Code of Conduct

Annual Report
2017-2018

Medicines Australia

MEDICINES AUSTRALIA
ABN 23 126 990 001

Level 1, 16 Napier Close

Deakin ACT 2600

Phone: 02 6122 8500

Fax: 02 6122 8555

Web: www.medicinesaustralia.com.au

Email: secretarycodecommittee@medaus.com.au

Where to find assistance

If you need any assistance in understanding the Code or complaints process you can contact Medicines Australia on Phone: 02 6122 8500; or Email: secretarycodecommittee@medaus.com.au

The following documents are available on the Medicines Australia website:

- Code of Conduct Edition 18
- Code of Conduct Guidelines (to be read in conjunction with Edition 18)
- Lodging a complaint (non-industry complainant)
- Complaints Submission Form for Non-Industry Complainants
- Responding to and lodging a complaint (pharmaceutical company)

This document is available for download in PDF format from the Medicines Australia website.

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The Year in Review

Medicines Australia Member Companies remain aligned with global standards of ethical conduct by demonstrating high levels of compliance with the Code

The Ethics and Compliance team assisted Medicines Australia Member Companies to prepare and publish their reports on the payments and transfers of value made to healthcare professionals. From 1 October 2016, companies must not make a payment or transfer of value to a healthcare professional without the healthcare professional having the reasonable expectation of the disclosure of that information. This transparency model continues to demonstrate the Australian innovative medicines industry's leadership in delivering even greater transparency for the Australian community about the support provided to healthcare professionals. Making these activities transparent reinforces the value of the engagement and the appropriateness of compensating healthcare professionals for their valuable expertise and advisory services provided to Member Companies.

Medicines Australia's Ethical Conduct activities in 2017-2018 continued to focus on ensuring ongoing implementation of Code of Conduct Edition 18, which has been effective since it was authorised by the ACCC in May 2015. The Ethics and Compliance team also established the Future of the Code Working Group in mid-2017 to conduct a thorough review of the Code and recommend its future direction.

Complaints, Appeals and Monitoring

Complaints handling

Medicines Australia considered 6 complaints in 2017-2018, with all complaints finalised before the end of the financial year. The number of complaints received by Medicines Australia remains static year on year.

Complaint	Subject Company	Complainant	Outcome
1142	MA Member Company	Healthcare Professional	No Breach
1143	MA Member Company	Non-Member Company	No Breach (appeal not upheld)
1144	Non-Member Company	MA Member Company	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Complaint referred to TGA
1145	MA Member Company	MA Member Company	Breach
1146	Non-Member Company	Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Complaint referred to TGA
1147	Non-Member Company	Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Complaint referred to TGA

As shown in the table above, three complaints lodged in 2017-2018 were received against a non-member company. In accordance with Section 25 of Edition 18 of the Code, Medicines Australia invited the non-member to have the complaint adjudicated by the Code of Conduct Committee. In each instance, the non-member company declined that invitation. Medicines Australia exercised its right to refer the complaints to the Therapeutic Goods Administration (TGA) for its adjudication.

Monitoring of Member Company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2017-2018. The Committee undertook five reviews of materials associated with specific therapeutic areas. The Monitoring Committee also undertook a review of Member Companies' HCO Support reports. In addition to these reviews, the Monitoring Committee conducted a review of Member Companies' policies and procedures relating to the provision of hospitality to healthcare professionals, to confirm Member Companies' compliance with the monetary limit on hospitality provided to healthcare professionals.

Transparency Reporting

Reporting Payments and Transfers of Value to Healthcare Professionals

Edition 18 of the Code requires member companies to report the cost of all flights, accommodation and registration fees provided to an individual healthcare professional to enable their participation in educational meetings and symposia and any honoraria, sitting or consulting fees. From 1 October 2016, companies may not make a payment or provide an airfare, accommodation or registration fee unless a healthcare professional is notified of the company's disclosure obligation and therefore reasonably expects the information to be disclosed.

In 2017-2018 Medicines Australia Member Companies published reports on their Australian corporate websites which detailed activities for the periods 1 November 2016 – 30 April 2017 and 1 May 2017 – 31 October 2017. These were the first full reporting periods in which 'mandatory' reporting by companies was in effect. It is expected that a diminishing number of interactions were contracted during the period where healthcare professionals had provided consent for these data to be published, and the associated payments or transfers of value were made in a later reporting period. Therefore, these data were reported in aggregate where consent was not granted.

Central Reporting System

Medicines Australia completed its investigations into the establishment of a Central Reporting System and following a robust tender process Pacific Commerce Pty Ltd were engaged to build and implement a system to publish these data. Pacific Commerce Pty Ltd demonstrated they met the criteria described in the tender and could further enhance the system by providing their own secure data hosting facility in Sydney with the necessary infrastructure already in place, and proactive systems for monitoring, daily back up and solid rotation, and clearly defined response times for any critical issues. Medicines Australia is in the processes of developing statements to assist members in obtaining consent from healthcare professionals to have their data collected and reported in the new system.

Third Party Meeting and Symposium Sponsorship Reports

Medicines Australia Member Companies continue to publish Third Party Meeting and Symposia Sponsorship reports. The activities captured in this report include where a company has provided a lump sum sponsorship to the event, have financially assisted an institution to hold a journal club, grand round, or in-institution meeting, and the purchase of trade displays in association with an educational event. The reporting periods for this report align with the Payments and Transfers of Value to Healthcare Professionals reports (above). The reports are published on Medicines Australia's website.

