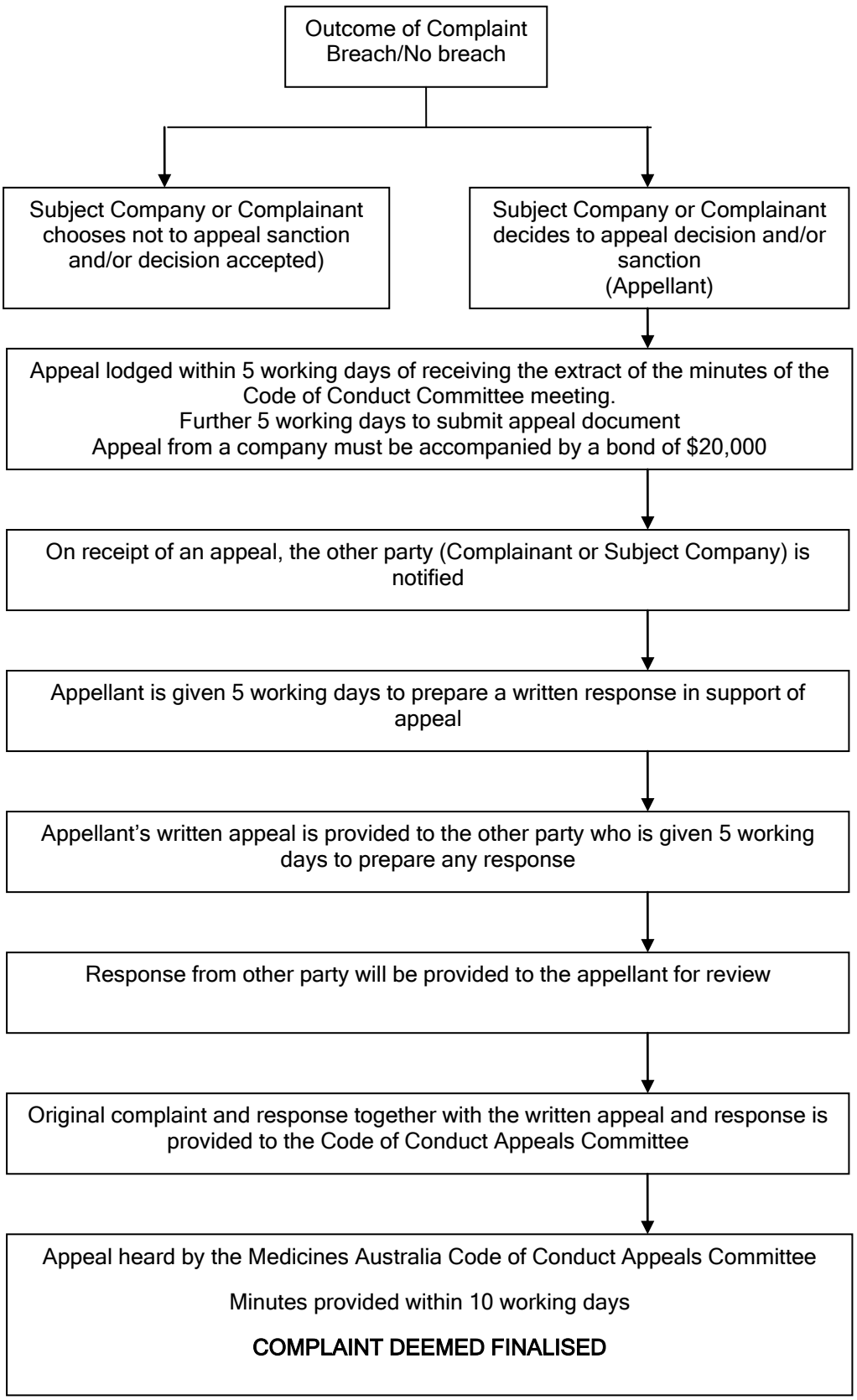
Medicines Australia Code of Conduct Complaints Handling Process



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 October - December 2011

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1076	Merck Sharp & Dohme (Aust) Pty Ltd	Sales Aid	Sevikar	Novartis Pharmaceuticals Australia	Breach of 1.1, 1.2.2 and 1.3	$25,000
1078	CSL Limited	Promotional materials used with healthcare professionals. Insert in patient information booklet	Flomaxtra	GlaxoSmithKline Australia	Breach of 1.2, 1.3 and 12.3	$75,000

