Medicines Australia Code of Conduct Quarterly Report October - December 2020

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 19 (effective 30 March 2020).

This report covers all complaints finalised between October to December 2020. Complaints finalised during this period were in relation to materials or activities conducted under both Edition 18 and Edition 19 of the Code.

The decisions of the Code of Conduct and Appeals Committees are relevant to the date of publication of the materials subject to complaint and approved Product Information (PI) at that time.

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

How to contact Medicines Australia

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How do I obtain a copy of the Code?

Copies of Edition 19 of the Code are available on the Medicines Australia website (http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/)

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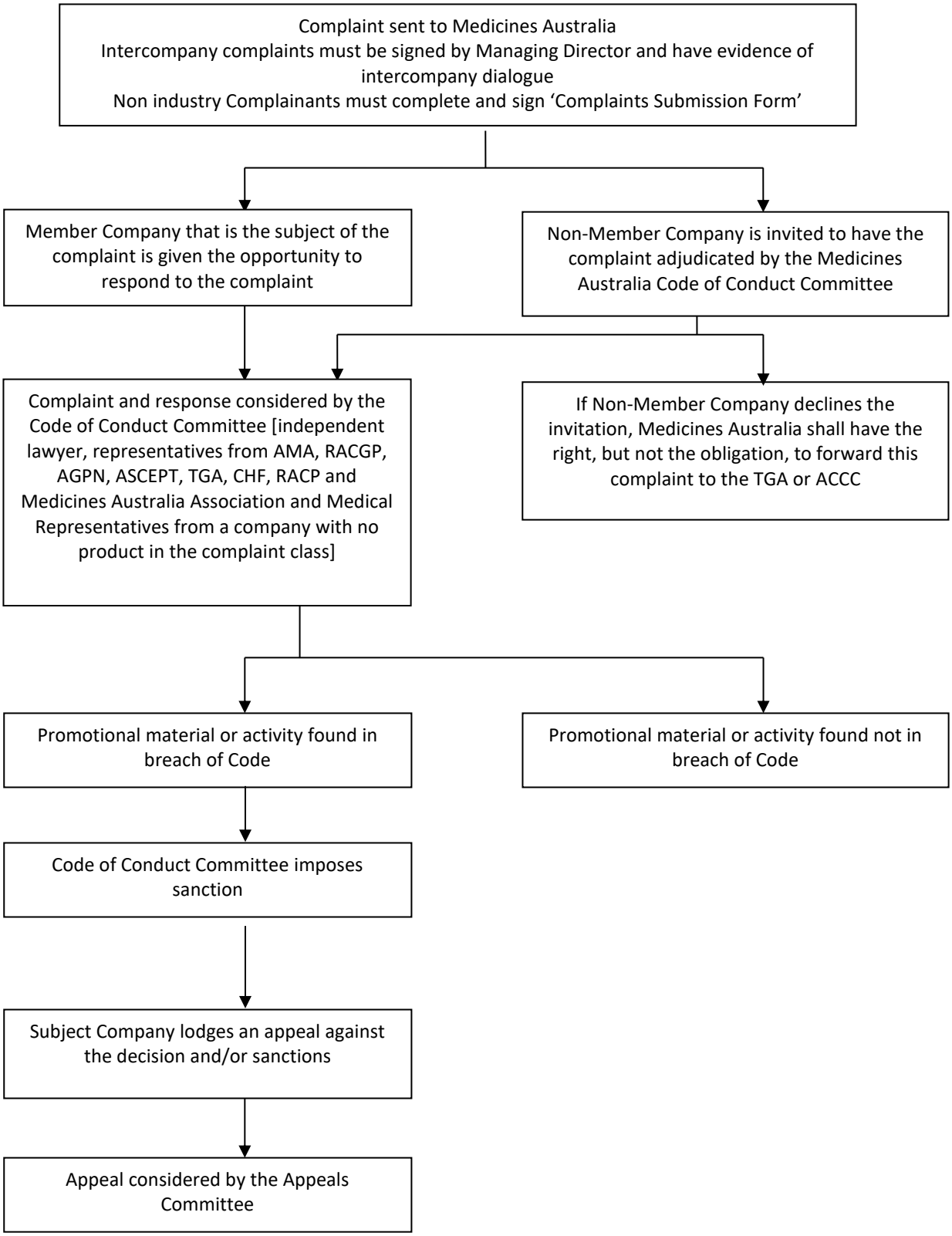
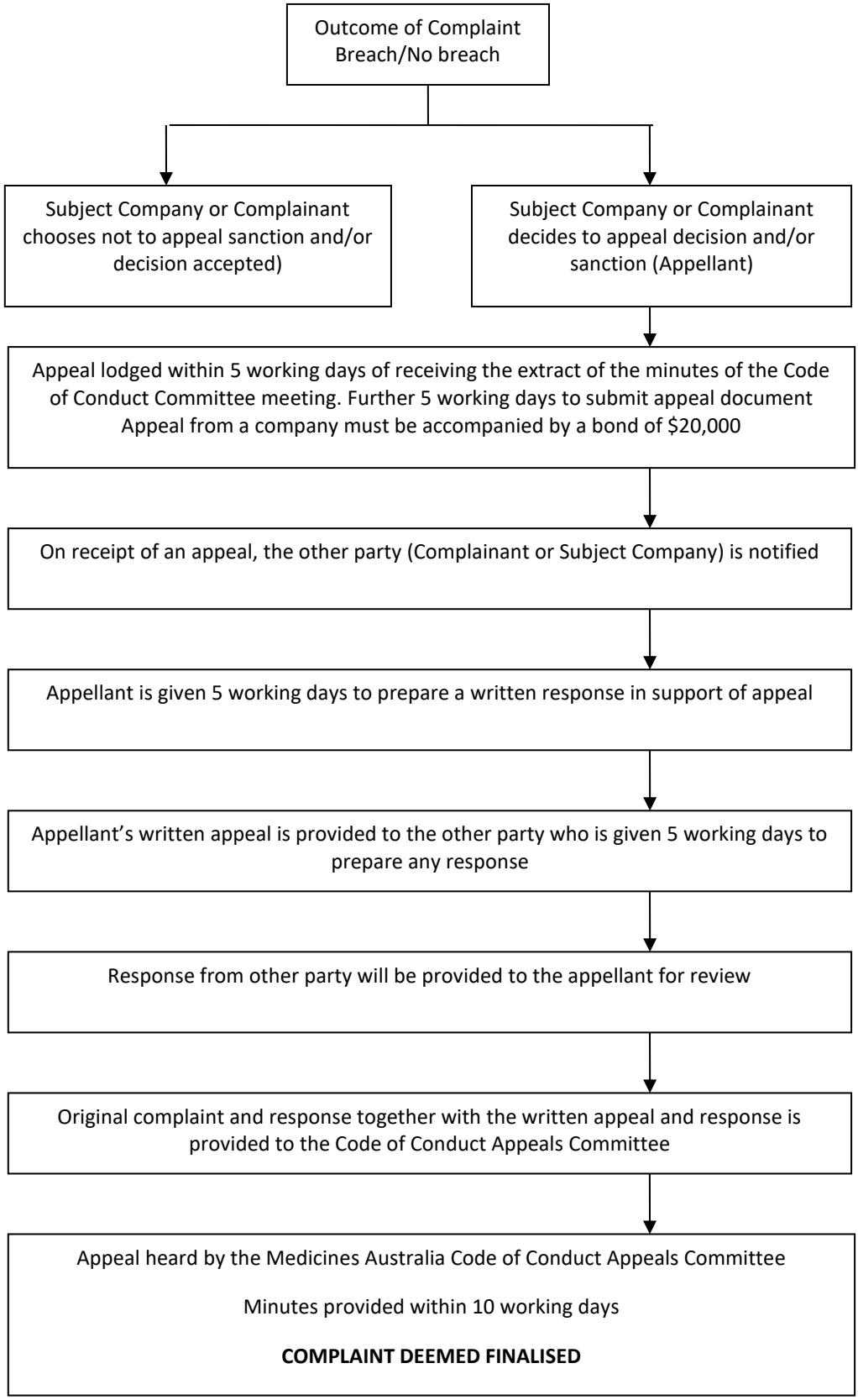
Medicines Australia Code of Conduct Complaints Handling Process



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.

Code of Conduct Committee

Full Members (Voting rights)

- Independent Lawyer (Chairman) selected from a panel of lawyers with competition law experience

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

Sanction	Description
Cessation of conduct and withdrawal	The Subject Company is required to take immediate action to discontinue or modify any conduct which is determined to constitute a breach of the Code, including the cessation and withdrawal of any promotional activity. Written notification of this action must be provided to Medicines Australia within five (5) working days of receipt of the reasons for the decision(s) of the Code Committee.
Corrective action	The Code Committee may require retraction statements, including corrective letters and advertising, to be issued by the Subject Company. The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements must be approved by the Committee or its delegates prior to release. Corrective statements will, in general, specifically correct the statement found in breach of the Code and be in the form prescribed by the Committee. No other material may accompany such statements unless the inclusion of such material has been approved by the Code Committee or its delegates. Any corrective action required by the Code Committee must be completed within 30 calendar days of the receipt of the decision(s) and the reasons for the decision(s) of the Code Committee meeting by the Subject Company (subject to any appeal that may be lodged under this Code). A Subject Company is required to provide a statement to the effect that the action has been undertaken together with a copy of the published advertisement or a copy of the final version of a corrective letter, signed by the Subject Company Managing Director or Medical Director.
Monetary fine	The Code Committee may impose a monetary fine on the Subject Company in accordance with the schedule of fines below.