Reports published on 31 October 2017 showed that there were 1,302 events sponsored by 33 Member companies in the period 1 November 2016 – 30 April 2017. On 30 April 2018, Member Companies published reports for the period May 2017 – October 2017, which reported on 1,898 events sponsored by 33 Member companies in that six month period.

Health Consumer Organisation Support Reports

In June 2018 Medicines Australia published the fifth annual reports of Member Companies' financial support for Health Consumer Organisations (HCO). Member companies supported 210 different HCOs across Australia in calendar year 2017, ranging from national consumer organisations to small local groups, relating to 357 different projects or events to the total value of $7,679,389 of support.

Communication and Training Activities

Medicines Australia regularly engages in communication activities to raise awareness, promote understanding of the Code and to encourage compliance. This is done in a variety of ways, including but not limited to, meetings with and educational seminars for pharmaceutical companies, healthcare professional organisations, consumers, health consumer organisations; and agencies and businesses working with the industry (such as advertising and public relations agencies, suppliers, event organisers).

In our communications with stakeholders external to the industry, we explain the standards by which the industry operates and the conduct that stakeholders should expect when engaging with individual companies. More information about Code training activities can be found on the Medicines Australia website.

Continuing Education Program

Medicines Australia's Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard. The CEP is offered as an online course through the University of Tasmania's Unit for Medication Outcomes, Research and Education (UMORE), which is backed by the resources of the University's School of Pharmacy. More information on these courses is available on the Medicines Australia website.

In 2017-2018 1,839 individual students enrolled in one or more Programs offered under the CEP which demonstrates the real value of the CEP to our Members and others. In 2017-2018 183 company personnel undertook the updated Refresher Module for Code Edition 18. This shows the high level of interest by Members in ensuring that their personnel and the external agencies they engage are well informed about the new Code requirements.

CEP Awards

Medicines Australia hosts an annual awards ceremony to celebrate the achievements of students in the Continuing Education Program. The CEP awards are presented annually to sales representatives who achieve the highest marks in the course. Additionally, the University of Tasmania offered a prize to students based on the level of engagement and quality of participation in the course. The CEP Awards for 2017 were presented in March 2018.

UTAS Prize for Excellence

CEP Course Facilitators at the University of Tasmania nominate one finalist for each semester from their program based on the level and quality of participation in group discussions and personal reflections in the online tutorials. The winners are selected by a panel from the University. The two UTAS Prizes for Excellence were presented to Jennilee Davidson from Boehringer-Ingelheim, and Katie Barrett from Servier Laboratories

Code of Conduct Award

Finalists for the Code of Conduct Award include all students who achieve the highest mark for Program 1, excluding anyone who has achieved final mark via resubmission or supplementary assessment.

Among finalists, the winner is determined through review of learning log book and online participation by a panel from the University of Tasmania which is made up of Program facilitators and program administration staff, with Medicines Australia to make final decision if it is difficult to identify a clear winner. The Code of Conduct Award was presented to Simon McErlane of Alexion Pharmaceuticals.

CEP Achievement Award

CEP Achievement Award winners are the students who achieve the 10 highest aggregate marks. CEP Achievement Award recipients for 2017 are:

- John Seeto – Hahn Healthcare
- Anwar Johnson – Novartis
- Shaynora Prasad – Hahn Healthcare
- Joshua Lennox – Hahn Healthcare
- Marion Arnott – Mundipharma
- Nina Clifford – Boehringer Ingelheim
- Monica MacGregor – Sanofi
- Briar Tietjens – Novartis

The Year Ahead

The Ethics and Compliance Team remain committed to leading the charge towards transparency for the Australian innovative medicines industry. The year ahead will see the team continue engagements with healthcare professionals, industry groups, healthcare professional groups and other key stakeholders to enhance support for these measures. We will also maintain our support of Member Companies as they continue to forge new relationships with healthcare professionals under this transparency regime. It is our firm belief that these relationships, and the education provided by the industry are valued by healthcare professionals and deliver valuable information that ultimately benefits Australian patients.

In 2018-2019, the team will have a number of other key projects including the launch of the Central Reporting System, the ongoing review of the Code of Conduct, and a wholesale review of the Continuing Education Program.

Governance

Complaints received by Medicines Australia are considered by the Code of Conduct Committee and, when required, by the Appeals Committee. The Medicines Australia Board and the Secretariat staff do not adjudicate on complaints or appeals.

Conflict of Interest

A person participating on a Code-related Committee must not have a conflict of interest with the therapeutic area/s or company/ies against which a complaint has been lodged or with the Complainant, or in the case of the Monitoring Committee no conflict of interest with either the therapeutic area subject to review or the companies who have submitted materials for review. This also extends to financial matters or any perceived bias with any of the matters considered at the meeting which they attend.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered in a meeting of any Committee, members must also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Committee may be influenced in reaching a decision by factors other than the merits of the case.

The effective and equitable implementation and administration of the Code of Conduct relies on the commitment, skill and professionalism of the Medicines Australia staff and members of the Code, Appeals and Monitoring Committees. We are very grateful for their continued commitment to assisting Medicines Australia to ensure that industry self-regulation through a world class industry Code of Conduct remains strong and effective.

