Medicines Australia Code of Conduct Quarterly Report October - December 2017

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 18 (Effective 16 May 2015).

This report covers all complaints finalised between October to December 2017. Complaints finalised during this period were in relation to materials or activities conducted under Edition 18 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/

How to contact Medicines Australia

Address:
Level 1, 16 Napier Close
DEAKIN ACT 2600

Phone: 02 6122 8500

Fax: 02 6122 8555

Email: secretarycodecommittee@medicinesaustralia.com.au

How do I obtain a copy of the Code?

Copies of Edition 18 of the Code (effective from 16 May 2015) are available from Medicines Australia. An order form is available from https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/

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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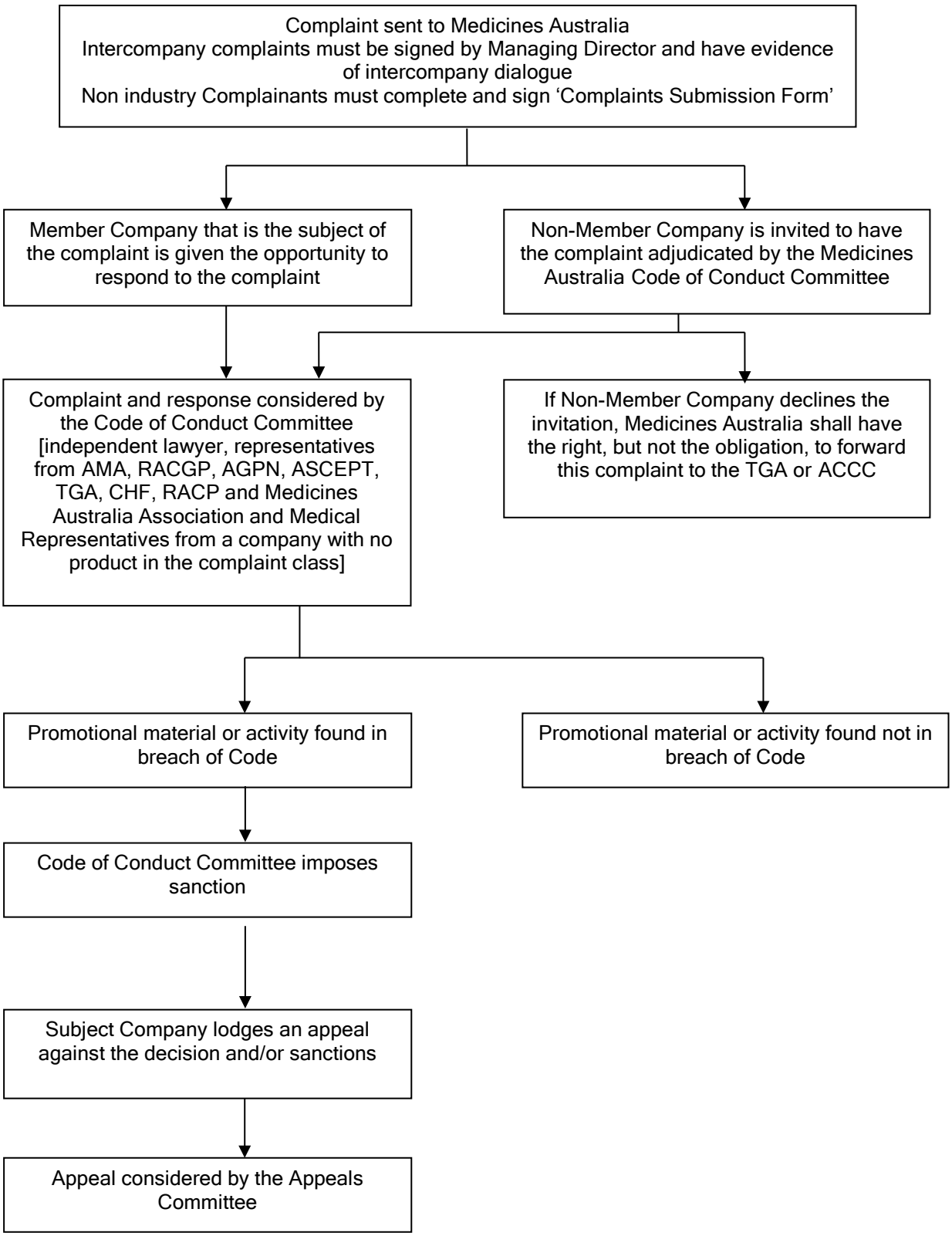
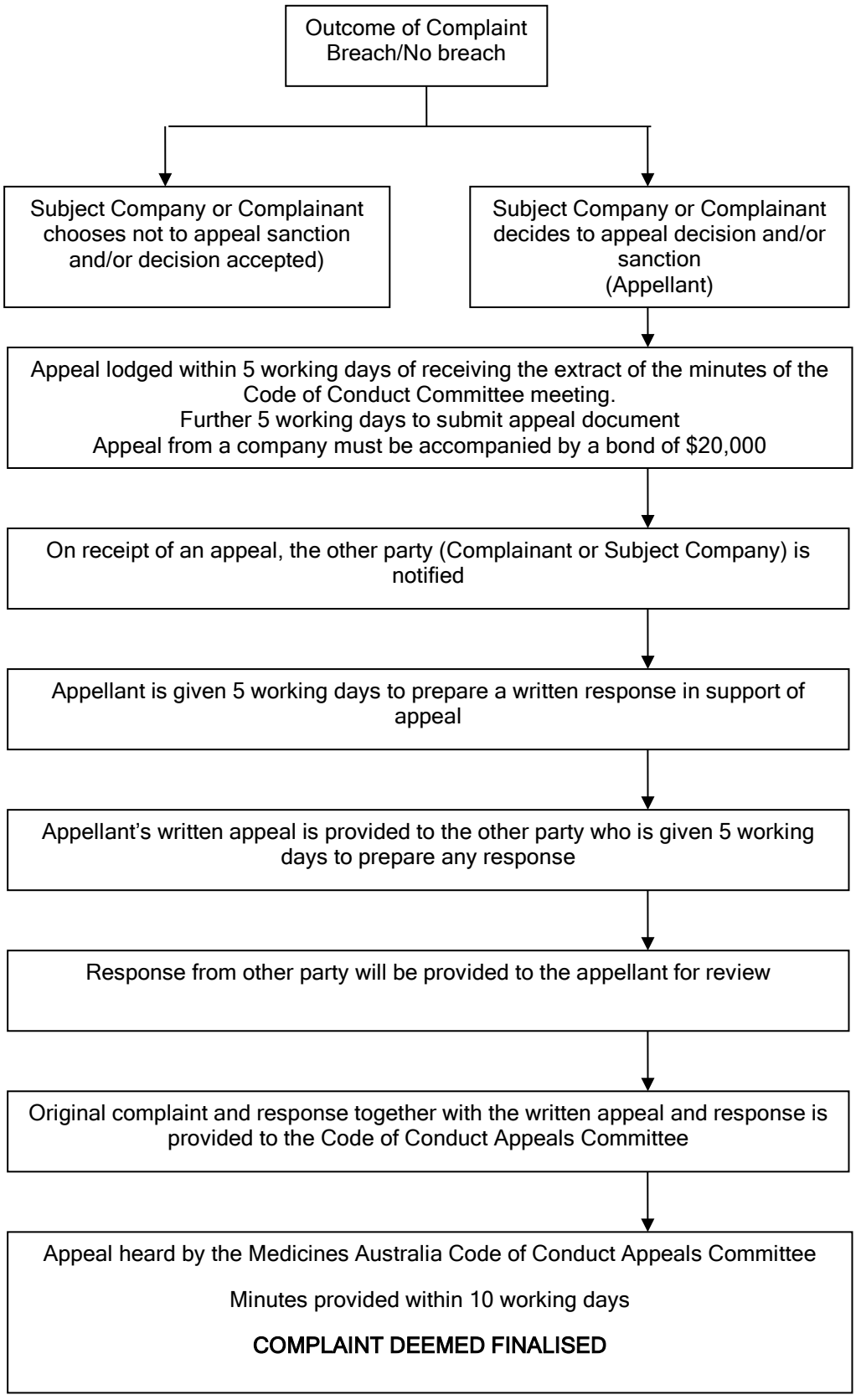
Medicines Australia Code of Conduct Complaints Handling Process



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 https://medicinesaustralia.com.au/code-of-conduct/committee-membership/

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of up to 4 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 up to 4 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
- 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 18 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 of $300,000
Failure to complete corrective action in 30 calendar days Failure to pay a fine in 30 calendar days	Maximum of $50,000
Abuse of the Code (in accordance with Section 25)	Maximum of $200,000