Sevikar Sales Aid - 1076

Subject Company: Merck Sharpe and Dohme (Aust) Pty Ltd

Complainant: Novartis Pharmaceuticals

Product: Sevikar

Complaint
Novartis alleged that several claims that appeared in the Sevikar sales aid were in breach of sections 1.1, 1.2.2 and 1.3 of the Code of Conduct. These claims are;

- "power to reach BP target in 7 out of 10 patients"
- "effective dose titration to achieve BP target of <140/90mmHG"
- "Sevikar offered powerful BP reductions and less oedema compared to Amlodipine monotherapy"

Novartis argued that the study used to support claims 1 and 2 was not designed to support a major efficacy claim and that the claims misrepresented the study outcomes and did not adequately convey the limitations of the study design to a reader. In relation to claim 3, Novartis argued that the referenced study outcome was not consistent with the body of evidence and was not consistent with the approved Product Information for Sevikar.

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

- 1.1 Responsibility
- 1.2.2 Level of substantiating data
- 1.3 False or misleading claims

Response
MSD responded that the three claims subject to complaint do not breach the Code of Conduct. MSD had agreed to implement some modifications to the Sevikar promotional material during intercompany dialogue, and had offered to provide further evidence that the results of the referenced study are consistent with the body of evidence and to provide additional supporting references for the claims. MSD requested the Committee to consider that these amendments were satisfactory to conclude this matter.

MSD also requested the Committee to consider whether Novartis should be asked to justify why its action in submitting the complaint was not in breach of Section 23 of the Code.

Code Committee decision
The Committee determined by unanimous decision that the Sevikar Detail Aid was in breach of Sections 1.1, 1.2.2 and 1.3 of the Code of Conduct.

Sanction
The Committee agreed by majority decision to impose a fine of $25,000.

Consideration of the complaint
The Committee noted that a number of issues in relation to the Sevikar detail aid had been resolved through intercompany dialogue; however issues remained in dispute regarding three claims used in the detail aid:

- "power to reach BP target in 7 out of 10 patients"
- "effective dose titration to achieve BP target of <140/90mmHG"
- "Sevikar offered powerful BP reductions and less oedema compared to Amlodipine monotherapy"

Claim 1: "Power to reach BP target in 7 out of 10 patients"

The Committee considered that the graphical representation of the study outcomes, which was the basis for the claim *"Power to reach BP target in 7 out of 10 patients"*, was a misrepresentation of the outcomes from the Punzi et al 2010 (AZTEC) study. The graph showed only those patients in the study that were up-titrated to the combination therapy (Sevikar) and omitted a histogram representing those patients who had achieved the blood pressure (BP) target on monotherapy (amlodipine) alone. The 23.8 percent of patients who achieved the target BP on amlodipine alone were a subset of the 76.8 percent of patients who reached the BP target in the histogram labelled 'Sevikar 40/10', which is the basis for the claim. The Committee agreed that the omission of this group of patients from the graph was a misrepresentation of the study data. The Committee noted that during intercompany dialogue MSD had offered to amend the graph to include the amlodipine monotherapy data.

The Committee noted Novartis' assertion that the claim *"…7 out of 10"* claims a higher proportion of patients achieve BP goal on Sevikar than set out in Table 3 of the Sevikar Product Information. The Committee noted that this table in the Product Information presents results from a double-blind, randomised, active-controlled study over 8 weeks. This study was conducted in 2008 and the Product Information was approved in May 2010. The Punzi et al study, which is the basis the claim, was published in 2010 and had studied patients for 12 weeks. The Committee considered that the results of the Punzi et al study were consistent with the data presented in the PI. In the Punzi study approximately 50 percent of patients, who were uptitrated on Sevikar combination treatment, achieved the BP goal, which is consistent with the 8 week study data included in the PI.

The Committee accepted that the audience for this detail aid would be clinicians who would have some awareness of the National Heart Foundation guidelines for BP targets and the recommendations to initiate treatment with monotherapy and not with a fixed-dose combination. Nevertheless, the Committee determined that the claim was not accurate or correct because it gave the impression that the outcome of 7 out of 10 patients achieving BP target was achieved only in patients using Sevikar combination therapy whereas this result was for patients on amlodipine monotherapy combined with those on the combination therapy.