Short biographies of all permanent members of the Code, Appeals and Monitoring Committees, as well as a schedule of meeting dates, is available on the Medicines Australia website.

Complaint determinations

This section of the Code of Conduct Annual Report provides the decisions and reasons for decisions of all complaints considered by the Code Committee and finalised in 2017-2018.

Each complaint is usually made up of several different aspects, where the complainant alleges that certain statements or claims in the materials or aspects of a company's conduct are in breach of one or more sections of the Code. Each element of the complaint is considered and a decision made.

No.	Subject Company	Material or information subject to complaint	Product	Complainant	Outcomes	Sanction
1142	iNova Pharmaceuticals	Staff Conduct	N/A	Healthcare Professional	No Breach	n/a
1143	Pfizer Australia	Promotional Material	Apomine	STADA Pharmaceuticals	No Breach, following appeal	n/a
1144	Non-Member Company	Promotional Material		Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Referred to TGA	
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
1146	Non-Member Company	Promotional Material		Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Referred to TGA	
1147	Non-Member Company	Promotional Material		Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Referred to TGA	

1142 – iNova Staff Conduct

Subject Company:	iNova Pharmaceuticals (Australia) Pty Limited	**Complainant:**	Healthcare Professional	**Product:**	Nil

Complaint
A healthcare professional complainant had alleged that certain conduct of several iNova staff members at the iNova Obesity Forum Dinner in August 2016 was in breach of the Code of Conduct and had brought the industry into disrepute.

The complainant had taken their young family member with them to the Obesity Forum and the Forum Dinner. The complainant and their child were seated at a table at the dinner with healthcare professional colleagues. The complainant alleged that they and their child were asked to leave the dinner and were told that if they did not leave voluntarily they would be removed by security staff in front of other guests at the table.

The complainant alleged that the conduct by iNova staff was unprofessional and intimidating, leaving the complainant feeling humiliated and as though their professional reputation had been damaged.

Sections of the Code
The conduct was alleged to be in breach of the following Sections of Edition 18 of the Code:
- 9.4 Company educational events held in Australia
- 9.5 Sponsored educational events
- 9.13 Discredit to and reduction of confidence in the industry

Response
iNova denied breaching the Code in respect of the conduct by its staff at the National Obesity Forum in August 2016. It was iNova's position that the annual event has been sponsored by iNova for the past 4 years, and that the educational content and speakers are determined by an independent faculty, that the organisation and management of the event are outsourced to a conference organiser, and that one of the critical elements of the contract with the organiser is the requirement to ensure strict compliance with the Code and Valeant (iNova's parent company) company policies.

iNova also stated that as part of the registration process for the Obesity Forum it had been clearly stated in capital and bold letters that the dinner would be restricted to registered delegates only. iNova stated it had no records to support the complainant's claim that the complainant had advised the company that they would be accompanied by a family member. iNova stated that the complainant had been asked by iNova staff to discuss the matter away from the table, but the complainant had refused to do so.

Code of Conduct Committee decisions
The Committee unanimously determined that the conduct by iNova representatives was not in breach of Sections 9.4, 9.5 or 9.13 of the Code of Conduct.

Consideration of the complaint
The Chair opened the discussion, providing a summary of the complaint. The Chair noted that clearly an unfortunate incident had occurred at this event. The Chair noted that the Committee should be aware that the complaint had been prepared with the assistance of an independent facilitator. Therefore, it reflects the views of the complainant but had not been exclusively prepared by the complainant.

The Committee reviewed the information supplied by both parties. The Committee noted there was dispute between the complainant and iNova concerning whether the company had been advised of the guest's attendance. It was not evident to the Committee whether the complainant, as stated in their complaint, had advised the company that they would be accompanied by a guest or that the guest was a child. iNova denied that it had been informed that a guest would be in attendance. iNova stated in its response to the complaint that it is its global company policy to not allow guests to accompany healthcare professionals to its educational meetings.

The Committee noted that iNova had stated that it had become aware of the attendance of the child when the complainant had brought their child into the educational sessions, and that on that occasion, iNova stated, iNova staff and the conference organiser had informed the complainant that the child could not be permitted to attend the meeting. iNova stated that as there had been no alternative arrangements made for the child, conference organiser staff had supervised the child in the conference secretariat until collected by the complainant.

In regard to the child's attendance at the dinner, iNova had stated in its response to the complaint that the conference organiser had checked that each guest was a registered delegate as they entered the dinner. iNova further stated that another delegate's guest had been excluded from attending the dinner. It was unclear to the Committee how the complainant's child might have gained entry to the dinner.

The Committee noted that the complainant had not provided any evidence, such as copies of correspondence, showing that iNova had been informed that a child guest would be brought to the conference or the conference dinner. The Committee also noted that the material submitted by iNova did state that only delegates could attend, prominently stating: "DINNER IS RESTRICTED TO REGISTERED DELEGATES ONLY".

The Committee noted that Medicines Australia strongly promotes enforcement of the provisions of the Code of Conduct, including the specific prohibition on subsidising or paying for partners, family members or guests to attend educational events. The Committee noted that the complainant had received an invoice for their child's dinner following the event. It was further noted that it was reasonable that an invoice could not have been provided to the complainant immediately, if the company had not expected any delegate's guest to attend the dinner. The Committee accepted that iNova appeared to have sought to resolve the issue.