Table of finalised complaints October – December 2017

No.	Subject Company	Material or Activity	Product	Complainant	Outcomes	Sanction
1145	GlaxoSmithKline Australia Pty Ltd	Promotional material	Breo® Ellipta®	AstraZeneca Pty Ltd	Breach of Sections 1.1, 1.2, 1.2.2, 1.3, 1.8, 2.1.2	Material not to be used again in the same or similar form Pay a fine of $100,000

1145 – Breo® Ellipta® Promotional Material

Subject Company: GlaxoSmithKline Australia Pty Ltd

Complainant: AstraZeneca Pty Ltd

Product: Breo® Ellipta®

Complaint
AstraZeneca allege that promotional materials for Breo Ellipta are false and misleading, and do not accurately reflect the body of evidence when making a comparison against the AstraZeneca product, Symbicort. Specifically, AstraZeneca asserts that the materials make incorrect comparisons between the products, implies a dosing equivalence that is inaccurate, and misrepresents data which may lead prescribers to believe that the products may be interchangeable.
Further, AstraZeneca allege that GSK articulate a position that the Symbicort dosing is complex, which is refuted by AstraZeneca and is not reflected in the body of evidence.

Sections of the Code
The conduct was alleged to be in breach of the following Sections of Edition 18 of the Code:

- 1.1 Responsibility
- 1.2 Substantiating Data
- 1.3 False and Misleading Claims
- 1.6 Unqualified Superlatives
- 1.8 Comparative Statements
- 2.1.2 Printed promotional material provided to, or used for discussion with, a healthcare professional

Response
GSK acknowledged that engaging in the intercompany dialogue process uncovered areas of improvement that could be incorporated into its materials. However, GSK believes that comparisons highlighting differences in dosing and potency in a balanced manner meet the requirements of the Code. GSK further believes that the materials not include or imply claims of clinical equivalence or interchangeability; and therefore there is no substantiation to the claim that patient safety is at risk.
GSK assert that the claims within the promotional materials are appropriately substantiated by the body of evidence.

Code of Conduct Committee decision
The Code of Conduct Committee made the following decisions in relation to the two items of promotional material:

Promotional Piece 1 "Give your asthma patients the choice"

Issue 1 – claim "Give your asthma patients# the choice"
The Committee found in a unanimous decision that the claim and associated imagery was in breach of Sections 1.1, 1.2, 1.2.2, 1.3 and 1.8 of the Code.
The Committee found in a majority decision that there was no breach of Section 1.6 of the Code

Issue 2 – Inaccurate description of Symbicort Turbuhaler Single Maintenance and Reliever Therapy not in line with Product Information
The Committee found in a unanimous decision that the promotional material was in breach of Sections 1.1, 1.2, 1.3 and 1.8 of the Code.

Issue 3 – "Give your asthma patients# the choice" – choice is unqualified
The Committee found in a unanimous decision that the promotional material was in breach of Sections 1.1, 1.2, 1.3 and 1.8 of the Code.
The Committee found in a majority decision that there was no breach of Section 1.6 of the Code.

Issue 4 – The qualifier for patients# in the statement "Give your asthma patients# the choice" misrepresents the approved indications for comparator brands presented
The Committee found in a unanimous decision that the qualifier was not in breach of Sections 1.3 or 1.8 of the Code.

Issue 5 – Australian Approved Names (AAN) not included in the body of the advertisement
The Committee found in a unanimous decision that the promotional material was in breach of Section 2.1.2 of the Code with respect to the omission of the AAN for Breo Ellipta.
The Committee found in a majority decision that the promotional material was misleading and was therefore in breach of Sections 1.3 and 1.8 of the Code.

Promotional Piece 2 "Dosing equivalence for Breo Ellipta"

Issue 1 – Australian Approved Names (AAN) not included in the body of the advertisement

The Committee found in a unanimous decision that the promotional material was in breach of Section 2.1.2 of the Code.
The Committee found in a majority decision that the promotional material was misleading and was therefore in breach of Sections 1.3 and 1.8 of the Code.

Issue 2 – Dosing equivalence for Breo Ellipta 100/25 and Dosing Equivalence for Breo Ellipta 200/25
The Committee found in a majority decision that the promotional material was in breach of Sections 1.1, 1.3 and 1.8 and 2.1.2 of the Code.
The Committee found in a majority decision that there was no breach of Section 1.6 of the Code.