Breach	Maximum Fine
Minor: • no safety implications to patient wellbeing; and • no major effect on how the medical profession will prescribe the product	$100,000
Moderate: • no safety implications to patient wellbeing; but • may have an effect on how the medical profession will prescribe the product	$150,000
Severe: • has safety implications to patient wellbeing; and/or • a major effect on how the medical profession will prescribe the product; and/or • activity that has brought discredit to upon or reduce confidence in the pharmaceutical industry Where a severe breach has been found, but there is no opportunity for corrective action	$200,000 $250,000
Repeat of Previous Breach	$250,000
Failure to complete corrective action in 30 calendar days	$50,000
Failure to pay a fine in 30 calendar days	$50,000
Abuse of the Code	$200,000

Complaint outcomes

Jardiance Promotional Material			
	Subject Company	**Product**	**Complainant**
1159	Boehringer Ingelheim/Eli Lilly Australia Alliance (The Alliance)	Jardiance (empagliflozin)	AstraZeneca (AZ)
Complaint	AstraZeneca alleged that promotional material for Jardiance (empagliflozin), being a presentation entitled "Swim Between the Flags: 5 Steps for Saving Lives in T2D" (Presentation) distorts the balance and accuracy of underlying evidence for the product, and claim a level of superiority that is not supported. The Presentation was presented to a large number of HCPs at multiple meetings.		
Sections of the Code *Heard under Edition 18*	• 1.1 Responsibility • 1.2.2 Level of Substantiating Data • 1.3 False or Misleading Claims • 1.4 Unapproved Products or Indications • 1.8 Comparative Statements • 9.1 HCP General Principles • 9.4.1 Educational Content		
Response to the Complaint	The Alliance believed that the educational program, including the Presentation, meets all standards of the Code. The Alliance contended that the educational program was developed by an expert steering committee, for an Australian Primary Healthcare audience, delivered by medical experts in a live setting that allowed for full explanation and dialogue. The Alliance also contended that intercompany dialogue requirements were not met by AstraZeneca and sought deferral until further attempts at resolution have been explored.		
Code of Conduct Committee Decisions	The Committee agreed by unanimous decision that the Presentation was, when considered in its entirety, misleading and in breach of Sections 1.1 and 1.3 of the Code of Conduct. In respect of the specific allegations made by AZ, the Committee determined as follows: • Complaint A – no breach of Sections 1.1 and 1.3, by unanimous decision. • Complaint B – breach of Sections 1.1, 1.2.2, and 1.3, by majority decision. • Complaint C – breach of Sections 1.1, 1.2.2, 1.3 and 1.4, by majority decision. • Complaint D – breach of Sections 1.1, 1.2.2, 1.3 and 1.8, by majority decision. • Complaint E – breach of Sections 1.1, 1.3, and 1.8, by unanimous decision. • Complaint F – no breach of Sections 1.1, 1.3, and 1.4, by unanimous decision. • Sections 9.1 and 9.4.1, no breach of the Code by unanimous decision		
Sanctions	The Committee agreed by majority decision that the overall conduct was a moderate breach of the Code, and imposed the following sanctions: • Withdraw the Presentation, cease its use in the same or similar context; • Issue a corrective letter to all healthcare professionals who attended or received the Presentation, with the template provided by Medicines Australia and approved by the Committee; and • Pay a $150,000 fine.		

Consideration of the complaint

The Presentation in issue was a multimedia PowerPoint slide presentation, which included embedded video excerpts from a healthcare professional. The Presentation was displayed at approximately 14 meetings with HCPs during 2019. The Committee considered six separate issues raised by AZ, and also the Presentation as a whole.

Intercompany Dialogue

In its complaint, the Alliance alleged that they were denied due process by AZ failing to comply with intercompany dialogue requirements. The Alliance submitted that AZ did not observe the requirement for active involvement of the most senior executive officer of the company in the complaint. The Committee discussed this allegation and agreed that the minutes from the intercompany dialogue contained in the complaint materials noted a number of apparently senior officers present in the dialogue. It was the Committee's view that there was sufficient evidence that intercompany dialogue was undertaken with purpose and commitment. The Committee agreed that the actions taken during intercompany dialogue satisfied the requirements and were sufficient for the Committee to proceed in hearing the matter.

Complaint A: Jardiance is inappropriately promoted as first line treatment or the only treatment for T2D patients

AZ alleged that the Presentation, when taken as a whole, could mislead the audience to believe that Jardiance should be the first line treatment; or should be considered as the first additional treatment or the only appropriate additional treatment for Type 2 Diabetes (T2D) patients for whom metformin or glucose-lowering medicinal products including insulin, do not provide glycaemic control.

The Committee agreed that Jardiance is indicated for use in people with T2D and established cardiovascular disease, and at the time the Presentation was used, was the only oral drug in the class with that indication for established cardiovascular disease. The Presentation clearly articulates treatment with metformin and lifestyle measures as first line measures. The Committee agreed that the Presentation does not disregard the need for metformin or lifestyle changes, nor does it neglect other therapeutic reasons for selecting metformin or other treatment options. The Committee noted, however, that use of the joint Consensus Report for the Management of Hyperglycaemia in T2D (Consensus Report) study chart that compares NNT trivialises the data from the 4S and HOPE trials as presented in the report. The Committee agreed that this was not sufficient to rise to the level of breach.

The Committee agreed unanimously that there was no breach of Sections 1.1 and 1.3 of Edition 18 of the Code.

Complaint B: The suggestion that HCPs may be endangering lives by not choosing Jardiance is unbalanced and misleading

AZ contended that the Presentation creates the impression to HCPs that the lives of the T2D patients may be at risk if they choose not to prescribe Jardiance. The Committee reviewed the Presentation and constituent video content and agreed that the video content imparted disingenuous information that implied that all T2D patients would be better treated with Jardiance (see in particular Slide 17 and embedded video when taken in the context of the whole Presentation). The Committee agreed that the Presentation provided biased information that does not balance all treatment options in the class.

The Committee discussed the Presentation title "Swim Between the Flags: 5 Steps to Saving Lives in T2D", and specifically addressed concerns that it evoked notions of heightened risk. The Committee noted that 'swimming between the flags' is often equated with safety but did not believe that the title created any such link. The Committee agreed that the content of the Consensus Report is complex, and that distilling the information into a simple five-step plan is easier to digest for the audience. That said, the Committee agreed with AZ in that this Presentation oversimplified the Consensus Report findings leaving the audience with no opportunity to compare the data sufficiently.

The Committee noted that the statements made by the HCP expert, such as *"I would not be saying should I put the patient on Jardiance, I would be saying why wouldn't I?"*, are misleading and propose that not prescribing Jardiance puts patient lives in danger.

The Committee agreed that while Jardiance is indicated for T2D patients with cardiovascular disease (ASCVD), the Presentation does not give sufficient weight to other factors in the Consensus Report. The Committee agreed by majority decision that this was in breach of Sections 1.1, 1.2.2, and 1.3 of Edition 18 of the Code.

Complaint C: Jardiance is promoted as a cardiovascular (CV) drug which is not consistent with its approved indications and is misleading

The complaint alleged that the Presentation gives an overall impression to the audience that Jardiance is a CV drug that may also be used for glycaemic control. In reviewing the Presentation, the Committee noted a number of slides that clearly set the focus of the presentation on the treatment of ASCVD, and specifically noted statements made by the HCP expert that Jardiance *"…was a cardiology drug that had the added benefit of reducing HbA1c"*.

The Committee noted that there were several sections within the Presentation that aligned the messaging with the approved indication in the Product Information – that Jardiance is approved for treatment of T2D, with ASCVD benefits. However, the Committee was persuaded that the statements made by the HCP Expert promote Jardiance beyond its registered indication.

The Committee discussed Slide 24 which compared Jardiance EMPA-REG OUTCOME trial against previous trails relating to cardiovascular drugs, namely the 4S and HOPE trials. The Committee noted that while the 4S and HOPE trial data were academically interesting, the context and populations used in those trials were not the same as those in the EMPA-REG OUTCOME trial and the comparison of the trials was therefore not balanced and accurate. Further, the Committee noted that the study design information was lacking from the slide. The Committee also agreed that the slides cherry-picked favourable data and implied the results to be typical. While the Alliance defended its use of the trials noting they had previously been compared in other publications, the Committee was not persuaded that it was in the spirit of the Code to be making such comparisons for promotional purposes, in the context in which they were made in the Presentation.

The Committee agreed that the Presentation is describing Jardiance as a CVD drug, and although it has a limited CVD indication, considered that this is not suitably expressed.

The Committee agreed by majority that there was a breach of Sections 1.1, 1.2.2, 1.3, and 1.4 of Edition 18 of the Code.

Complaint D: Comparison of EMPA-REG OUTCOME trial with 4S and HOPE trials is not balanced or appropriate, and is likely to mislead

The Committee noted that there was a significant amount of overlap between the complaints, and this issue was substantively addressed in Complaint C above. The Committee reiterated its determination that the utilisation of the trial data in the Presentation did not adequately address changes in age and patient population between trials, nor does it provide clarity on study design. The Presentation represents these trials as being sequential, and therefore comparable, when they are not. The Committee agreed, however, that the comparison between the trials is academically interesting and if presented appropriately would be informative to the audience.

The Committee addressed the use of the subheading *"Jardiance as the new standard of care – why?"* and agreed by majority that it was an unqualified superlative which would further influence the audience's opinion.

The Committee agreed by majority that there was a breach of Sections 1.1, 1.2.2, 1.3 and 1.8 of Edition 18 of the Code.

Complaint E: Comparison of the EMPA-REG OUTCOME and DECLARE TIMI 58 trials is inappropriate and misleading.

The Committee reviewed Slide 26 of the Presentation which details 'CV death outcomes from SGLT2 Inhibitor CVOTs' and included a comparison between the EMPA-REG OUTCOME and DECLARE TIMI 58 trials. The Committee noted that as with the previous comparative information, the slide did not include sufficient information about the study design such as baseline characteristics and patient demographics. This is compounded by the additional video content which included statements that the data in question (set out in a graph on the slide) was not intended for comparison, before then proceeding directly to compare the data with reference to the graph.

The Committee agreed that the content of this slide relied on qualifying statements which were small and difficult to read on a slide, and that the commentary of the expert in the video infers that choosing not to prescribe Jardiance will lead to patient death. The Committee agreed that the comparison misrepresented the data in both the EMPA-REG OUTCOME and DECLARE TIMI 58 trials, and that this comparison was disparaging to other products in the therapeutic class.

The Committee agreed by unanimous decision that there was a breach of Sections 1.1, 1.3, and 1.8 of Edition 18 of the Code.

Complaint F: Jardiance is promoted for unapproved indications

AZ alleged that the Presentation represented that Jardiance is indicated for uses which are not approved (including myocardial infarction and stroke) and that the Presentation omits the distinction in the Product Information between use of Jardiance as monotherapy and combination therapy.