The Committee agreed that the exchange between the healthcare professional complainant and the company personnel was likely to have been awkward and was most unfortunate. However, whilst unfortunate, the Committee did not consider that the nature of the interchange between the complainant and the conference organiser or iNova staff reached the level of bringing the industry into disrepute.

The Committee unanimously determined that there had been no breach of Sections 9.4, 9.5 or 9.13 of the Code of Conduct.

Sanction
Having found no breach of the Code of Conduct, the Committee did not impose a sanction.

1143 – Apomine Promotional Material

Subject Company:	Pfizer Australia Pty Ltd	**Complainant:**	STADA Pharmaceuticals Australia Pty Ltd	**Product:**	Apomine

Complaint
STADA alleged that an advertising campaign run by Pfizer for the product Apomine was misleading and that the statement central to that campaign "Apomine is back" was inaccurate and misleading. STADA stated that Apomine had been sold in Australia by Hospira, a company that has recently been acquired by Pfizer. The Apomine sold by Pfizer was provided under licence by Britannia, a STADA subsidiary company. In 2016 STADA reacquired the marketing authorisation for the formula of apomorphine sold by Hospira as Apomine, at which time Hospira ceased selling Apomine. STADA then commenced marketing apomorphine under the brand name MOVAPO.

STADA alleged that marketing a new formulation of apomorphine under the brand name Apomine with the tag line "Apomine is back" was misleading because it implied that it is the same product as the apomorphine marketed by Hospira prior to 2016 and manufactured by STADA. Further, STADA asserted that the claim "Apomine is back" misleads the reader to think that the apomorphine formulation marketed as Apomine prior to 2016 had been unavailable, whereas the STADA apomorphine product had never left the market; it had continued to be available with the brand name MOVAPO.

STADA argued that the claim "Apomine is back" had led to significant confusion in the marketplace.

Sections of the Code
The promotional claims were alleged to be in breach of the following Sections of Edition 18 of the Code:
- 1.1 Responsibility
- 1.3 False or Misleading Claims
- 2.1.2 Printed promotional material provided to, or used for discussion with, a Healthcare Professional
- 2.1.3 Mailing of printed promotional material to healthcare professionals.

Response
Pfizer denied that its promotional campaign had breached the Code of Conduct. Specifically, Pfizer contended that the claim "Apomine is back" related only to the use of the brand name and not the

formulation. Pfizer further contended that as apomorphine is available in a number of presentations and brand names, they have the responsibility to correctly inform healthcare professionals of the attributes of the Pfizer branded apomorphine, Apomine.

Pfizer argued that its promotional materials for Apomine were not false or misleading; rather they are current, accurate, correct and balanced and in compliance with the Code of Conduct.

Code of Conduct Committee decisions
The Committee determined by unanimous decision that the claim "Apomine is back" was:

- In breach of Section 1.1
- In breach of Section 1.3
- In breach of Section 2.1.2
- Not in breach of Section 2.1.3

Sanction
The Committee agreed by majority decision this was a minor breach of the Code and imposed the following sanctions:

- Materials using the claim *"Apomine is back"* must be withdrawn from further use and the claim must not to be used again in the same or any similar format
- Pay a fine of $15,000

Consideration of the complaint
The Chair provided a summary of the complaint to the Committee. He suggested that that there were a number of distinctions regarding the use of the terms 'product' and 'brand' that would assist the Committee to consider the complaint and reach a decision on whether the promotional material was in breach of the Code.

Generally speaking, the complainant, STADA, had referred to Apomine as a product, whilst Pfizer, the Subject Company had argued that Apomine was a brand or trademark and not a specific product. The Committee noted that usually a product and a brand or trademark travelled together in the market. However, in this instance the brand name Apomine and the earlier products containing apomorphine manufactured by STADA or its subsidiary Britannia had parted ways.

The Committee reviewed the history of the supply of Apomine in the Australian market. There was some complexity to this history.

It appeared to the Committee that:

1. At least some apomorphine products ("the older apomorphine products") manufactured by STADA/Britannia had been continually available on the market during the period relevant to the complaint, although these had been marketed by different companies with different brand names including both "Apomine" and "MOVAPO"
2. There was a period when no products were marketed or sold under the name "Apomine", but there was no period when the older apomorphine products previously sold under that name were unavailable.
3. The product registration for the older apomorphine products had been reacquired by STADA on the expiry of the licensing agreement between Britannia/STADA and Hospira in 2015
4. In obtaining the licence to the trademark "Apomine" through its acquisition of Hospira, Pfizer had obtained the brand/trademark "Apomine" and goodwill associated with it, and was properly entitled to use the brand/trademark in its marketing.
5. Pfizer had registered a new formulation and product presentation of apomorphine for injection with the brand Apomine ("current Apomine product").
6. The current Apomine product was marketed in 2016/2017 by Pfizer.
7. The current Apomine product is a different formulation and concentration to that previously marketed by Hospira prior to its acquisition by Pfizer. It is different to any of the older apomorphine products.

The Committee also noted that an information service associated with the Apomine brand name had remained in use throughout the period relevant to the complaint, including during the period when no product was available under the Apomine brand.

The Committee considered the meaning of the words "Apomine is back" and their likely interpretation by doctors to whom the material was directed.