Sanctions
The Committee determined that the following sanctions should be imposed:

- Noting that the promotional materials had already been withdrawn from use, the two items of promotional material found in breach must not be used again in the same or similar form.
- In a majority decision the Committee imposed a fine of $100,000.
- In a majority decision, the Committee determined that no additional corrective letter should be required to be sent.

Consideration of the complaint
The Chairman provided a brief summary of the complaint, which related to two items of promotional material for Breo Ellipta that had been in use between February and June 2017. One item had the heading "GIVE YOUR ASTHMA PATIENTS# THE CHOICE" (promotional piece 1) and the other the heading "Dosing equivalence for BREO ELIPTA (100/25 mcg)", with the same heading for the 200/25 mcg inhaler on the reverse (promotional piece 2). The Chairman noted that the complaint primarily relates to comparative claims, which the complainant AstraZeneca had alleged extended to comparative efficacy with its product Symbicort which could not be substantiated. GSK had responded that it considered that its claims had been confined to its product Breo Ellipta and its dosing regimen, and to maintenance (as opposed to "rescue" or relief) in relation to asthma, and did not overtly claim or imply comparisons of efficacy, safety or of clinical equivalence or interchangeability with Symbicort.

The Committee decided to consider each aspect of the complaint by working from AstraZeneca's letter of complaint, and with reference to the response and other material, in detail.

Promotional Piece 1 "Give your asthma patients the choice"

Issue 1 – claim "Give your asthma patients# the choice"
The promotional item provided a comparison of daily doses between Breo Ellipta and a range of other inhaler products including the Symbicort Turbuhaler. Whilst only the Symbicort Turbuhaler was identified by name, the other inhalers were illustrated by shape and colour in a manner that would be easily recognised by prescribers.

The Committee agreed with the complainant that the description of the dosing for the Symbicort Turbuhaler SMART regimen implied that the number of daily doses is much higher, more complex and therefore more burdensome on patients than "one dose" per day stated for Breo Ellipta. In relation to the Symbicort Turbuhaler, the Committee considered that the use of the word "PLUS", in large, bold, capital letters with "extra puffs as needed", and the further detailed description of the Symbicort Turbuhaler dosing regimen that appeared below the imagery with up to 24 inhalations a day, was not a fair or accurate comparison of the dosing regimens for the two products. The qualification that a reliever inhaler is recommended for all patients prescribed Breo Ellipta was not similarly emphasised. On one hand the dosing of Breo Ellipta had been oversimplified and on the other the dosing of Symbicort Turbuhaler had been inaccurately communicated as being more complex and with a higher number of daily doses.

The Committee discussed whether the comparison implied that Breo Ellipta had superior efficacy when compared to Symbicort Turbuhaler or the other inhalers shown. The Committee agreed that the claim "Give your asthma patients# the choice" and imagery did not necessarily imply superior efficacy, but did at a minimum imply that Breo Ellipta would provide equivalent asthma maintenance efficacy with a lower number of daily doses compared to the other inhalers, which could not be substantiated. The Committee agreed that the comparison was misleading as the promotional material did not make it clear that the comparison was only in relation to the

number of daily doses of inhaler and was not a comparison of safety or efficacy of the different products.

The Committee unanimously agreed that the comparisons were not accurate or balanced, were misleading and could not be adequately substantiated. The Committee found by a unanimous decision that the claim and associated imagery was in breach of Sections 1.1, 1.2, 1.2.2, 1.3 and 1.8 of the Code.

The Committee discussed whether the claim, which referred to "the choice" rather than "a choice", was an unqualified superlative or implied a special merit or quality for Breo Ellipta. The Committee determined that the promotional claim and imagery did not imply superiority of Breo Ellipta but did imply equivalence with fewer doses per day, the claim was not an unqualified superlative. The Committee found in a majority decision that the claims was not in breach of Section 1.6 of the Code.

Issue 2 – Inaccurate description of Symbicort Turbuhaler Single Maintenance and Reliever Therapy (SMART) not in line with Product Information

The Committee noted that GSK had acknowledged in its response to the complaint that the description of the use of the Symbicort Turbuhaler SMART regimen in the promotional material was not consistent with the Product Information for Symbicort Turbuhaler. The Product Information states that the product may be taken either once daily or in two divided doses morning and night, whereas the comparison in the promotional material only referred to twice daily dosing. GSK had sent a corrective letter to 15,000 healthcare practitioners to clarify this information.