The Committee considered that the Product Information does establish a limited indication for patients with T2D mellitus and established CVD, to reduce the risk of cardiac death versus placebo. The Committee considered that the Presentation did not promote Jardiance as a monotherapy for the prevention of CV death, when viewed as a whole. Relevantly, the Presentation articulates Jardiance's role in treatment being subsequent to metformin and lifestyle changes. To the extent that the Committee considered comments by the expert went beyond the approved indication in the Product Information, this was otherwise dealt with by the Committee in respect of in Complaint C.

The Committee agreed unanimously that there was no breach of Section 1.1, 1.3, and 1.4 of Edition 18 of the Code.

Overall Complaint: Failure to properly review the material

AZ alleged that the Alliance failed in its obligations under the Code in allowing this content to be presented. Specifically, AZ pointed to a lack of review, and that giving such a presentation undermines the requirements of Section 9.1 which define educational activities as enhancing the quality use of medicines.

While the Committee considered that, on the whole, the Presentation was misleading and contained inappropriate comparative information and biased information, it did not have sufficient evidence that the Alliance was negligent in its duties of content review. Further, the Committee were not convinced that the Presentation was not educational in nature.

The Committee therefore agreed unanimously that there was no breach of Sections 9.1 and 9.4.1 of Edition 18 of the Code.

Sanctions

The Committee found that several breaches of the Edition 18 of the Code had occurred. It agreed by majority that these breaches constituted a moderate breach of the Code, in that there were no safety implications to the patient, but the conduct may have an effect on how the medical profession would prescribe the product.

The Committee agreed unanimously that the Alliance must:

- Withdraw the Presentation from circulation, and not use it in the same or similar context;
- Distribute a corrective letter to all healthcare professionals who were in attendance or received the Presentation after the event; and
- Pay a fine of $150,000

The template for the corrective letter was supplied by Medicines Australia and approved by the Code Committee.

Beovu Promotional Material

	Subject Company	Product	Complainant
1160	Novartis Pharmaceuticals Australia Pty Ltd (Novartis)	Beovu (brolucizumab)	Bayer Australia Limited (Bayer)

Complaint	Bayer alleged that promotional material in circulation during January and February 2020 breached Edition 18 of the Code of Conduct. Specifically, the material contains superiority claims such as *"Demonstrated robust vision gains"*, *"Demonstrated superior fluid resolution"*, and *"Superior fluid resolution that lasts"* that Bayer asserted portrayed an overly favourable clinical profile of Beovu, which lacked the required qualification or balance and in so doing has the potential to mislead clinicians and negatively impact patient safety. Bayer considered that these numerous breaches were of the highest severity, were highly likely to have misled prescribers, and have significant safety implications that may negatively impact patient wellbeing. Bayer asserted that Novartis intentionally omitted key safety data from their promotional activities. As such Bayer believed that Novartis' actions also risked bringing the industry into disrepute. Bayer further contended that one piece should be considered a repeat breach of section 1.3 in which Novartis claims a superior clinical benefit of Beovu based on its molecular properties. Bayer asserted that these implied clinical benefit claims were subject to a previous complaint adjudicated by Medicines Australia in 2017.
Sections of the Code *Heard under Edition 18*	• 1.1 Responsibility • 1.2.2 Level of Substantiating Data • 1.3 False or Misleading Claims • 1.6 Unqualified Superlatives • 1.8 Comparative Statements
Response	Novartis denied the allegations made by Bayer and contended that Bayer's complaint was not an appropriate use of the Code and should be dismissed on procedural grounds. Specifically, Novartis alleged that intercompany dialogue requirements were not met in this matter; and that the original complaint was expressed in contravention of Australian Consumer Law (ACL). Novartis contended that Bayer is attempting to impede genuine competition through sustained 'forum shopping'. Novartis counter argued that Bayer's complaint is frivolous and vexatious.
Code of Conduct Committee Decisions	1. Allegation of repeat breach: unanimous, no breach of the Code 2. Claim – *'The masterfully engineered anti-VEGF'*: breach of Section 1.3, by unanimous decision 3. Claim – *'Beovu was well tolerated with overall AE rates comparable to aflibercept'*: breach of Sections 1.1, 1.3, and 1.8 by majority decision 4. Claim – *'demonstrated robust vision gains'*: breach of Sections 1.1, and 1.3 by unanimous decision; and no breach of Section 1.6 by unanimous decision 5. Claim – *'superior fluid resolution'*: breach of Sections 1.1, 1.2.2, 1.3, and 1.8 by majority decision 6. Claim – *'superior fluid resolution that lasts'*: breach of Sections 1.1, 1.2.2, and 1.3 by majority decision; and no breach of Section 1.6 by unanimous decision 7. Claim – *'Maintained a majority of patients on the q12w interval immediately after loading through to week 48'*: breach of Sections 1.1, and 1.3 by unanimous decision 8. Claim – *'Picture the difference longer treatment intervals could make'*: breach Section 1.8 by unanimous decision, and no breach of Section 1.6 by unanimous decision
Sanction	The Committee determined by unanimous decision that this was a severe breach of the Code and imposed the following sanctions on the subject company: • cease using materials with all claims found in breach, and not to use the claims in the same or similar context in future materials • distribute a corrective letter to all healthcare professionals who have received the material, with the template supplied by Medicines Australia and approved by the Committee • Pay a $200,000 fine

Appeal *Made by the Subject Company*	Novartis appealed the decision on a number of grounds, citing that the decision contained substantive errors, mischaracterised the expertise of the audience, and was a misinterpretation of the Code. Novartis also contended that the Code Committee erred in deciding that Novartis was promoting outside its approved indication. Further, Novartis considered the Code Committee's dismissal of arguments relating to the Australian Competition Law were erroneous. Novartis asserted that, should the Appeals Committee uphold the findings of the Code Committee, the severity of the breach should be considered minor; the claims should be allowed to be in continued use with appropriate qualification; and that the corrective letter should be removed.	
Appeal Response	Bayer rejected Novartis' appeal, noting that Novartis has not raised any significant matter in their appeal that has not already been considered and addressed by the Code Committee. Bayer contended that Beovu is not a product with which healthcare professionals are familiar, increasing the reliance on promotional materials. Bayer sought that that the Appeals Committee not only confirm the Code Committee's decision, but further strengthen the corrective letter to specifically correct the statements found in breach.	
Appeal Committee Decisions	*'The masterfully engineered anti-VEGF'*	Unanimously upheld the decision of the Code Committee
	'Beovu was well tolerated with overall AE rates comparable to aflibercept'	Unanimously upheld the decision of the Code Committee
	'demonstrated robust vision gains'	Unanimously overturned the decision of the Code Committee, and found no breach of Sections 1.1 and 1.3 of the Code of Conduct
	'superior fluid resolution'	Unanimously upheld the decision of the Code Committee
	'superior fluid resolution that lasts'	Unanimously upheld the decision of the Code Committee
	'Maintained a majority of patients on the q12w interval immediately after loading through to week 48'	Unanimously upheld the decision of the Code Committee
	'Picture the difference longer treatment intervals could make'	Unanimously upheld the decision of the Code Committee
Sanctions	The Appeals Committee unanimously confirmed the sanctions imposed by the Code of Conduct Committee. The Appeals Committee agreed that as the appeal was not upheld, the bond paid by Novartis would be retained by Medicines Australia.	

Consideration of the complaint

The material at issue consists of four items of promotional material distributed to ophthalmologists in January and February 2020, each containing similar claims relating to Beovu.

Intercompany Dialogue

In its response to the complaint, Novartis alleged that they were denied due process by Bayer failing to comply with intercompany dialogue requirements, and not making genuine attempts to resolve the complaint prior to submission of the complaint. Further, Novartis submitted that Medicines Australia should dismiss the complaint on procedural grounds as the Bayer characterised its complaint as being in breach of the Australian Consumer Law, and identifying issues that were not appropriate to be heard through the Code of Conduct processes. Novartis alleged that in submitting the claim to Medicines Australia, Bayer was being frivolous and vexatious.

The Committee discussed this allegation and agreed that the minutes from the intercompany dialogue contained in the complaint materials demonstrated that meetings had been conducted, correspondence passed between companies. The Committee agreed unanimously that the actions taken during intercompany dialogue satisfied the requirements and were sufficient for the Committee to proceed in hearing the matter.

The Committee discussed the allegation of frivolous and vexatious complaint, and procedural correctness in hearing the complaint. The Committee noted that while the complaint materials discuss both the Code of Conduct and the ACL, the documentation meets the criteria defined in accepting a complaint. Further, the matter is not currently being heard in a court of law, enabling the matter to be heard by the Committee. The Committee agreed by unanimous decision that the Code of Conduct is the appropriate avenue to review this complaint, and there was merit in continuing the hearing.

Previous rulings by the Federal Court of Australia

The complaint response by Novartis highlighted the Federal Court's decision in *Novartis Pharmaceuticals Australia Pty Ltd v Bayer Australia Ltd (2015) FCA 35* which involved similar factual circumstances. Novartis asserted that this new complaint would require Medicines Australia to express a view on established legal issues. The Committee discussed this matter and noted that the decision related to materials directed to ophthalmologists and optometrists, with a discussion on the professional ability for the audiences to understand the information presented. Further, the Committee noted that the nature of the claims was different. The key points from the case that would relate to the matter presented are:

- The court had a view that ophthalmologists were highly trained specialists, making serious decisions that take into account individual factors of the patient before them. This gave them superior skills in analysing materials presented in a promotional matter.
- The case sought for the court to view materials in an extreme way, relating to dosing frequency for each product. In this determination, the court found that none of the claims had an absolute meaning.
- While the court decided that an ophthalmologist could take a more contextual and holistic view of the information presented, it does not follow that they could not be misled by the material being presented.

The Committee agreed with the court's finding that ophthalmologists are informed viewers of promotional material, who are not going to be limited by their understanding of the content by the presentation. They can be expected to take a wider view of the material, using their knowledge and experience as a highly trained specialist in their field. That said, the Committee agreed that the decision is one taken in the Federal Court in relation to the ACL, and it is conceivable that the Code of Conduct would have a different effect on advertising to healthcare professionals than the law.