The Committee considered that the Punzi et al study had an acceptable study design which reflected 'real world' treatment of hypertensive patients. However, the study could not substantiate a claim that 7 out of 10 patients who take Sevikar will reach a BP target of 140/90 mmHg. As noted previously, a proportion (23.8%) of the 76.8 percent of patients who had achieved BP target had done so on monotherapy with amlodipine. The Committee considered that the claim overstates the efficacy of the combination therapy, was not accurate or correct and could not be substantiated.

The Committee unanimously determined that the claim *"Power to reach BP target in 7 out of 10 patients"* was in breach of Sections 1.1 and 1.2.2 of the Code of Conduct.

Claim 2 – "Effective dose titration to achieve BP target of <140/90mmHg"

The Committee considered that this claim is linked to claim 1 "*Power to reach BP target in 7 out of 10 patients"* and the histogram graph which are also referenced to the Punzi et al 2010 (AZTEC) study. The Committee's concerns with claim 2 were similar to the rationale for its concerns with claim 1. The Committee agreed that the graph and associated claim gave the misleading impression that up to 76.8 percent of patients achieved the BP target on one of the three strengths of Sevikar combination therapy, whereas 23.8 percent of patients in the up-titration study achieved this target on monotherapy. It would not be clear to a reader that the histograms present cumulative results encompassing the amlodipine monotherapy patients who achieved the BP target.

The Committee concluded that claim 2 was misleading by omission and gave a false and misleading impression that overstated the results of the Punzi et al study. The Committee unanimously determined that the claim *"Effective dose titration to achieve BP target <140/90 mmHg"* was in breach of Section 1.3 of the Code of Conduct.

The Committee noted that the explanatory statement *"Sevikar is indicated for the treatment of hypertension. Treatment should not be initiated with this fixed dose combination"* should be in a larger font and placed closer to the *"effective titration"* claim.

Claim 3 – "Sevikar offered powerful BP reductions and less oedema compared to Amlodipine monotherapy"

The Committee discussed the COACH study used to reference the claim. The Committee noted that the study was specifically designed to actively assess the incidence of oedema at each clinic visit. The Committee agreed that the specific assessment for oedema may show a higher incidence. The Committee noted that the Product Information states that the incidence of oedema was significantly lower in patients who received Sevikar compared with those who received amlodipine monotherapy. The claim in the detail aid was consistent with this statement. The Committee recommended that MSD update the Product Information to include the COACH data.

The Committee determined by majority decision that the claim *"Sevikar offered powerful BP reductions and less oedema compared to Amlodipine monotherapy"* was not in breach Sections 1.1 or 1.3 the Code of Conduct.

Allegation of vexatious complaint

In its response, MSD asked the Committee to consider whether Novartis had breached Section 23 – Abuse of the Code in lodging a complaint before intercompany dialogue had concluded. The Committee noted that both companies had actively engaged in the intercompany dialogue and that a number of issues had been resolved prior to lodgment of the complaint.

The Committee noted that MSD had offered to make some changes to the detail aid, however were unable to reach agreement with Novartis on those changes. The Committee agreed that as the companies had been unable to resolve the matters in dispute, it was appropriate to bring the complaint to the Code Committee. Further, the Committee had found several breaches of the Code in relation to the detail aid, which would not have been fully

resolved by the changes proposed by MSD in intercompany dialogue.

The Committee determined by unanimous decision not to seek justification from Novartis of its actions in submitting the complaint.

Decision
The Committee determined by unanimous decision that the Sevikar Detail Aid was in breach of Sections 1.1, 1.2.2 and 1.3 of the Code of Conduct.

Sanction
The Committee determined that the breach was moderate, and would not influence the prescribing habits of a healthcare professional. The Committee agreed by unanimous decision to impose a fine of $25,000. The Committee also determined that the sales aid should be withdrawn and that the claims and associated graphs should not be used again in the same or similar form.

Flomaxtra Promotional Materials - 1078

Subject Company: CSL Limited

Complainant: GSK Australia

Product: Flomaxtra

Complaint
GSK asserted that the content of the following promotional materials breached the Code:

- Flomaxtra Leave behind CSLB3252.7
- Flomaxtra Leave behind CSLB3252.4
- Flomaxtra Promotional leave behind titled (*Once daily in BPH* – (no CSL code) found inserted each Healthworks Patient Information booklet titled *Living with BPH* 10 per box.

GSK alleged that the materials were misleading, unbalanced, inaccurate and substantially hindered clinicians from making informed assessments of the body of evidence relating to the treatment of benign prostatic hyperplasia/lower urinary tract symptoms in their patients.