The Committee noted that the words “Apomine is back” implied that something had left the marketplace and then returned. On one view, the words referred to a product as distinct from a brand or trademark. On another view, they referred to a brand or trademark as distinct from a brand. The Committee noted that it was the emphatic view of Pfizer that “a pharmaceutical brand name is understood by healthcare professionals to be a company asset that does not necessarily related to a single product presentation”; that is, that the brand name is not consonant with any specific product or product presentation. Thus, it was Pfizer’s position that it was not relevant whether the older apomorphine products had remained available, since it was the “brand” Apomine that was “back”.

While it appeared to be factually correct that no product using the brand name Apomine as a trademark/brand was available in the marketplace for more than a year. However, the Committee accepted that the original formulation of the product apomorphine had not left the market and had been continuously available and that an information service under the Apomine name (the Apomine Nurse Support Service or “ANSSER”) had also been continuously available. The Committee noted that if Apomine were, as Pfizer argued, a brand that was not identifiable with any one specific product, then it could not be said that Apomine (as a brand) had ever left the marketplace as long as the ANSSER remained available.

In the Committee’s view, therefore, neither the products themselves, nor the brand/trademark, had ever left the market. There was neither a product nor a brand that could be “back”, in the sense of having left the marketplace and then returned to it.

Since neither the brand/trademark nor the products had ever left the marketplace, the claim “Apomine is back” had to be regarded as misleading whether “Apomine” was taken to refer to a product or a brand/trademark.

It was on this basis that the Committee agreed unanimously that the promotional material breached section 1.1, 1.3, and 2.1.2 of the Code.

The Committee also noted that whilst there is a distinction between a brand and a product, this would potentially be lost when promotional material is viewed by a doctor. There was, in the Committee’s view, a real risk that the claim “Apomine is back” would convey that a product that had been unavailable had now returned, and that the current Apomine product was identical in formulation to one or several of the older apomorphine products. A doctor who interpreted the claim in this manner could be misled in two ways – firstly, by concluding that all of the older apomorphine products had been unavailable when they had not been, and secondly by concluding that the current Apomine product was identical to the older apomorphine products.

The Committee agreed that the nature of the misleading conduct was relatively minor, but agreed unanimously that the claim was in breach of Section 1.3 of the Code. The Committee further unanimously agreed that it followed that the claim was also in breach of Section 1.1 and the printed promotional materials that included the claim were in breach of Section 2.1.2. The Committee agreed unanimously that there had been no breach of Section 2.1.3 of the Code as promotional materials bearing the claim found in breach had not been distributed by mail.

Appeal
Pfizer asserted that the Code Committee’s decision had involved several errors because it was based on a finding of fact which was wrong, did not form part of the complaint and was not open to the Committee to make on the evidence before it. Further, Pfizer argued that the Code Committee had erred in not finding that the tag line “Apomine™ is back” relates only to the brand/trademark, which had been absent from the marketplace since 2016.

Pfizer also contended that the Code Committee had not given sufficient regard to the limited and specialist audience that the promotional material had been distributed to, and the context in which they received it. Pfizer argued that in the overall context in which the specialist healthcare professionals had received the promotional material subject to complaint, there was no possibility that the healthcare professionals would have been misled.

Appeal Response
STADA rejected Pfizer’s arguments in its appeal submission and reasserted that the claim “Apomine™ is back” was misleading and had caused confusion in the market.

STADA acknowledged that the parting of intellectual property and product is not common practice. However, STADA maintained that it had evidence to show that the Apomine™ brand/trademark did not leave the marketplace in 2016.

Appeals Committee decision
The Appeals Committee was persuaded that the decisions of the Code of Conduct Committee in relation to the complaint had involved some errors and therefore unanimously determined that the decision be set aside. The Appeals Committee upheld the appeal by Pfizer and determined that the claim "Apomine™ is back" was not in breach of the Code.

Sanction
The Appeals Committee unanimously determined to remove all sanctions imposed by the Code of Conduct Committee and refund in full the bond paid by Pfizer.

Consideration of the Appeal
The Chairman explained the process for consideration of an appeal. The Appeals Committee must be persuaded that the findings of the Code of Conduct Committee (Code Committee) involved an error on the basis of which the decisions of the Code Committee should be set aside or varied.

The Chairman invited Pfizer to give their appeal presentation. The following summarises that presentation and discussion with the Appeals Committee.

Pfizer stated that it takes its obligations as a Medicines Australia member very seriously and, although the Code Committee determined that the claim in question was a minor breach of the Code, Pfizer doesn't want any breach to be found in relation to its conduct, especially where it does not believe a finding of breach was justified as in this case.

Pfizer stated that the decisions of the Code Committee in finding breaches of the Code resulted from one procedural error, along with a number of instances where the Code Committee had misunderstood the submitted materials. These errors had led the Code Committee to find that the claim was in breach. Pfizer intended to describe to the Appeals Committee the context in which the healthcare professionals had received the promotional material in order to show that original decision should be set aside. Pfizer strongly believed that the allegations brought by STADA have not been supported by the documentation provided to the Appeals Committee and were based primarily on hearsay.

Pfizer agreed with the Code Committee's interpretation that the statement "Apomine™ is back" is a claim, which was intended to communicate that the brand Apomine™ had been off the market and had come back. Pfizer noted that in the Reasons for Decision of the Code Committee the trademark symbol had been omitted, whereas the claim clearly refers to the trademark or brand "Apomine™". Pfizer noted that whilst products containing the active ingredient apomorphine, supplied by STADA, had continued to be available, there was a distinct period of 9 calendar months in 2016 where the brand Apomine™ was not present in the marketplace.