Claim - 'The masterfully engineered anti-VEGF', and allegation of repeat breach of the Code

The Committee turned to the allegation a breach of Section 1.3, where Bayer asserts that Novartis claims a superior clinical benefit of Beovu based on its molecular properties. The Committee noted that the crux of this complaint is that the claim "*The masterfully engineered anti-VEGF*" is supported by in vitro data rather than clinical evidence. The Committee noted that the Code permits the use of in vitro data when it is suitably qualified as such. Such qualification when present provides context to the viewer to inform their decision making. The Committee agreed that this qualification is necessary as laboratory data does not necessarily predict clinical effects. The Committee agreed that while an ophthalmologist will have the skills and knowledge to make a determination based on the information presented, and to undertake continued information gathering before prescribing, the Code does not assume that a healthcare professional can or will make the time to gather the additional data. Therefore, the Committee agreed unanimously that the absence of the qualifying statement that the study results are based on in vitro data, has the potential to mislead the reader, constituting a breach of Section 1.3 of Edition 18 of the Code.

In discussing the allegation of a repeat breach of the Code, the Committee agreed that while the claims included in the current advertising are similar to those for Beovu they were made in a different context and for a different product. The Committee agreed unanimously that this does not constitute a repeat breach of the Code.

Claim – 'Beovu was well tolerated with overall AE rates comparable to aflibercept'

The Committee discussed the allegation that the table outlining percentage of patients with common adverse drug reactions in clinical trials intentionally omitted increased rates of ocular inflammation. In this table, 16 eye disorders are listed, as well as one immune system deficiency, which Novartis asserted demonstrates that overall adverse event rates for Beovu are comparable to aflibercept. The Committee noted that iritis and uveitis, both forms of ocular inflammation, were reported separately rather than in the more common form of being reported as a combined figure. This table was referenced to Dugel et al 2019 American Academy of Ophthalmology, HAWK and HARRIER: Phase 3, Multicenter, Randomized, Double-Masked Trials of Brolucizumab for Neovascular Age-Related Macular Degeneration (HAWK & HARRIER). The Committee agreed that the table, and the accompanying information is misleading in terms of clinical outcomes, and that as a non-inferiority study, HAWK & HARRIER is unable to support that claim.

The Committee acknowledge that at the time of circulation, the claim *"…well tolerated with overall AE rates comparable to aflibercept"* a direct quote from the HAWK & HARRIER trial. However, the Committee noted that as a new product, Beovu is still developing a history of adverse events, and that the definitive claim made in the piece could not be accurately supported by the evidence. The Committee further noted that the TGA had issued alerts regarding Beovu and spontaneous data reports, which were in review at time of publication. The Committee acknowledged that the TGA activity follows a set process with defined timelines. The Committee recognised, however, that there was a growing body of evidence that there was a concern with the safety of Beovu which was of clinical significance. The Committee believe that it is the onus of the company to clearly communicate with the audience, and that suspending the material pending outcome of the TGA's review would have been appropriate.

The Committee again acknowledged Novartis' reliance on the Federal Court decision that Ophthalmologists would have satisfactory knowledge to understand the context. The Committee determined that while this may be the case, HAWK & HARRIER was not of sufficient design to support the claim being made. The Committee agreed that companies are not required to provide every conceivable safety nuance in the promotional material, however abrogating responsibility to the healthcare professional to determine applicability of common adverse events is not appropriate. The Committee noted that the TGA's review was running concurrently to the intercompany dialogue process between the companies. It was the Committee's opinion that a more constructive conversation during this process, showing intent and transparency in relation to the forthcoming PI review may have mitigated this rising to the level of complaint.

The Committee acknowledges that there is the role of the regulator to assess the evidence, and to determine what safety information is presented. A minority of the Committee noted that the company was, at the time of publication, promoting within its approved indication. That said, the Committee determined that the claim *"…well tolerated with overall AE rates comparable to aflibercept"* was not sufficiently supported by the evidence. Therefore, the Committee agreed by majority that this constituted a breach of Section 1.8 of the Edition 18 of the Code.

Claim – 'Demonstrated robust vision gains'

The Committee noted that the design of this piece was to imply superiority in terms of clinical outcomes measured in the HAWK & HARRIER trial. Specifically, the Committee determined that bullet points under an overarching statement are, by extension, set up as comparative. In this piece, the statement *"demonstrated robust vision gains"* was directly under the opening statement *"in two head-to-head trials vs aflibercept, Beovu:"*. It is the Committee's opinion that this automatically renders the following statements comparative to aflibercept.

The Committee noted, as in the previous complaint, that this claim is referenced to the HAWK & HARRIER trial. As a non-inferiority study, it is not satisfactory evidence to support a claim of superiority. Further, the Committee noted Novartis' reliance on the Federal Court ruling that considers ophthalmologists elevated skills and knowledge would give them context and confirms its opinion that such a narrow ruling in that case has little weight in this decision. The Committee determined that in using a non-inferiority study for an absolute claim of superiority has taken a premise in validity that is not supported by the trial.

The Committee agreed by unanimous decision that this claim was in breach of Sections 1.1 and 1.3 of Edition 18 of the Code. The Committee noted, however, that the claim did not contain an unqualified superlative, and therefore determined by unanimous decision that there was no breach of Section 1.6 of the Code.

Claim – 'Superior fluid resolution'

The Committee noted that this complaint related the overarching claim and the qualifying statement *"Beovu exhibited superior fluid resolution, with fewer patients with IRF and/or SRF vs aflibercept at weeks 16 and 48".* Both the claim and qualifying statement were referenced to the HAWK study, and the product information. In reviewing the product information, the Committee noted that the pharmacodynamic effects listed a number of statistics that presented advantages for Beovu. These data are derived from contrast studies which demonstrated fluid change, however there is no substantiation of a clinical significance of that change.

The Committee acknowledge that intraretinal fluid (IRF) is a well-established biomarker that has consistently shown to impact visual outcomes if not effectively controlled. Conversely, subretinal fluid (SRF) reductions have not been demonstrated to translate into clinical benefits. The Committee recognised that IRF is currently the only meaningful biomarker in this area. The Committee noted that when IRF and SRF were separated into two distinct endpoints, the data showed no difference between the products. Further, the Committee acknowledged that IRF and SRF were combined in the HAWK study but were separated in the appendix.

The Committee discussed whether the target audience would be sufficiently skilled to interpret the data based on clinical experience. The Committee agreed that fluid is a key treatment criteria from an ophthalmologists point of view, and that global therapeutic guidelines support fluid biomarker in the treatment protocol. However, the Committee agreed that there is insufficient evidence that links fluid resolution measured by aggregate IRF/SRF to clinically relevant outcomes such as vision gain. Further, the majority of the Committee agreed that the use of select data from the HAWK study – a non-inferiority study – to support claims of superiority is inappropriate.

The Committee agreed by majority decision that this claim is in breach of Sections 1.1, 1.2.2, 1.3, and 1.8 of Edition 18 of the Code.

Claim – 'Superior fluid resolution that lasts'
The Committee acknowledged that this complaint restated matters from the previous claim and agreed that the conclusions it drew in that matter follow through to this complaint.

The Committee agreed that presentation of selected and favourable timepoints from the HAWK study, which were inconsistent with other more favourable timepoints used in the advertising, does not correlate with the outcomes of the research. Therefore, the Committee agreed by majority decision that the claim was in breach of Sections 1.1, 1.2.2, and 1.3 of Edition 18 of the Code. The Committee maintained its unanimous position that the use of the word superior in this context is not a breach of Section 1.6 of Edition 18 of the Code.

Claim – 'Maintained a majority of patients on the q12w interval immediately after loading through to week 48'
The Committee noted that while the claim *"maintained a majority of patients…"* was factually correct on its face, it omitted key data presented in the Beovu PI and the HAWK & HARRIER trials. These omitted data demonstrate that the percentage of patients maintained on a q12w interval declined to 45% and 39% in the HAWK and HARRIER trials, respectively, at the end of the study. The Committee recognised that the inclusion of the 96-week data would have ensured the claim and graphical representations were consistent with the approved product information and the body of evidence.

The Committee agreed by unanimous decision that this claim was in breach of Sections 1.1, and 1.3 of Edition 18 of the Code.

Claim – 'Picture the difference longer treatment intervals could make'
The Committee noted that the substantive arguments in relation to this claim had been dealt with in the previous complaints. The Committee agreed that the conclusions drawn in relation to those claims follow through in this matter.

In relation to this claim, the Committee noted the use of the word 'picture' and agreed that it has connotations of visual acuity and implies linkages to the outcomes of HAWK & HARRIER trials that were not measured. The Committee agreed that while there is no mention of competitive products, in context of the piece, this claim becomes a hanging comparison.

The Committee acknowledged the findings of the Federal Court Case which contained discussion on the benefits of longer treatment intervals, specifically in regional and rural areas, or areas where access to specialist services is limited. This argument acknowledged that there could be reasons above and beyond the clinical benefit for longer treatment intervals.

That said, the Committee agreed by unanimous decision that the claim was a hanging comparative and therefore in breach of Section 1.8 of Edition 18 of the Code of Conduct. The Committee agreed by unanimous decision that there was no breach of Section 1.6 of Edition 18 of the Code.

Sanctions
The Committee found that several breaches of the Edition 18 of the Code had occurred. It agreed by majority that these breaches constituted a severe breach of the Code, in that there were safety implications to the patient's wellbeing and has a major effect on how the medical profession would prescribe the product.

The Committee agreed unanimously that Novartis must:

- cease using materials with all claims found in breach, and not to use the claims in the same or similar context in future materials

- distribute a corrective letter to all healthcare professionals who have received the material, with the template supplied by Medicines Australia and approved by the Committee
- pay a $200,000 fine

The template for the corrective letter will be supplied by Medicines Australia and approved by the Code Committee. Any alterations to the letter must be approved before distribution.

Consideration of the Appeal
In order for an appeal to be successful, 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 Novartis representatives were asked to present their appeal to the Appeals Committee, and the following summarises their presentation and their written submission:

- Novartis asserted that due process was not followed as it did not receive a copy of the Bayer response to its appeal submission until short notice. Novartis noted that the Bayer submission contained additional material not previously raised by Bayer; and the delay in receipt had not allowed Novartis to properly consider Bayer's response to this appeal. The Medicines Australia Secretariat noted that it is a courtesy for the non-appellant company's submission to be shared with the appellant and not a mandated requirement, recognising the presentation and response process during the appeal hearing allowed the appellant to rebut any new information provided during the hearing.