In addition, GSK alleged that CSL had directly promoted Flomaxtra to the general public through the insertion of the promotional leaflet in patient literature, which may lead patients to seek a prescription from their healthcare professional for a specific prescription medicine.

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

- 1.1 Responsibility
- 1.2 Substantiating claims
- 1.3 False or misleading claims
- 1.3.1 Unapproved products or indications
- 1.7 Comparative statements
- 2 Promotional material directed at healthcare professionals
- 12.1 Relationship with the General Public – general principles
- 12.3 Promotion to the General Public

Response
CSL rejected the breaches alleged by GSK and argued that GSK had not been accurate in its representation of CSL's position. CSL stated that it had made considerable efforts to resolve the

complaints with GSK and had committed to a number of actions including the withdrawal of all materials related to the complaint and agreement to cease using or revise the majority of the claims subject to complaint.

CSL considered that GSK's assertion that CSL was directly promoting to the general public was disingenuous. CSL asserted that at no time did CSL specifically direct healthcare professionals to place the patient information booklets in surgery waiting rooms. Further the patient booklet display box was clearly labelled with an instruction to remove the promotional insert before giving the item to a patient.

Code Committee decision

Across the various alleged breaches in the complaint, the Committee found:

- Complaint 1: By unanimous decision a breach of Sections 1.2 and 1.3
- Complaint 2: By majority decision a breach of Section 1.2
- Complaint 2: By unanimous decision a breach of Section 1.3
- Complaint 3: By majority decision no breach of Sections 1.1, 1.2 and 1.3
- Complaint 4: By unanimous decision no breach of Sections 1.2 and 1.3
- Complaint 5: By majority decision no breach of Sections 1.1, 1.2, 1.3 and 1.7
- Complaint 6: By majority decision breach of Sections 1.1, 1.3 and 12.3
- Complaint 6: By majority decision no breach of Section 12.1

Sanction

The Committee imposed a fine of $75,000.

Consideration of the complaint

The Committee noted that GSK had presented its complaint as six individual complaints. The Committee considered the complaint following the order of issues raised in the letter of complaint.

Complaint 1

- *Flomaxtra for male LUTS. It works. So your patients can too*
- *Flomaxtra. Less nocturia. More energy*
- *Go less at night, more 'go' the next day*

The Committee noted that Complaint 1 related to two issues: claims relating to less nocturia, which were referenced to a study by Abrams et al (1995), and claims relating to more energy and improved ability to work.

The Committee reviewed the Abrams et al study (1995) used to substantiate the nocturia claims *"Flomaxtra for male LUTS. It works"* and the tag line *"Less nocturia. More energy"*. The Committee noted that the study used a modified release formulation of tamsulosin whereas Flomaxtra is an oral controlled absorption (OCAS) formulation. However a study by Chapple et al (2005) showed that there is no clinically significant difference in efficacy between tamsulosin MR and tamsulosin OCAS (Flomaxtra). The Committee therefore accepted that Abrams et al study was sufficient to substantiate the claims relating to less nocturia with Flomaxtra, which has also been shown in several other studies in nocturia. The Committee noted that CSL had agreed to cease using the Abrams study to reference the nocturia efficacy claims. The Committee unanimously found that the use of the Abrams et al study to reference the nocturia claims was not in breach of either Section 1.2.2 or 1.3 of the Code.

The Committee reviewed the studies used to reference the "(It works.) *So can your patients can too", "More energy"* and *"More 'go' the next day"* claims. The Committee noted that these claims had been referenced to several studies which examined duration of undisturbed

sleep and quality of life measures. The Asplund (2005) and Stanley (2005) studies investigated the impact of nocturia on sleep disruption, but did not examine energy or capacity to work. Only the Kobelt G et al study (2003) investigated the impact of nocturia on quality of life and vitality. The Committee discussed whether improved vitality could be interpreted to mean having 'more energy' or ability to work. The Committee concluded that the cited studies did not provide sufficient evidence to substantiate the energy claims, because none of the studies specifically examined energy or ability to work. The Committee noted that whilst it might be intuitive that unbroken sleep may give patients with more energy the next day, there could be other factors which could impact unbroken sleep duration that are not attributable to Flomaxtra.

The Committee agreed by unanimous decision that the claims relating to patients having more energy and ability to work could not be substantiated and were false and misleading and therefore were in breach of Sections 1.2 and 1.3 of the Code of Conduct.