Pfizer contended that the use of the words "New Apomine™ Solution for Infusion" within the centre pages of the promotional piece would lead readers to understand that the product being advertised by Pfizer is a new formulation. This is reinforced by the different Australian Approved Name of apomorphine hydrochloride hemihydrate, which is the active pharmaceutical ingredient in a newly registered formulation that no longer requires reconstitution before administration and is in a pre-filled vial that does not require syringes and needles to be prepared for self-administration. Given this is a new formulation and a newly registered product, Pfizer asserted that it would not want to imply that its new product is the same as or replaces Britannia/STADA's product.

Pfizer then described the audience who had received the material. Pfizer stated that the promotional materials were given to 97 specialist neurologists and nurses during face-to-face meetings. These specialists were those who had a specific interest in movement disorders including Parkinson's Disease and who are authorised to prescribe apomorphine. The Chairman queried the allegation from STADA that patients had been misled by the materials and potentially were at risk of confusion. Pfizer responded that the promotional materials were solely for healthcare professionals (specialist doctors or their nurse assistants). Pfizer had been careful not so share any information outside the specialist audience. In addition, the promotional material should be considered in the context of letters sent to healthcare professionals by both Hospira (now part of Pfizer) and STADA in January 2016 notifying them of the change of sponsorship of apomorphine formulation (whose active pharmaceutical ingredient is apomorphine hydrochloride) and the delisting from the PBS of the Apomine™ brand, and notification sent to these healthcare professionals in early 2017 informing them that Pfizer was re-entering the market with a new formulation, a solution for infusion.

Pfizer responded to a question from a Committee member in relation to the ANSSER program. Pfizer stated that one of the Code Committee's prime concerns, which led it to find a breach of the Code, was the continued availability of the ANSSER service. Pfizer understood that the Code Committee had made its decision on the basis of a leave behind provided by STADA in its complaint, which referred to the ANSSER

service as the “Apomine™ Nurse Support Service”. Pfizer noted that the preparation date printed on that leave behind was January 2017. During the time that Apomine™ was not available in the market, Pfizer had maintained the ANSSER service, but had removed all references to Apomine™ from the materials and from the name of the service. The acronym was used as a word “ANSSER”. Pfizer considered that it would have been irresponsible for it to cease the program simply because Apomine™ was not available during most of 2016. Pfizer argued that the Committee’s reliance on the fact that the ANSSER program had been continuously available as indicating that the Apomine™ brand had not left the marketplace in 2016 was in error. Further the Code Committee had erred because it had relied on evidence that had not been part of STADA’s complaint. Pfizer had not had any opportunity to respond to this misunderstanding that had led the Code Committee to the finding of breach.

Pfizer presented a timeline that detailed the history of Apomine™ availability in Australia, and the marketing arrangements related to its supply. This timeline showed that there had been no Apomine™ branded apomorphine product on the market between April and November 2016.

The Appeals Committee asked what would have happened during the absence of Apomine™ from market if a healthcare professional had written a script for it. Pfizer responded that it understood that a pharmacist would have provided the patient with MOVAPO™. The Appeals Committee also asked Pfizer whether any compassionate supply of Apomine™ product had occurred during this period. Pfizer confirmed that the only supply by it during this time was the maintenance of the ANSSER service and the provision of consumable products associated with the treatment of the condition. The Appeals Committee asked whether there were had been any complaints, adverse events or any reports of confusion during that time. Pfizer confirmed that it had not received a single complaint or report of an adverse event during that time.

An Appeals Committee member questioned Pfizer about confidence in the brand Apomine™, in consideration that the brand now being promoted and supplied has little resemblance to the original product and whether Pfizer was overstating the value of the brand. Pfizer responded that many products in the marketplace have changed ownership over time, through company mergers and acquisitions or through changed marketing arrangements. The continuity of a brand/trademark such as Apomine™ through merger and acquisition processes and changed licensing arrangements does have value through the recognition of a product that is known and trusted. Pfizer also noted that during the lifecycle of any product there may be changes of manufacturer or sponsor company, but the inherent value in the brand continues throughout.

Pfizer concluded its presentation by noting it considered that STADA’s complaint lacked merit and should be dismissed. Pfizer asserted to the Appeals Committee that it is not sensible to suggest the claim “Apomine™ is back” in the context of the promotional material could have been understood by prescribers to mean anything other than Apomine™ branded apomorphine, now in an entirely new presentation, was again available in Australia.

The Chairman thanked the Pfizer representatives for their presentation and invited the STADA representatives to make their presentation to the Appeals Committee.

STADA opened its presentation stating that it considered that the Code Committee had made the correct decisions. Because neither the brand/trademark or the products had left the marketplace, the claim “Apomine™ is back” had to be regarded as misleading whether “Apomine™” was taken to refer to a product or a brand/trademark. Further, STADA agreed with the Code Committee’s understanding that it was unusual that the brand name and product had parted ways and that the new Apomine™ formulation is not the same as the old product. Therefore, STADA felt strongly that it was important that communications to healthcare professionals were not crafted to deceive or mislead them.