- Novartis outlined the regulatory and clinical evidence framework which bears on this matter. Namely, the regulatory environment in Australia that approves the product for registration and the accompanying product information (PI); and the body of evidence associated. Primarily, the key points of evidence relevant to this matter are the approved product information and the HAWK and HARRIER studies. Novartis assert that all other publications are secondary to these two large multinational phase III studies.

- Novartis stepped through the relevant Australian timelines associated with the matter as evidence that the Code Committee had made an error in judgement in determining breaches associated with safety claims. Specifically:
  - 6 January 2020: Beovu registered in Australia
  - 5 February 2020: Physician enrolment in a Product Familiarisation Program (PFP)
  - 11 March 2020: Novartis voluntarily agreed with the TGA to not supply Beovu
  - 16 April 2020: Medical assessment report submitted to TGA
  - 25 June 2020: Revised PI approved by TGA
  - 2 July 2020: Dispensing under PFP commenced
  - 3 July 2020: Dear HCP letter sent updating physician and patient information to 1,064 ophthalmologists
  - 6 July 2020: Stock released for the PFP access program

The Appeals Committee queried the availability of the product on the basis of the timeline presented. Novartis advised that there is an active PFP for Beovu, which aligns with the principles in Edition 18 of the Code of Conduct and which contains prescribed educational information set by the TGA. Novartis asserted that Beovu is only available through this PFP or by private prescription. Novartis noted that as at time of the hearing, 100 physicians were participating, and 300 patients had been enrolled in the PFP. Physicians had been enrolled into the PFP since January 2020, but patients were not supplied the product until 6 July 2020. Each physician was entitled to enrol up to ten patients.

Novartis added that it agreed with the TGA not to supply Beovu until the safety issues had been satisfied. Following the approval of the revised PI in late June 2020, the TGA and Novartis agreed to commence supply.

- Novartis provided a succinct overview of disease progression in neovascular Age-related Macular Degeneration (nAMD), to provide the Appeals Committee sufficient understanding of the key markers used in determining efficacy of treatment. Specifically, outlining that fluid control is the key to effective treatment in nAMD. Novartis also provided global context for the assessment of fluid control and impact on decision making for treatment recommendations. In the absence of Australian guidelines, ophthalmologists look to these global guidelines.

- In discussing the HAWK and HARRIER trials, Novartis outlined that they were the largest brother and sister trials in ophthalmology. The primary endpoint of Non-inferiority (NI) to aflibercept in mean BVCA change from baseline to Week 48 (NI margin, 4.0 letters) was met. Novartis noted that the protocol pre-specified secondary endpoints

allow statistical comparisons and therefore can be used to support claims. Novartis also noted that the safety claims used in the materials were derived from the approved PI at the time, which importantly relates to the timeline previously discussed as it was the prevailing evidence at the time of publication, rendering those claims to be consistent.

In contemplating this evidence, the Appeals Committee sought clarification on the secondary data. The Appeals Committee questioned, given the number of secondary endpoints, whether the data was adjusted for multiplicity. Novartis advised that the data was adjusted for multiplicity of testing. This led the Appeals Committee to accept the clinical findings of the data as being statistically significant however it remained unclear as to their clinical significance. Novartis advised that the data was presented in accordance with the study design including the statistical plan for the secondary pre-specified endpoints, and used in the approved PI. The Committee noted that the adverse event data were presented with descriptive statistics, as is appropriate. Novartis asserted it is for the physician to determine what is appropriate for the patient in front of them, and it was its duty to allow physicians to make clinical judgements.

- Novartis reiterated its opinion that the safety information should not be considered comparative. The data represented in materials is directly supported by the approved PI at the time of publication. Novartis contended that the safety information compared total number of adverse events as an overall safety profile, not a direct comparison of individual adverse events. The presentation of individual adverse events in Table 1 of the PI allows the physician to make clinical decisions at the time of prescription. The Appeals Committee questioned whether, in the amendment to the PI in June 2020, Table 1 was amended to reflect any additional safety findings. Novartis confirmed that the table was not amended, no additional adverse event data was incorporated by the TGA in approving the revised PI. Novartis noted that the TGA had the complete clinical study report and risk benefit profile. The adverse events listed in the promotional material highlight the overall most prominent adverse events. Novartis asserted that all medicines have safety profile data, which healthcare professionals must take into account in their prescribing decision.

  Novartis acknowledge that the material compares the total number of adverse events, leading to the claims of comparative safety between Beovu and aflibercept. Once safety events were initiated with the TGA, Novartis maintained they had amended practice to ensure no patients were put at risk, through agreement to not make the product available, outside the PFP programme, and to educate physicians on the new safety profile. Novartis asserted, however, that it is within its right to supply, but chose not to because of the ambiguity of the emerging data.

- Novartis reiterated that the promotional material is not a comprehensive summary of the HAWK & HARRIER trials, nor was it meant to be. The materials were designed to highlight key features of the product for expert ophthalmologists to assess the risks and benefits before prescribing. Novartis maintained its opinion that the material is not inconsistent with PI that was approved at the time of promotion. Novartis further restated that the material is directed to ophthalmologists, a highly trained and knowledgeable specialist audience who would be well aware of the characteristics of Beovu. Novartis referred to findings in the Federal Court which express that healthcare professionals are not easily misled, and that the Code Committee was in error in not giving sufficient weight to that expertise in making its judgement.

- Novartis restated its belief that the promotional materials are not in breach of the Code of Conduct and sought the Appeals Committee to overturn the decision. If, however, the Appeals Committee determined to uphold the findings, Novartis asserted that any breach of the Code should be considered as minor. This opinion is supported by the fact that Beovu was not available to be prescribed by ophthalmologists in Australia at the time of circulation, and it was only available through a PFP from July 2020. It is Novartis' opinion that this mitigates any patient safety implications which are a threshold for categorisation as a severe breach. Further, the inability for Beovu to be prescribed would not give rise to changing in prescribing habits or have a commercial impact.

The Appeals Committee sought correction to statements (Submission of Novartis in Support of the Appeal, Section, 5.2), where Novartis put the case for the validity of the claim that "Beovu was well tolerated with overall AE rates comparable to aflibercept". Specifically, it was stated by Novartis that their claim, compared to aflibercept, was one of non-inferiority of Beovu with respect to AE *based on the fact that their studies were non-inferiority studies*. It was put to Novartis by the Appeals Committee that the primary endpoint for the design of their studies was non-inferiority based on a primary clinical endpoint, namely, 'best-corrected visual acuity change from baseline to week 48 (margin; 4 letters; Hawk and Harrier, 2019) . The Committee noted that a non-inferiority claim is only valid for this primary

endpoint. It does not allow any such statement with respect to the comparative AE data. Novartis acknowledged that they had made an incorrect assertion with respect to this point.

Bayer was invited to provide its response to the Novartis appeal, and the following summarises that response:

- Bayer acknowledged and agreed with the Code Committee's decision, noting that there were no new facts or arguments presented in the written submission or presentation that would justify the overturning of the decision.

- Bayer also provided the Appeals Committee with a timeline of events associated with the materials, however this timeline included additional information relating to intercompany dialogue handling and global registration and safety findings for Beovu. Specifically, Bayer noted that a higher incidence of serious ocular adverse events was highlighted in the FDA in October 2019, and EMA in December 2019 which are prior to the registration of Beovu by TGA in January 2020. Bayer asserted that Novartis was aware of increased safety events relating to the product, yet continued to market the product and encourage the use of the product. Bayer maintains that ophthalmologists have no experience with Beovu, however are encouraged to prescribe the product through reliance on promotional materials.

- Bayer strongly rejected the allegation made by Novartis in its written appeal that the complaint was part of a coordinated global campaign to impede competition. Bayer refers to significant and multiple misrepresentations in Beovu's promotional materials, which include misleading efficacy and safety data that would have an impact on patient safety.

- Bayer contended that Novartis had failed in its obligations to cease using claims found in breach upon receipt of the Code Committee's decision. Bayer provided evidence of the promotional material available on Novartis' MedHub portal, as well as advertisements published in the September issue of MiVision, and Eye2Eye Magazine dated 15 October 2020. Further, Bayer outlined that while Beovu is only available through a PFP, this program is actively promoted to ophthalmologists.

- Bayer addressed Novartis' response relating to the application of the Australian Competition Law (ACL), noting that the Code requirements are in addition to legislative and regulatory requirements. Bayer asserted that Novartis referred to Federal Court cases which dealt with entirely different sets of facts and were not useful in making factual findings in context of the current complaint.

- Bayer agreed with the Code Committee's findings that it is the onus of the company to clearly communicate with the audience, and suspending the material pending outcome of the TGA's review would have been appropriate. Bayer maintained that Novartis did not volunteer information during intercompany dialogue that related to its exchange with the TGA, and none of the promotional material seen up until time of this hearing informed physicians of the update safety information. Further, Bayer asserted that some of the materials were not withdrawn totally, and continued to be in circulation after the Code Committee's findings.

- Bayer again agreed with the Code Committee's findings that clinicians are time poor, and that it is spurious to consider that all recipients of the material would seek additional clarification from the PI before prescribing. Bayer maintains that to comply with the Code, materials should be appropriately qualified and provide sufficient information for a prescriber to make an informed decision. Additionally, qualifiers and references should not be used to correct a claim.

- Bayer concluded by seeking that the Appeals Committee confirm the Code Committee's findings. However, Bayer also sought amendment to the corrective letter, noting that the template provided by Medicines Australia did not contain sufficient information to match the severity of the breach found. Bayer asked the Appeals Committee to consider inclusion of the required corrections given the serious risk posed to patients.

Novartis were then given the right of reply to Bayer's presentation. The following summarises that response:

- Novartis again expressed its disappointment that Bayer's written response to the appeal was not provided until close to the hearing, which impeded their ability to make a satisfactory review and response to the document.

- Novartis refutes that Beovu is unsafe, contending that it remains registered by the TGA.

- Novartis rejects that it was less than collegiate during intercompany dialogue, noting that conversations with the regulator are commercial in confidence. It is not appropriate to expect a competitor to disclose the nature of these discussions.

