Medicines Australia Code of Conduct Quarterly Report July - September 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 July and September 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/

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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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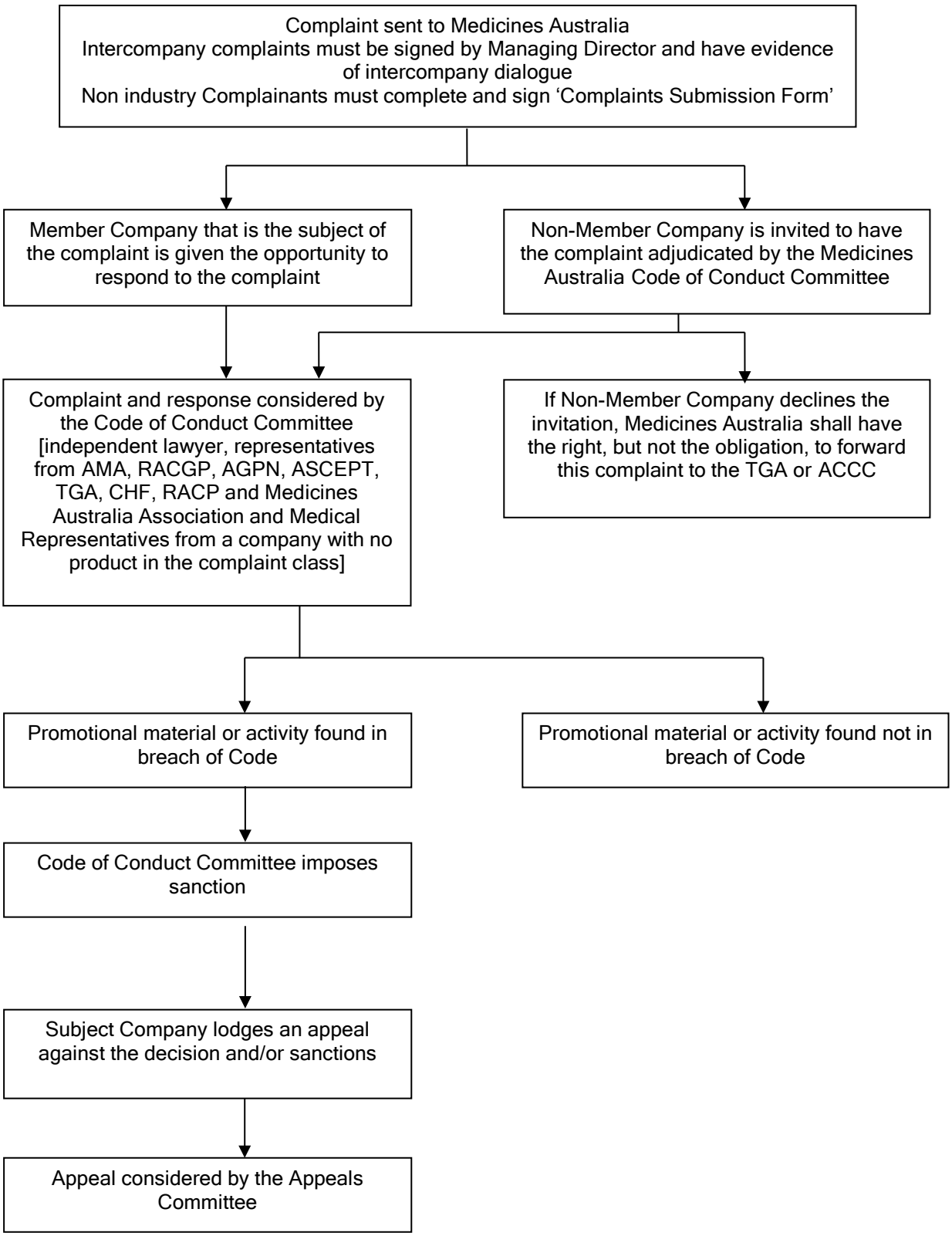
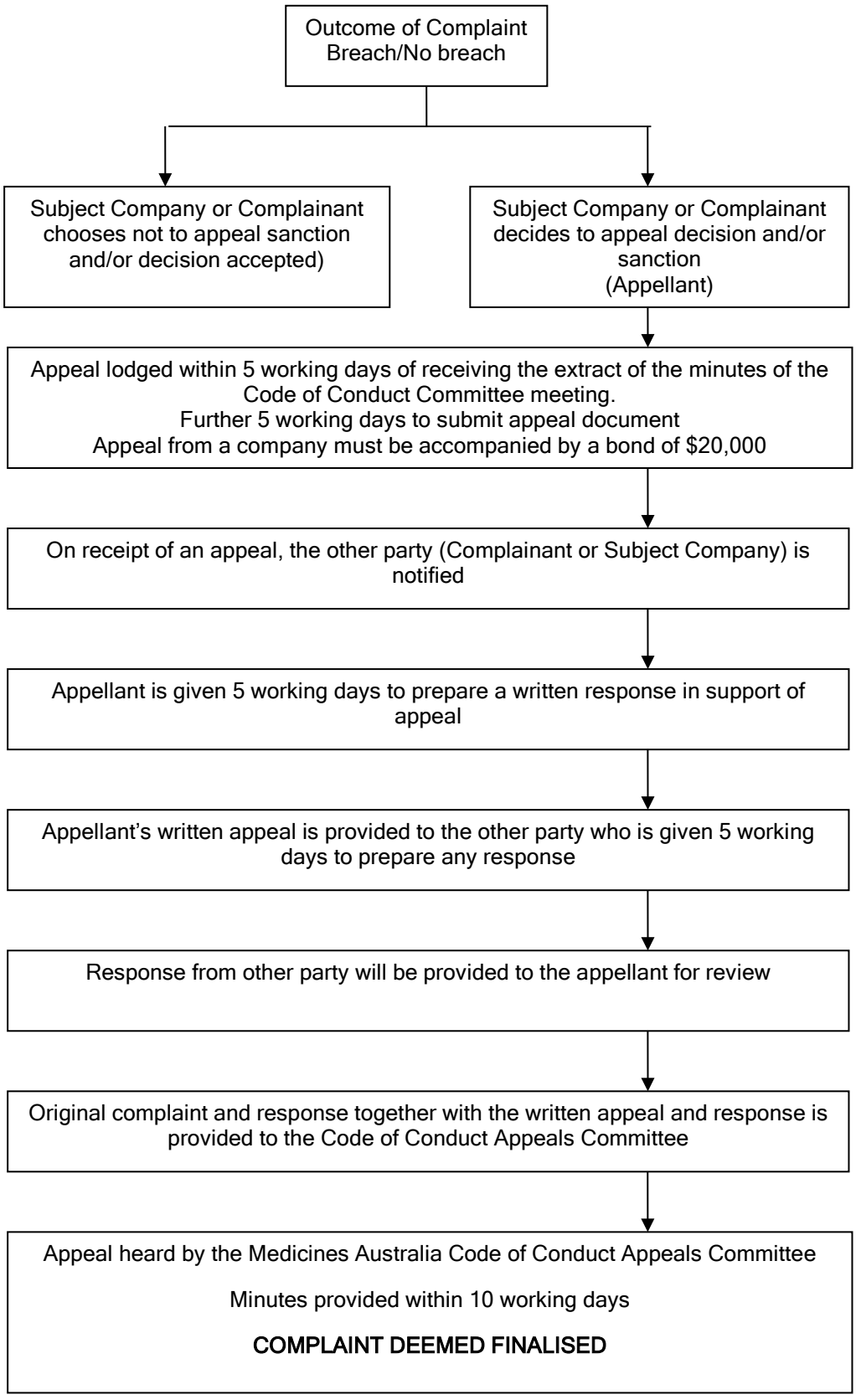
Medicines Australia Code of Conduct Complaints Handling Process



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 July – September 2017

No.	Subject Company	Material or Activity	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	n/a

1142 – iNova – Staff Conduct

Subject Company: iNova Pharmaceuticals (Australia) Pty Limited

Complainant: Healthcare Professional

Product: N/A

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 subject to Appeal

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 believes 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.