The Committee found by unanimous decision that the description of the maintenance an reliever therapy was in breach of Sections 1.1, 1.2, 1.3 and 1.8 of the Code.

The Committee discussed AstraZeneca's assertion that the wording from the Symbicort Turbuhaler Product Information should be stated without amendment, parapharasing or interpretation. The Committee did not agree. Clearly, Product Information must be presented accurately, without the omission of relevant information, and in a manner that is not misleading. However, the Code does not require that Product Information must be used verbatim.

Issue 3 – "Give your asthma patients# the choice" – choice is unqualified

The Committee noted that the complaint in issue 3 was essentially the same as issue 1; that is, the comparison purports to be only related to dosing frequency but implies that Breo Ellipta is equivalent in efficacy and safety to the other inhalers depicted, including Symbicort Turbuhaler, but has the advantage of once daily dosing in maintenance therapy. Whilst "choice" suggests that the options displayed are equivalent, the use of coloured background in the horizontal bar chart for Breo Ellipta at the top of the images with the words "ONE DOSE", whereas the other inhalers' bars are in pale grey with "FIRST DOSE" and "SECOND DOSE", implies that Breo Ellipta is the preferred choice. The Committee agreed that the comparison was misleading because it did not qualify for a reader that it was only in relation to the number of daily doses of inhaler and was not a comparison of safety or efficacy of the different products.

The Committee found by unanimous decision that the promotional material was in breach of Sections 1.1, 1.2, 1.3 and 1.8 of the Code.

For the same reasons as discussed in relation to Issue 1, the Committee found by a majority decision that the claim was not in breach of Section 1.6 of the Code.

Issue 4 – The qualifier for patients# in the statement "Give your asthma patients# the choice" misrepresents the approved indications for comparator brands presented

AstraZeneca alleged that because the various inhaler products may be used in a broader group of patients than those with moderate to severe asthma, whereas Breo Ellipta is only indicated in patients with moderate to severe asthma, the qualifying statement that appeared below the three bar imagery was misleading because it implied that all of the products were only indicated for moderate to severe asthma. The Committee did not agree that the qualifying statement implied that the products with which Breo Ellipta was compared are also restricted to use in patients with moderate to severe asthma. The Committee understood that the qualifying statement, which was linked to the claim by a hash symbol, was merely qualifying the patients for whom Breo Ellipta may be prescribed.

Code of Conduct Section 1.3 requires that a qualifying statement must appear directly below or adjacent to the relevant claim. The Committee noted that the qualifying statement

– "#Moderate to severe asthma patients ≥ 12 years of age, who require a medium to high dose ICS with a LABA" – appeared underneath the bar imagery that compared Breo Ellipta and other inhalers and Symbicort Turbuhaler, whereas the claim that it qualified appeared above the imagery. AstraZeneca had not argued in its complaint that the qualifying statement was in an incorrect position. Therefore, the Committee made no finding with respect to the position of the qualifying statement, but noted it as a possible matter of concern.

In relation to the specific breaches alleged by AstraZeneca, the Committee found by unanimous decision that the qualifier was not in breach of Sections 1.3 or 1.8 of the Code.

Issue 5 – Australian Approved Names (AAN) not included in the body of the advertisement
GSK had acknowledged that the AAN for Breo Ellipta did not appear in the promotional material adjacent to the most prominent presentation of the brand name as required by Section 2.1.2 of the Code. The Committee found by unanimous decision that the promotional material was in breach of Section 2.1.2 of the Code with respect to the omission of the AAN for Breo Ellipta.

AstraZeneca had further alleged that it was misleading to omit the AANs for all other products being compared with Breo Ellipta in the promotional material. The Committee noted that the qualifying statement in relation to Symbicort Turbuhaler refers to "Symbicort Turbuhaler 200/6 mcg" and the Minimum Product Information for Breo Ellipta refers to "Breo Ellipta 200/25 mcg" and "100/25 mcg". Whilst most prescribers should know that these strengths refer to different inhaled corticosteroids and long-acting beta agonists contained in the different products, it is possible that some prescribers would understand from the presentation of the comparison that they refer to the same active ingredients as contained in Breo Ellipta. The Committee concluded that the omission of clarifying information regarding the name of the active ingredients contained in the Symbicort Turbuhaler, with which Breo Ellipta was specifically compared in the promotional material, was misleading.