Complaint 2

- *Heading: "Monotherapy with an α-blocker is recommended first-line for men with LUTS"*

The Committee reviewed the European Association of Urology Guidelines (EAU Guidelines - 2010) and noted that the recommendation 3.1.6 states that alpha-blockers should be offered to men with moderate to severe LUTS (lower urinary tract symptoms). The Committee agreed that the claim subject to Complaint 2 did not contain the limitation to use in men with *moderate to severe LUTS*; the claim was therefore more generalised than the EAU Guideline recommendation. The Committee agreed that the claim misrepresented the EAU Guidelines, as not every man presenting with LUTS should be started on an alpha-blocker; treatment will depend on symptomatology. The Committee stated that it is not good practice to paraphrase or reword Guideline recommendations for a promotional piece because a slight change in wording may change the meaning and thereby inappropriately alter the prescribing habits of healthcare professionals. The Committee noted that CSL had undertaken to use the exact wording from the EAU Guidelines in future materials.

The Committee agreed that in its current form, the claim *"Monotherapy with an α-blocker is recommended first-line for men with LUTS"* does not accurately represent the EAU Guidelines recommendation to which the claim is referenced; the claim does not adequately qualify the group that should receive treatment with an alpha-blocker. The Committee agreed by majority decision that the claim was in breach of Section 1.2 of the Code and unanimously agreed that it was in breach of Section 1.3 of the Code of Conduct.

Complaint 3

- *Key points section within both Leave Behinds*

The Committee noted that the issues concerning the first bullet point in this section: *"alpha-blockers still represent the first-line drug treatment of choice"* were discussed under Complaint 2. The wording of this bullet point also differs from the EAU Guidelines to which it is referenced through the inclusion of "still" and "(treatment) of choice)". The Committee considered that its decision in relation to Complaint 2 also applied to the first dot point in the Key Points section of the promotional materials.

The Committee reviewed the second and third bullet points in the Key Points section of the promotional materials and noted that the statements were generally consistent with the information and recommendations in section 3.6.1.4, 3.6.1.5 and 3.6.1.6 of the EAU Guidelines – combination therapy is associated with more adverse events, as would be expected when two drugs are used together, and combination therapy should be used primarily in men with moderate to severe LUTS and are at risk of disease progression.

The Committee noted that similarly to Complaint 2 and the first dot point in the Key Points section, CSL had not used the precise wording from the EAU Guidelines and recommendations but had selectively extracted some of the wording for use in the Key Points. Some members of the Committee were concerned that this selective use of the EAU Guidelines text inappropriately emphasised the negative effects of combination therapy and did not include the balancing statements from the Guidelines about combination therapy resulting in a greater improvement in LUTS and superior prevention of disease progression or the recommendation to consider ceasing the alpha-blocker after 6 months in men with moderate LUTS. These members considered that the emphasis from this extraction from the Guidelines was on monotherapy and was therefore misleading and not balanced. A majority of the Committee accepted that the wording in the second and third bullet points adequately paraphrased the EAU Guidelines and contained sufficient information in order to not be misleading or unbalanced.

The Committee determined by a majority decision that the second and third bullet points were not in breach of Sections 1.1, 1.2 or 1.3 of the Code of Conduct.

<u>Complaint 4</u>

- *Flomaxtra relieves the most bothersome symptoms of BPH/LUTS, including nocturia*

The Committee noted that the study used to support this claim was the Abrams et al study considered in relation to Complaint 1. The Committee confirmed its decision that the Abrams study was sufficient to substantiate claims for Flomaxtra relating to nocturia.

The Committee determined by unanimous decision that the claim was not in breach of Sections 1.2 or 1.3 of the Code of Conduct.

<u>Complaint 5</u>

- *Flomaxtra has an established safety profile*
- *Adverse events may be more likely with combination therapy*

The Committee noted that the safety claims were all referenced to the Product Information and the EAU Guidelines discussed in relation to Complaint 3. The Committee noted the statement on page 8 of the Product Information was consistent with the second dot point under the heading Flomaxtra *has an established safety profile* and adequately supported the claims “generally well tolerated” and “no relevant differences between adverse events reported in the Flomaxtra and placebo arms”. The Committee had previously accepted the claims that adverse events may be more frequent with combination therapy in relation to Complaint 3.

The Committee agreed by a majority decision that the claims were not in breach of Sections 1.1, 1.2, 1.3 or 1.7 of the Code of Conduct.