- Novartis assert that evidence supplied in this presentation should be set aside, as it is new evidence that it has not had the ability to make an informed response. This particularly related to whether MedHub is a promotional website, and whether the PFP could be considered commercialisation of the product.

  The Chair acknowledged Novartis' comments, however noted that Novartis had included reference to the PFP in its submission and in primary discussions with Bayer, so should have anticipated the argument. Further, the Chair noted that Novartis is experienced in such hearings that it would know to come prepared to respond to matters raised by the opposing company or Appeals Committee during the hearing.

- Novartis strongly asserted it is its opinion that availability of Beovu through the PFP only does not render the product commercially available. The use of PFPs is common practice, and agreed that the physician is required to write a prescription for the product. However, Novartis insisted that the decision on availability of the product to patients impacts the decision of severity of breach found. Novartis restated its claim that the Code Committee erred in its decision of finding a severe breach, as the product is only available through the PFP and to 300 patients. Novartis are of the opinion that the finding of an affect on patient safety and prescribing habits discordant to the availability of the product.

- Novartis addressed the allegation that materials were in circulation after the Code Committee's findings were delivered. Novartis assured the Appeals Committee that they had made best efforts to comply with the cessation of the claims, however a number of printed publications were too advanced in their editing to enable Novartis to remove materials.

The following summarises the Appeals Committee's deliberations and decisions.

Reliance on Australian Competition Law (ACL)

The Appeals Committee commenced its discussions by addressing the reliance by both parties on the ACL. In its written submission on the appeal, and in argument before the Appeals Committee, Novartis launched an attack on the Code Committee's handling of the complaints, based on what Novartis claimed was a failure to "consider the evidential burden on Bayer". Novartis noted that Bayer had "provided no evidence that ophthalmologists are being misled" and suggested the Code Committee had merely reviewed the promotional material and formed "its own subjective view". This, Novartis alleged, was an error under section 20.1 of the Code. The Appeals Committee considered this submission and rejected it. Novartis also took issue with the statement in the Code Committee's decision that "it is conceivable that the Code of Conduct would have a different effect on advertising to healthcare professionals than [the Australian Consumer Law]".

It would not be appropriate to undertake a review of the operation of the procedures under the Code, or the relative procedures in the Courts under the ACL. These have been stated many times, including in the Federal Court authorities referred to by Novartis. Suffice to say that, given that the processes under the Code do not involve the calling of witnesses, it would be very unusual for there to be evidence that persons in a particular class to which promotional material was directed had been misled. Moreover, it has been stated authoritatively that such evidence, while helpful, is not required in proceedings under the ACL itself. The way in which the Courts have interpreted the corresponding provisions of the ACL (section 18 in particular, as well as its predecessor, s.52 of the Trade Practices Act), and the principles the Courts have spelled out, are clearly of assistance in interpreting Section 1.3 of Edition 18 of the Code. It does not necessarily follow that the same decision would be reached by both forums in relation to the same material. Nor does it follow that factual findings in cases involving different promotional claims should be adopted uncritically in considering complaints under the Code.

In the view of the Appeals Committee, the Code Committee gave proper consideration to the target audience at which the claims were directed, and had proper regard to their level of professional qualification, as it stated in its decision. The complaints were stated to be in relation to specified provisions of the Code (including relevantly Section 1.3), and it was not necessary for the complainant to allege that ophthalmologists were being misled, as appears to be asserted by Novartis.

The Appeals Committee therefore found no error by the Code Committee in its approach to determining the complaints before it. The Appeals Committee then took to addressing each complaint as stated in the Code Committee's findings, to determine if evidence provided in the hearing was sufficient to amend the finding.

'The masterfully engineered anti-VEGF'
The Appeals Committee recognised that the science of engineering this molecule was impressive, however the extrapolation of the basic characteristics of the molecule to infer an advantage is inappropriate. The Appeals Committee was of the opinion that in the context of the claims which infer direct comparisons with aflibercept, the statement suggests a clinical advantage which is not supported by clinical evidence.

The Appeals Committee were not persuaded by Novartis that the Code Committee had erred in its finding and agreed unanimously to uphold the decision. The claim *'the masterfully engineered anti-VEGF'* is determined to be in breach of Section 1.3 of Edition 18 of the Code of Conduct.

'Beovu was well tolerated with overall AE rates comparable to aflibercept'
The Appeals Committee acknowledged that the use of the word 'comparable' is in step with industry practice when discussing safety and adverse events. The Appeals Committee noted, however, that it was clear from the PI there were AE that were downplayed or combined into overall rates. Again, while overall safety profile rates are industry practice, the Appeals Committee agreed that combining pain and discomfort, or abnormal sensation AEs, with serious AEs such as blindness or blinding infection that patients would not recover from, was problematic.

The Appeals Committee were not persuaded by Novartis that the Code Committee had erred in its finding and agreed unanimously to uphold the decision. The claim *'Beovu was well tolerated with overall AE rates comparable to aflibercept'* is determined to be in breach of Sections 1.1, 1.3, and 1.8 of Edition 18 of the Code of Conduct. by majority decision of the Code Committee

'Demonstrated robust vision gains'
While the Appeals Committee understood the Code Committee's decision that the claim *demonstrated robust vision gains* could be considered false and misleading, and unsubstantiated, the Appeals Committee considered the claim in its whole context. The Appeals Committee noted that the statement was qualified by the statement *"Mean BCVA improvement of 6.6 letters (HAWK) and 6.9 letters (HARRIER) from baseline at Week 48"*, and agreed that this contextualised the improvement to baseline, which negated a comparison to aflibercept.

The Appeals Committee were persuaded that the claim was appropriately qualified and contextualised, and conceded that the Code Committee had erred in its decision. Therefore, the Appeals Committee agreed unanimously to overturn the decision of the Code Committee and found that the claim '*demonstrated robust vision gains'* was not breach of Sections 1.1 and 1.3 of Edition 18 of the Code of Conduct.

'Superior fluid resolution' and *'Superior fluid resolution that lasts'*
The Appeals Committee reviewed these two findings together as the arguments were similar in nature.

The presentations by Novartis and Bayer provided context for the assessment for treatment decisions, namely the presence of intra-retinal fluid (IRF) and sub-retinal fluid (SRF) through the use of optical coherence tomography scans (OCT). The Appeals Committee recognised that the fluid control in wet AMD has the impact of improved visual acuity.

The Appeals Committee noted that a claim of superiority can only be inferred for Beovu when IRF and SRF data is combined. When separated into individual data, the Appeals Committee determined that the claim is not supported. The Appeals Committee were of the opinion that a general ophthalmologist would be misled by the information, however a retinal specialist would likely have a different view based on their expertise and experience. The Appeals Committee acknowledged that the combined endpoint was accepted for the registrational study and the statistical hierarchy doesn't allow for the assessment of the individual component endpoints. Further, the Appeals Committee recognised the view that IRF as a more relevant marker is relatively new, and the trial design may pre-date this information. That said the Appeals Committee agreed unanimously that it should not be the basis of the claim as it does not show substantiating data to support clinical relevance.

The Appeals Committee was not persuaded that the Code Committee had erred in its findings and agreed unanimously to uphold the decision. The claim *'superior fluid resolution'* is in breach of Sections 1.1, 1.2.2, 1.3, and 1.8 of Edition 18 of the Code of Conduct. Additionally, the claim *'superior fluid resolution that lasts'* is in breach of Sections 1.1, 1.2.2, and 1.3 of Edition 18 of the Code of Conduct.

'Maintained a majority of patients on the q12w interval immediately after loading through to week 48'
The Appeals Committee discussed the evidence provided by Novartis in the original submission, its appeal submission and the presented materials which supported this claim. The Appeals Committee were of the opinion that the claim

misrepresented the data. Juxtaposing claims based on different time points of analysis had the potential to mislead the audience.

The Appeals Committee were not persuaded by Novartis that the Code Committee erred in its findings and agreed unanimously to uphold the decision. The claim *'Maintained a majority of patients on the q12w interval immediately after loading through to week 48'* is in breach of Sections 1.1, and 1.3 of Edition 18 of the Code Committee

'Picture the difference longer treatment intervals could make'
The Appeals Committee were of the opinion that the claim is referring to long-term maintenance of wAMD, which was referenced to shorter term data. The Appeals Committee were of the opinion that the structure of the claim was a hanging comparative, and therefore misleading by omission.

The Appeals Committee were not persuaded that the Code Committee erred in its findings and agreed unanimously to uphold the decision. The claim *'Picture the difference longer treatment intervals could make'* is in breach of Section 1.8 of Edition 18 of the Code of Conduct.

Failure to cease use of, or withdraw materials found in breach
The Appeals Committee discussed the availability of the promotional materials after Novartis had received the Code Committee's reasons for decision, and the impact this may have had on prescribing.

The Appeals Committee discussed the evidence presented by Bayer that the promotional materials were still available on Novartis' MedHub website, as well as in printed third party publications. In its rebuttal, Novartis contended that its MedHub was a medical information website, which was password protected to AHPRA verified healthcare professionals. Novartis contended that, by definition, such websites are considered to be non-promotional, and the statements were factual representations of the HAWK & HARRIER study that a healthcare professional would access after an appropriate keyword search. The Appeals Committee noted screenshots submitted by Bayer in its presentation that showed several identical claims seen in the promotional material found in breach, as well as imagery and graphical representations. Promotional websites for healthcare professionals must be password protected. The Appeals Committee agreed unanimously that the claims found in this website would be considered promotional as defined in Edition 18 the Code of Conduct (glossary, page 89), and therefore would be captured in the requirement for cessation or withdrawal issued in the Code Committee's reasons for decision.

The Appeals Committee were sympathetic to the assertion by Novartis that the withdrawal of advertisement from printed publications was difficult and that deadlines may have passed when the findings had been handed down. The Appeals Committee, however, was not persuaded that Novartis was unprepared for this line of argument, noting that the Medicines Australia Secretariat had reminded Novartis by email on 10 September 2020 of its obligations under Section 28.1 of Edition 18 of the Code to immediately comply with actions handed down by the Code Committee. The Appeals Committee had expected Novartis to pre-empt any commentary on this matter given the possible impact it would have on the decision-making process.