STADA noted that the discussion had only focussed on 2 mL and 5 mL ampoule formulations of apomorphine, marketed as Apomine™, which were transferred to STADA in February 2016 at the end of the marketing agreement between the companies. STADA advised the Appeals Committee that a 1 mL ampoule of apomorphine marketed as Apomine™ was also produced by Pfizer, which was not part of the marketing agreement with STADA. This 1 mL ampoule formulation was relisted on the PBS in 2015 by Pfizer. STADA noted it had evidence to hand that showed that 1 mL ampoules of Apomine™ were dispensed during the period in 2016 in which Pfizer contends there was no Apomine™ in the marketplace.

The Chairman asked whether this evidence had been submitted to the Appeals Committee prior to the meeting. STADA responded that it formed part of the presentation and accompanying materials it intended to present at the hearing. The Chairman reminded STADA of companies’ obligations under the Code of Conduct. Any new evidence must be submitted in accordance with the timelines set out in the Code and stated in correspondence from Medicines Australia. The appeals process under the Medicines Australia Code of Conduct is designed to provide procedural fairness to all parties. All evidence to support an appeal or response to an appeal needs to be submitted in advance to allow the Appeals Committee and both

parties to review it before attending the hearing. The purpose of the presentations at the hearing is for the parties to an appeal to present key facts to the Appeals Committee and provide clarification of the materials previously submitted. Any materials received by Medicines Australia outside those specified timelines cannot be accepted or considered by the Appeals Committee.

The Chairman queried the Pfizer representatives whether they were in a position to comment on the new allegation that the 1 mL Apomine™ ampoule had been supplied or available during the time in question. The Pfizer representatives acknowledged that the registration for the product had been maintained on the ARTG, however it had not been produced since 2008 and therefore could not have been supplied in 2016. The Chairman thanked Pfizer for the information and noted that without additional evidence to the contrary, the Appeals Committee should take that advice at face value and the line of enquiry should not be pursued any further.

STADA contested Pfizer's assertion that the ANSSER service was de-linked from the brand name Apomine™ satisfactorily, because for years the program had been recognised as the Apomine™ support service; nor was this change in name properly communicated. STADA further argued that it had evidence that leave behinds containing the brand name Apomine™ had not been actively removed from the market and were still available to healthcare professionals at the time. In addition, a product catalogue listing Apomine™ had been continuously available on Pfizer's website. Again, the Chairman questioned this argument and whether any evidence had been submitted to the Committee or available to Pfizer to respond to in advance of the meeting. STADA advised that it was available to be tabled. The Chairman therefore declined to consider the argument or evidence as it had not been provided in advance in accordance with the timelines for submissions set out in the Code.

STADA asserted that the Code Committee did not make an error in failing to make a distinction between the product name with or without the trademark symbol. STADA argued that the use of ™ or ® symbol is not required to designate a trademark. Further, STADA asserted that it was unreasonable to expect that any target audience will make a distinction between Apomine and Apomine™, or even understand such a distinction, when considering the claim in the promotional materials. Finally, STADA noted that the trademark for Apomine™ has not lapsed since it was registered in1997, and was renewed in September 2015. STADA argued that this further supported its position that Apomine™ had not left the market and therefore it was misleading to claim that it "was back".

STADA then turned to discuss the audience for the promotional material. It noted that regardless of the highly specialised nature of the individual, the audience in total could be varied in their experience and could easily misinterpret the materials. STADA noted that several of its team members had spent considerable time engaging with healthcare professionals during 2016 and had encountered confusion. Many healthcare professionals reported that they believed they were prescribing the same product as they had previously, even though it was in a new formulation. This in turn leads to confusion amongst the patient population. The Chairman queried how such confusion could occur, given that the materials were directed at healthcare professionals. STADA advised that when a healthcare professional prescribed new Apomine™, believing that it is the same formulation as the original product, the patient could be dispensed a product that does not match their current consumables used to administer the product. The consumables include an infusion pump, syringe, connectors and other materials to assist the patient in self-administering the product. STADA noted there is an obvious difference between the products (ampoules vs vials), but there is still the possibility that the patient may not notice and possibly experience an adverse event if they incorrectly administer or skip their treatment.

The Chairman asked STADA what they believed the term "formulation" encompasses. STADA responded that according to the ARTG listing, the formulation of the product is what is approved for use in the Australian market and registered. This includes the primary packaging but not the outer packaging and labelling. The Chairman questioned whether a change from ampoule to vial required a new registration, to which STADA responded that this is a legal requirement.

STADA concluded its presentation reasserting that it did not believe that the Code Committee had erred in making its decision and Pfizer had not provided sufficient evidence to show any error by the Code Committee.

The Chairman thanked the STADA representatives for their presentation an asked Pfizer to give its short response.

Pfizer disputed STADA's assertion that the materials were part of a sustained campaign and noted that the leave behind containing the claim subject to complaint was only in use for 3 months when the product was relaunched in early 2017. Pfizer noted that all ANSSER materials had been carefully rebranded during the absence of Apomine™ from the market and that the withdrawal of the nurse service program itself would

have been inappropriate. Pfizer consciously had stopped supplying Apomine™, and ceased all promotional activities, but as Parkinson's disease is ongoing Pfizer felt it was responsible to continue providing support to patients.

Pfizer declined to respond to evidence that had not been submitted to the Appeals Committee or that it had the opportunity for review. Pfizer asserted that Apomine™ had not been on the market, meaning not promoted or sold in the Australian market, for nine months in 2016. The appearance of a small number of dispensed units from PBS data could possibly be the result of patients receiving a number of months' supply, delayed delivery of product, or delayed processing of PBS data.