Complaint 6

- *Promotion to the general public*

The Committee considered that there was a high risk that the promotional item inserted into each patient information booklet would end up being given to patients; it could not be guaranteed that all health professionals would remove the promotional insert before providing the booklet to the patient. The Committee noted that there were instructions included in the box of booklets as well as on the top of each insert for it to be removed prior to being given to a patient. Nevertheless, the Committee considered that the promotional item inserted in each patient educational booklet was inconsistent with the Code of Conduct's prohibition against direct to consumer promotion; if a patient received the promotional insert they would be encouraged to request that their doctor prescribe Flomaxtra. The Committee also noted that there had been some examples of the box of booklets, with the promotional leaflet remaining in each booklet, being made available in waiting rooms. The majority of members of the Committee did not agree that it was the intention of CSL to promote its product to consumers. A minority of members considered that the insertion of the promotional material in each booklet was deliberately intended to promote the product to consumers. Irrespective of whether the intent was to promote the product to consumers, a majority of the Committee considered this to be the likely result.

The Committee commended the informative booklet that would be useful to men with benign prostatic hypertrophy. The Committee was disappointed that this informative material was detracted from by the insertion of a promotional item directed at a healthcare professional.

The Committee considered this to be a severe breach of the Code and agreed by a majority decision that the promotional insert in the patient educational booklet breached Section 12.3 of the Code.

The Committee discussed whether the availability of the promotional leaflet inside the patient education booklet, where in a few instances the booklets were found in practice waiting rooms, brought discredit to the industry. As already noted, the majority of the Committee did not consider this was a deliberate attempt to promote the product to consumers. The Committee agreed by majority decision that no breach of Section 12.1 of the Code should be found.

The Committee had previously discussed the claim "Go less at night. More 'go' the next day" under Complaint 1 and confirmed its previous decision that the claim was in breach of Sections 1.2 and 1.3 of the Code.

Decision

Across the various alleged breaches in the complaint, the Committee found:

- Complaint 1, nocturia claims: By unanimous decision no breach of Sections 1.2 or 1.3
- Complaint 1, energy claims: By unanimous decision a breach of Sections 1.2 and 1.3
- Complaint 2: By majority decision a breach of Section 1.2
- Complaint 2: By unanimous decision a breach of Section 1.3
- Complaint 3: By majority decision no breach of Sections 1.1, 1.2 or 1.3
- Complaint 4: By unanimous decision no breach of Sections 1.2 or 1.3
- Complaint 5: By majority decision no breach of Sections 1.1, 1.2, 1.3 or 1.7

- Complaint 6: By majority decision breach of Sections 1.2, 1.3 and 12.3
- Complaint 6: By majority decision no breach of Section 12.1

Sanction
The Committee discussed appropriate sanctions and noted the actions proposed by CSL during the intercompany dialogue with GSK. The Committee determined that the claims that were found in breach of the Code should not be used again in any future material in the same or in a similar form.

Corrective Action
The Committee discussed corrective action in relation to this complaint:

Complaint 1
The Committee agreed by a majority decision that a corrective letter should not be imposed.

Complaint 2
The Committee noted that CSL had agreed to change the claim "monotherapy with an α-blocker is recommended first-line treatment for men with LUTS" to the exact wording from the EAU Guidelines. The Committee agreed by majority decision that this action was sufficient and no corrective action should be required.

Complaint 6
The Committee agreed that CSL should ensure that patient education material does not contain promotional material intended for healthcare professionals. The Committee confirmed that the actions agreed by CSL and GSK during intercompany dialogue, including that CSL had instructed its sales team to remove all promotional inserts from the BPH booklets already distributed to medical practices and CSL had sent a reminder letter asking health professionals to ensure that the insert is removed prior to giving the item to a patients. The Committee determined that CSL must provide confirmation to Medicines Australia that these actions have been completed and an undertaking that the distribution of patient booklets with promotional inserts will not continue.

Monetary Penalty
The Committee noted that much of the revision of claims subject to the complaints had been agreed by both parties and a number of actions were taken to resolve this complaint prior to its submission to Medicines Australia.

The Committee agreed that this was overall a moderate breach of the Code of Conduct and imposed a financial sanction of $75,000 on CSL. In imposing the fine, the Committee took into consideration the resolutions to the complaints that had been agreed during intercompany dialogue, balanced with the Committee's concern that promotion of a prescription medicine to the general public had been found.