Availability of Beovu
The Appeals Committee discussed the timelines presented by both parties that determined the availability of Beovu. The Appeals Committee was of the opinion that the arguments put by Novartis were not unreasonable, however it disagreed with the assertion that a PFP does not constitute commercialisation. The Appeals Committee recognised that a PFP enacted in accordance with Section 8 of Edition 18 of the Code of Conduct would have limitations in the number of patients that could be enrolled per physician, but no limitation in the number of physicians that could be enrolled into the program. Novartis reported 100 physicians had enrolled 300 patients, which represented fewer than the cap specified in the Code (whereby a physician can enrol no more than 10 patients in a PFP). The Appeals Committee agreed that the number of physicians participating in the PFP and the number of patients each enrol would be influenced by the promotional material that is in circulation, and that Novartis was still actively seeking to increase enrolment into the program thereby increasing the influence prescribing of Beovu through the PFP.

The Appeals Committee noted that Novartis is actively engaging with the TGA on the safety monitoring, with increased educational requirements for prescribers. The Appeals Committee acknowledged the TGA's involvement may mitigate the safety implications, though it does not remove safety concerns entirely. For the Appeals Committee to overturn the finding of a severe breach and substitute a finding of moderate or minor breach, it would have to determine no safety implications on the patient's wellbeing.

The Appeals Committee acknowledge the risk management plan that Novartis and the TGA have devised which impacted the delivery of the PFP. The Appeals Committee agree that it is a legitimate enterprise for Novartis to continue with the PFP. However, the Appeals Committee agreed that this continuation does not compensate for the fact that the claims of comparable safety have been found to be misleading and potentially are a risk-inducing communication. The Appeals Committee noted that physicians were exposed to these promotional claims as recently as at least September 2020, which has the potential to increase the number of physicians in the PFP and in turn the number of patients.

The Appeals Committee agreed unanimously that there is sufficient evidence of safety implication specified, and therefore confirmed the Code Committee's finding of severe breach.

Sanctions

The Appeals Committee discussed the sanctions imposed by the Code Committee.

The Appeals Committee noted that it had confirmed the Code Committee's findings in six of the seven claims in the complaint. It further noted that the one complaint that was overturned was part of series of claims where the remaining claims were found in breach. The Appeals Committee also confirmed the Code Committee's finding of a severe breach. The Appeals Committee agreed unanimously that this was sufficient grounds for it to not make any alteration to the sanctions imposed by the Code Committee. Therefore, the sanctions imposed by the Code Committee stand, that is Novartis must:

- cease using materials with all claims found in breach, and not to use the claims in the same or similar context in future materials;
- distribute a corrective letter to all healthcare professionals who have received the material, with the template supplied by Medicines Australia and approved by the Code Committee; and
- pay a $200,000 fine.

The Appeals Committee gave consideration to the corrective letter, and Bayer's request to amend the content of the letter to outline the nature and severity of the breach. The Appeals Committee agreed that in light of the 'dear doctor' letter imposed by the TGA which included additional safety information, the template letter provided by the Code Committee does not require alteration.

Bond

The Appeals Committee agreed that as the appeal was not upheld, the bond paid by Novartis would be retained by Medicines Australia.

FORXIGA, XIGDUO XR, and QTERN Promotional Materials

	Subject Company	Products	Complainant
1161	AstraZeneca Pty Ltd (AstraZeneca)	• FORXIGA (dapagliflozin propanediol monohydrate) • XIGDUO XR (dapagliflozin propanediol monohydrate/metformin hydrochloride) • QTERN (saxagliptin/dapafliglozin)	Boehringer Ingelheim/Eli Lilly Australia Alliance (the Alliance)

Complaint

The Alliance alleges that multiple materials produced by AstraZeneca to promote a new indication for FORXIGA and XIGDUO XR:

- omit important information regarding the approved patient population for a new FORXIGA and XIGDUO XR indication;
- misrepresent the scientific body of evidence of data from the DECLARE-TIMI 58 trial; and
- omit relevant QTERN patient safety warnings and precautions specified in the QTERN Product Information.

The Alliance allege that HCPs viewing AstraZeneca's promotional materials are likely to prescribe the products in a manner that is inconsistent with the approved Product Information, which may pose a risk to patient safety and wellbeing.

Sections of the Code

Heard under Edited 19

- Principle 1: All activities undertaken by Companies have the purpose of supporting the quality use of medicines.
- Principle 3: As the primary repository of information relating to their products, Companies are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use. The same standards apply to all other Company communications.
- Principle 7: Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials. Promotional materials are designed by Companies to not only create awareness of Therapeutic Goods Administration (TGA) approved medicines, but to support proper assessment of their risks and benefits.
- Principle 8: All promotional claims are consistent with the Australian Product Information document, including claims about competitor products, irrespective of the source on which the claim is based.
- Section 1: Requirements for promotional claims directed at healthcare professionals
- Section 1.1: Substantiating Data
- Section 2: Requirements for material directed to healthcare professionals

Response

AstraZeneca denies each of the allegations made by the Alliance and considers each promotional item in the complaint to comply with Edition 19 of the Code of Conduct. AstraZeneca asserts that each allegation of breach is dependent on construing the claim in a contextual vacuum, without regard to the remainder of the relevant promotional document. AstraZeneca considers such an approach to be divorced from the reality of how a HCP would construe the promotional material.

Code Committee Decisions	Off-label promotion of FOXIGA and XIGDUO XR for the prevention of hospitalisation for heart failure, without specifying its limitations to patients with type 2 diabetes and misleading and incorrect claims regarding FORXIGA and XIGDUO XR.	Majority breach of Sections 1, 2 and regard given to overarching principle 1 and 7. No breach of Section 1.1 by unanimous decision; overarching principles 3 and 8 were found not to be relevant

	Insufficient qualification and inappropriate inclusion of promotion for QTERN in material promoting claims for reduction in hospitalisation for heart failure	Unanimous breach of Section 1, and regard given to overarching principle 1, 3, 7 and 8. No breach of Section 1.1, and 2 by unanimous decision
	Misleading claims for FORXIGA and XIGDUO XR for the primary and secondary prevention of hospitalisation for heart failure	No breach of Section 1, 1.1, and 2 by unanimous decision. Overarching principles 1, 3, 7, and 8 were found not relevant in this decision
	Off-label major claims for FORXIGA and XIGDUO XR for renal-specific composite endpoint based on exploratory data	Unanimous breach of 1, 1.1, 2, and regard given to overarching principle 1, 3, 7. Overarching principle 8 was found not to be relevant in this decision
	Misleading claims and inappropriate qualification for XIGDUO XR and QTERN promotion	Unanimous no breach of Sections 1, 1.1, 2, and overarching principles 1, 3, 7, and 8 were found not relevant in this decision.
Sanction	The Committee unanimously agreed that the breaches were classified as moderate, and agreed to impose the following sanctions: • Issue a corrective letter as drafted and agreed by the Code Committee (in respect of materials the subject of complaint 2) • Cease using all materials found in breach (where they are still in circulation) and not use the claims in the same or similar format in future materials • Pay a fine of $100,000	

Consideration of the Complaint
The Chair noted that the Alliance had alleged that multiple pieces of promotional material for the prevention of hospitalisation for heart failure (hHF) associated with type 2 diabetes (T2D) have contravened Edition 19 of the Code. The Chair advised the Committee that this is the first complaint to be heard under Edition 19 of the Code, and that the Committee will have regard to the overarching principles, as well as the individual sections in each complaint.

The Committee noted that materials were provided to Medicines Australia and the Committee in electronic copy only. While it acknowledged that electronic submissions are common, and necessary where offices are closed due to COVIDSafe requirements, this can limit the Committee's ability to understand the placement of an item or a claim in the physical copy of the material as provided to HCPs. The Committee would therefore prefer to receive physical copies of the actual material provided to HCPs. However, in this case the Committee made its decisions based on digital copies of the promotional items, but had regard to how those materials would have been considered by an HCP in hard copy.

<u>Complaint 1: Off-label promotion of FOXIGA and XIGDUO XR for the prevention of hospitalisation for heart failure, without specifying its limitations to patients with type 2 diabetes and misleading and incorrect claims regarding FORXIGA and XIGDUO XR.</u>
The Committee noted this complaint refers to two separate instances of similar claims in use:

- A printed double-page advertisement in Australia Doctor published in the May and June 2020 editions, in which AstraZeneca promoted a new indication for their products FORXIGA and XIGDUO with the statement *"the only T2D treatment approved for the prevention of hospitalisation for heart failure."* which is further qualified with *"in adults with established CVD or risk factors for CVD to reduce the risk of hospitalisation for heart failure."*
- An article published on *AusDoc.PLUS* titled *"Which diabetes drug is effective against heart failure?"* which describes the DECLARE-TIMI 58 trial, as well as the benefits of FORXIGA and XIGDUO in reducing cardiac outcomes.

The Committee recognised that the indication in the approved Product Information (PI) clearly defines the use for adults with type 2 diabetes (T2D) mellitus. The benefit of the product in patients with cardiac failure is also included in the indication, and the Committee acknowledged that this indication is not extended to patients in the absence of the T2D diagnosis.

In reviewing the printed article, the Committee noted that the physicality of the materials may have had a bearing on its decision had that material been provided to the Committee. The Committee recognised that the advertisement was printed over two pages with a crease separating the pages. When viewed as a flat-laid spread, the Committee acknowledged that the required mandatory features of a promotional item are included. However, the Committee was of the opinion that the piece was designed to draw the attention to the hHF indication which appears disassociated from the T2D indication if a reader only views the initial pages of the document.

The Committee noted that there are a number of references to T2D in the piece, noting that it has overall balance in qualifying the patient population. However, the Committee agreed that in creating the piece, AstraZeneca did not take into account that a reader may only read one page at a time and therefore the placement of the qualification did not provide balance on each page of the advertisement. In this regard, various Committee members expressed the view that the material was capable of misleading the reader.

The Committee agreed by majority decision that the placement of the claims and associated qualifiers could lead a reader to be misled into thinking these products could be prescribed for hHF in the absence of a T2D diagnosis.