Pfizer noted STADA's main argument is that Pfizer is trying to claim that Apomine™ is the same as the old formulation. Pfizer contended that it was actually trying to do the opposite, because Pfizer's new Apomine™ formulation is superior to the old one in terms of convenience, safety and ease of use. With regard to alleged confusion by patients, who are not the audience for the promotional material subject to complaint, this argument is not relevant to the complaint. There is no evidence of confusion by healthcare professionals; STADA is solely relying on hearsay.

Pfizer acknowledged that the Movapro™ and Apomine™ products are different formulations. Therefore, it is usual for pharmacists and nurses to ask which consumables patients require in order to supply the correct ones.

This concluded the presentations and both parties were then excused from the hearing to allow the Appeals Committee to deliberate on the appeal.

The Appeals Committee discussed the concerns raised by Pfizer that the Code Committee's decisions were based on an error of interpretation of the use of the Apomine™ brand/trademark in association with the ANSSER service and didn't take into account the use of the ™ symbol in association with the claim. The Appeals Committee reviewed the reasons for decision of that Code Committee and acknowledged that the ™ symbol was not used in that document. The Appeals Committee agreed that the symbol is relevant and necessary to clarify that it refers to the brand name.

The Appeals Committee determined that the Code Committee's conclusion that the Apomine™ brand name had not been absent from the market for a period of nine months in 2016 was in error. The Appeals Committee understood that an information service under the name "ANSSER" had been continuously available, but for at least nine months it existed without reference to the Apomine™ brand/trademark. By not recognising that the ANSSER flyer, which included the Apomine™ brand/trademark, was only produced in January 2017 after the new Apomine™ vials for infusion came onto the market, containing a different active pharmaceutical ingredient, apomorphine hydrochloride hemihydrate, the Code Committee was in error, which led the Committee to find that the claim "Apomine™ is back" in breach of the Code.

The Appeals Committee agreed with the evidence supplied that products branded Apomine™ were in fact absent from the marketplace for a period of 9 months in 2016 and therefore it was not misleading for Pfizer to use the claim "Apomine™ is back". The Appeals Committee accepted that Pfizer and STADA had informed the relevant specialist neurologist prescribers of the change of sponsor and brand name to MOVAPRO™ in January 2016. Further, the promotional materials for the Apomine™ solution for infusion are clear that this is a 'new' formulation and presentation.

While the Appeals Committee was of the view that the history of the product itself was complicated and complex and could lead to confusion, any confusion which may have resulted from the leave behind rose no higher than the confusion that was already in existence in the marketplace and did not amount to false and misleading conduct.

The facts of this case were very singular, and the conclusion that has been arrived at and the facts it was based on should be used with caution in interpretation or application to other cases. The Appeals Committee also noted that the Code Committee had concluded that although it had found the material to be in breach of the Code, it would have no impact on prescribing or have safety implications. The Appeals Committee agreed with this assessment.

The Appeals Committee agreed unanimously to uphold the appeal by Pfizer and overturned the decisions made by the Code Committee in finding breaches of Sections 1.1, 1.3 and 2.1.2 of the Code of Conduct. The Appeals Committee further found by unanimous decision that the sanction to withdraw the material containing the claim "Apomine™ is back" from further use should be removed and removed the fine of $15,000.

The Appeals Committee unanimously agreed that as the appeal had been upheld, the $20,000 bond paid by Pfizer should be returned in full.

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.

Monitoring Committee Report

The aims of the Monitoring Committee are to encourage compliance with the Code, provide advice on compliance where necessary, obtain and publish statistical data on the degree of compliance and to provide an ongoing mechanism for the identification of potential future amendments to the Code.

The Monitoring Committee may review materials across a range of therapeutic areas and types of activities. If the Committee has concerns about an activity or material, or wishes to seek further information, Committee members must direct the Secretariat to write to the company identifying the issues of concern and what additional information should be provided to the Committee. After the review of this additional information, if the Committee still has significant concerns, a formal complaint may be lodged with the Code Committee for a determination. The Monitoring Committee cannot find a company in breach of the Code.

In each financial year the Monitoring Committee reviews at least three types of promotional material (for example advertisements and printed promotional material) across three different therapeutic classes (for example alimentary system, eye and contraceptive agents); and three different types of conduct covered by the Code across all therapeutic classes (for example websites, media releases and starter packs). This is in addition to the Committee's review of educational event reports.

Therapeutic Class	Types of material or activity subject to review	Number of companies	Number of items	Number of meetings to undertake review
Central Nervous System	Advertisements, Printed Promotional Material and E-Ads	9	69	1
N/A	Hospitality Procedures	15	15	1
All therapeutic classes	Patient Education Materials	18	88	2
Skin	Journal Advertisements	1	1	1
N/A	CEP Procedures	32	32	2
All therapeutic classes	Media Releases to the general public	6	7	1
TOTAL		**72**	**143**	**7**

Referrals to the Code of Conduct Committee

The Monitoring Committee may refer any material or activity to the Code of Conduct Committee for review if it considers there is a potential breach of the Code of Conduct. From its reviews of materials and activities, the Monitoring Committee did not refer any materials or activities to the Code of Conduct Committee for adjudication in 2017-2018.