The Committee found by a majority decision that the promotional material was misleading in its comparison between Breo Ellipta and Symbicort Turbuhaler and was therefore in breach of Sections 1.3 and 1.8 of the Code.

Promotional Piece 2 "Dosing equivalence for Breo Ellipta"

Issue 1 – Australian Approved Names (AAN) not included in the body of the advertisement
The Committee noted that the complaint concerning the omission of the AANs for Breo Ellipta and the other inhaler products with which it was compared was essentially the same as Issue 5 in relation to promotional piece 1. GSK had acknowledged that the AAN for Breo Ellipta did not appear in the promotional material adjacent to the most prominent presentation of the brand name as required by Section 2.1.2 of the Code. The Committee found by unanimous decision that the promotional material was in breach of Section 2.1.2 of the Code with respect to the omission of the AAN for Breo Ellipta.

The Committee discussed the omission of the active ingredient names for the various inhalers with which Breo Ellipta (both 100/25 mcg and 200/25 mcg strengths) was compared. The Committee considered that the omission of the active ingredient names from the promotional material made it uninterpretable for a healthcare professional because the identity of the inhaled corticosteroid and long acting beta agonists (LABA) ingredients and their doses are essential to the proper interpretation of the claimed dosing equivalence. The Committee found by majority decision that the promotional material was misleading by omission and was therefore in breach of Sections 1.3 and 1.8 of the Code.

Issue 2 – Dosing equivalence for Breo Ellipta 100/25 and Dosing Equivalence for Breo Ellipta 200/25
The Committee considered that the basis for comparison of the different inhaler products in this promotional material was unclear for healthcare professionals. Each strength of the Breo Ellipta inhaler was visually compared with four other inhalers, which were named and the quantity of their active ingredients stated, however the active ingredients in each inhaler were not identified. The Committee noted that the different brands of inhaler contain different inhaled corticosteroids (ICS), different doses of ICS, different LABAs and different doses of LABA. It is therefore important for healthcare professionals to know the relative equivalencies of the different ICS components so they may interpret the claimed dosing equivalence. Although the heading that referred to dosing equivalence was referenced

to the National Asthma Council Australia Asthma Handbook, which includes this information for each ICS, the promotional material does not include the names of the ICS components. The Committee considered that unless this information is clear for a healthcare professional, the promotional material would be very difficult to interpret.

AstraZeneca had also argued in its complaint that the promotional material should have included information in relation to the different properties, modes and onsets of action, dosing and administration, indications and clinical efficacy of the LABA components. The Committee did not agree that promotional material must describe every element of each product that is compared, but it did consider that if a comparison is made on the basis of a particular parameter, such as dosing equivalence in this instance, all information relevant to that comparison should be included. The Committee considered that the omission of key differences between Breo Ellipta and the other inhalers shown, including the omission of the names of the active ingredients for each product and that the Symbicort Turbuhaler can be used for both maintenance and as a reliever whereas Breo Ellipta requires a separate reliever medication, was misleading and made an unfair comparison that was based on undue emphasis on one parameter.

The Committee found in a majority decision that the promotional material was in breach of Sections 1.1, 1.3 and 1.8 and 2.1.2 of the Code.

Similarly to its consideration of the complaint raised in relation to promotional piece 1, the Committee did not consider that the claim of dosing equivalence was an unqualified superlative and did not imply any special merit for Breo Ellipta. The emphasis of the promotional material was equivalence between Breo Ellipta and other inhalers, rather than superiority. The Committee found in a majority decision that there was no breach of Section 1.6 of the Code.

Sanction

Having found that the two items of promotional material were in breach of the Code, the Committee considered appropriate sanctions. The Committee discussed the severity of the breaches and determined that they were in the moderate category, noting that (a) the promotional materials may have an effect on how a healthcare professional would prescribe the product but (b) there were no apparent safety implications for patients arising from the materials.

The Committee determined that the following sanctions should be imposed:

- Noting that the promotional materials had already been withdrawn from use, the two items of promotional material found in breach must not be used again in the same or similar form.
- In a majority decision the Committee imposed a fine of $100,000.
- In a majority decision, the Committee determined that no additional corrective letter should be required to be sent to healthcare professionals.