The Committee then turned to the article published on *AusDoc.PLUS* titled *"Which diabetes drug is effective against heart failure?".* The Committee noted AstraZeneca's response that the article was a draft piece that had been placed on a searchable pre-production section of its website by the AusDoc team. The Committee noted it was not live and was only viewed by two HCPs. When finalised, the approved article was published under the heading *"which therapy for T2DM is indicated to reduce the risk of hospitalisations for heart failure?"*.

The Committee acknowledged the intercompany dialogue (ICD) that inferred AstraZeneca was not prepared to provide the revised article and agreed that a company is not required to provide updated material to a complaining company. If a company wishes to demonstrate remediation steps taken they may, however there are no requirements for what must or must not be provided to a complaining company. The Committee agreed that it was asked to deal with the article as initially published (not the revised article). The Chair further noted that the complaint included allegations that ICD was not carried out in the spirit of the Code. The Code affirms that ICD is an important and valuable part of the Code of Conduct Complaints process, and that dialogue should be conducted openly with accurate minutes taken.

Notwithstanding the above, the Committee agreed that the draft article in question was misleading. It failed to identify the patient population and suggested that only one product is effective against heart failure, whether diabetes is present or not, and referred to FORXIGA only. The Committee agreed unanimously that this article is in breach of the Code of Conduct.

The Committee agreed by majority that the printed advertisement breached Sections 1 and 2 of Edition 19 of the Code and the article breached Section 1. The Committee agreed unanimously that there was no breach of Section 1.1 of Edition 19 of the Code in either piece.

The Committee were of the opinion that the presentation of information in the advertisement did not support principles of quality use of medicines, as it did not allow the clinician to have sufficient information in front of them to make an adequate decision. The Committee also agreed that the presentation did not satisfy the principle of supporting proper assessment of risks and benefits. Therefore, the Committee agreed by majority decision that this advertisement was in breach of Overarching Principles 1 and 7.

<u>Complaint 2: Insufficient qualification and inappropriate inclusion of promotion for QTERN in material promoting claims for reduction in hospitalisation for heart failure</u>

The Committee discussed the FORXIGA Family Dosing Guide which includes the sections 'FORXIGA Today', 'FORXIGA Family', 'Dose Guide', and 'Safety'. The Guide includes information on FORXIGA, XIGDUO XR, and QTERN. The Committee noted that the Alliance allege the inclusion of QTERN, which has a special warning for use in patients with cardiac failure, in a document that is focussed on the benefits of these products in hHF represents a patient safety issue.

The Committee recognised that the materials have been retracted and revised by AstraZeneca as a result of the ICD, however the Committee made its decision on the basis of the materials as presented in the complaint.

The Committee reviewed the FORXIGA Family Dosing Guide and noted that the overall design of the materials is to convey that these products are a group of medicines that a clinician can choose from to help patients with a variety of

T2D profiles. The Committee agreed that the emphasis in the design is around the new indication for hHF, and that QTERN is mentioned on 2 of the pages. The Committee agreed that in using the word *'Family'* in the guide suggested that all three products were indicated for use in hHF, when QTERN does not carry that indication. The Committee noted that although there were a number of disclaimers present when QTERN was mentioned, the renal impairment and heart failure risks were not sufficiently expressed and could lead to confusion given the context of the advertisement (being the inclusion of QTERN in the '*Family'* group).

The Committee unanimously agreed that FORXIGA Family Dosing Guide breached Section 1 of Edition 19 of the Code. The Committee agreed unanimously that there was no breach of Sections 1.1 or 2 of Edition 19 of the Code. The Committee noted that, while it was not alleged by the complainant, this material did not contain the mandatory information set out in Section 2.2 of the Edition 19 of the Code in that it did not include appropriate Minimum Product Information.

The Committee were of the opinion that the FORXIGA Family Dosing Guide did not support the principles of quality use of medicines, nor was it balanced or contain sufficient evidence to support the proper assessment of risks and benefits. Therefore, the Committee agreed by majority decision that this advertisement was in breach of Overarching Principles 1, 3, 7, and 8.

<u>Complaint 3: Misleading claims for FORXIGA and XIGDUO XR for the primary and secondary prevention of hospitalisation for heart failure</u>

The Committee reviewed the promotional brochure which details the DECLARE-TIMI 58 trial and claims for FORXIGA and XIGDUO XR. Specifically, the Committee noted the claim "*FORXIGA: The only SGLT2i indicated for the prevention of hospitalisation in heart failure"* featured on page three under the heading PREVENT. This page also includes information on primary prevention and secondary prevention linked by a graphic featuring a heart with a tick, a graphic which is used consistently throughout the materials to represent FORXIGA'S new indication for hHF.

The Committee recognised that primary and secondary prevention have generally understood meanings in both literature and the profession. The Committee noted that the piece included a footnote identifying what both terms meant in context of the piece. The Committee recognised that the information contained on this page is consistent with the PI, as well as the DECLARE-TIMI 58 trial.

The Committee agreed unanimously that the use of primary and secondary prevention as presented in the DECLARE Brochure were not in breach Sections 1, 1.1, and 2 of Edition 19 of the Code. Further, the Committee agreed unanimously that no breach of overarching principles 1, 3, 7, or 8 was found.

<u>Complaint 4: Off-label major claims for FORXIGA and XIGDUO XR for renal-specific composite endpoint based on exploratory data</u>

The Committee noted that this complaint centred on renal-specific claims contained in both the FORXIGA Family Dosing Guide and the DECLARE Brochure which the Alliance alleges misled by omission, oversimplified the DECLARE-TIMI 58 trial dataset, are based on exploratory data, and are not consistent with the PI.

The Committee reviewed the DECLARE-TIMI 58 trial, noting that the study is a non-inferiority study (NI) with two co-primary endpoints, which resulted in the new indication for hHF and is included in the PI. The Committee also noted that the PI states that *"the composite of confirmed sustained eGFR decrease, ESRD, renal or CV death was a secondary variable in the DECLARE study. Because confirmatory testing stopped before the secondary variables were addressed, the analyses of the secondary variables should be considered exploratory."*

The Committee noted that in the pieces, AstraZeneca utilise this data set to support claims that the product results in renal risk reduction, this claim derived from the renal-specific composite. These claims are given the same prominence as claims for reduction in hHF in the promotional material. Further, the Committee noted the inclusion of a nominal *p*-value attributed to the renal-specific composite exploratory endpoint. The Committee recognised that this statistical analysis of the exploratory endpoints, notably the renal composite endpoint, were not in the DECLARE-TIMI 58 trial nor in the PI.

The Committee acknowledged that the renal-specific claims include qualification that it is a pre-specified exploratory endpoint, however the Committee disagreed with the assertion by AstraZeneca that it was appropriate to base claims on this data. The Committee were of the opinion that such claims would not be consistent with the PI, and overstate the indication beyond that claimed in the DECLARE-TIMI 58 trial. The Committee agreed that using data to support these claims to a level beyond what is found in the DECLARE-TIMI 58 trial and the PI is misleading and do not meet the

requirements of Section 1.1. The Committee further observed that the DECLARE-TIMI 58 trial and PI both stated that these data should be considered hypothesis-generating, and agreed that such claims as found in the advertising material may suggest to a reader that the renal benefits have been proven.

The Committee discussed when it would be appropriate to use such data in promotional items. The Committee agreed that all data should be consistent with the PI. Further, companies are able to use any data as primary references for claims where there is a strong evidentiary basis that supports claims made. Companies should avoid presentations that infer such use (such as in these renal-specific claims) would be on-label. Further, the Committee agreed that, in this instance, the inclusion of the nominal *p*-value was inappropriate. While data supporting the renal claims had subsequently come to light, outside the DECLARE-TIMI 58 trial, it was not included in the PI, and the reference containing the data had not been submitted in support of the renal claims.

The Committee agreed unanimously that the pre-specified exploratory endpoints used in renal-specific claims was in breach of Sections 1, 1.1, and 2 of Edition 19 of the Code. The Committee were of the opinion that such data did not support the principles of quality use of medicines, nor was it balanced or contain sufficient evidence to support the proper assessment of risks and benefits. Therefore, the Committee agreed by unanimous decision that this advertisement was in breach of Overarching Principles 1, 3, 7, and 8.

Complaint 5: Misleading claims and inappropriate qualification for XIGDUO XR and QTERN promotion

In this final complaint, the Committee noted that the Alliance queries the use of 'simple' in the FORXIGA Family Dosing Guide. The Committee further noted that, as previously discussed in above complaints, a number of changes had been agreed by the companies during ICD. These changes significantly amend the statements in the FORXIGA Family Dosing Guide to omit QTERN references; and include additional qualification to the dosing claims.

The Committee observed from the FORXIGA Family Dosing Guide that the products in the range were a single 10mg dose of dapagliflozin, and acknowledged that other combination products in the therapeutic range have multiple dose permutations. The Committee noted that as a dosing guide, the document outlines clearly the single dose strength in the products advertised.

The Committee agreed unanimously that the claim *"Simple 10mg dapagliflozin dose across all presentations"* was not in breach Sections 1, 1.1, and 2 of Edition 19 of the Code. Further, the Committee agreed unanimously that no breach of overarching principles 1, 3, 7, or 8 was found.

The Committee were of the opinion that, while the word *simple* was not in breach of the Code, a more satisfactory word to describe the dosing permutations would be *consistent*.

Sanctions

The Committee discussed classification of the breaches found in the materials, and noted that the breaches had a potential (although likely not significant) safety impact on patient wellbeing relating to the way the product may be prescribed. Therefore, the Committee agreed unanimously that this constituted a moderate breach of Edition 19 of the Code of Conduct.

The Committee discussed requirements to correct misconceptions among prescribers related to this material. The Committee agreed that corrective action for the materials published in Australian Doctor and *AusDoc.Plus* would be counterintuitive given the small number of healthcare professionals exposed to the error before it was corrected. The Committee agreed, however, that the FORXIGA Family Dosing Guide claims that could lead to prescribers making the assumption that QTERN was indicated for hHF even in individuals without diabetes.

The Committee agreed unanimously to impose the following sanctions:

- All claims and materials found in breach should be withdrawn, and should not be used in the same or similar format in the future without the addition of suitable qualifiers or substantiating evidence
- Issue a corrective letter to healthcare professionals who received the FORXIGA Family Dosing Guide clarifying that QTERN was not indicated for hHF. A template letter would be drafted by the Code Committee.
- Pay a fine of $100,000