

COMPLAINT OUTCOME

1185 - Promotional material related to FORXIGA®

DETERMINATIONS OF THE MEDICINES AUSTRALIA CODE OF CONDUCT AND APPEALS COMMITTEES

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.

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. A complaint is not deemed finalised until both parties have advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Committee's Reasons) or, in the case of an appeal, the Appeals Committee Reasons have been provided to both parties.

This report is an extract of the minutes of the complaint heard by the Code Committee on 22 June 2026 and an extract of the minutes of the appeal heard by the Appeals Committee on 20 August 2026.



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SUBJECT COMPANY

AstraZeneca

PRODUCT

FORXIGA® (dapagliflozin)

COMPLAINANT

Boehringer Ingelheim

COMPLAINT

Boehringer Ingelheim alleged that AstraZeneca engaged in multiple breaches of the Code through the promotion of Forxiga®. The complaint concerned two promotional materials directed at healthcare professionals, being a Forxiga® New PBS Listing electronic direct mail (EDM) and a leave-behind (together, “**the Materials**”). The complaint focused on AstraZeneca’s use of the statement that Forxiga® can be initiated “irrespective of uACR” and whether this promoted Forxiga® beyond its approved indication.

The central issue concerned a discrepancy between the Therapeutic Goods Administration (TGA)-approved indication and the broader Pharmaceutical Benefits Scheme (PBS) eligibility criteria. Forxiga® is approved by the TGA for use in “proteinuric CKD” only, and the complaint centred on whether the Materials conveyed that treatment can be commenced across the expanded PBS population, including patients both with and without proteinuria. Boehringer Ingelheim argued that AstraZeneca’s reliance on PBS-based claims - such as “irrespective of uACR” - promoted Forxiga® beyond its TGA-approved indication.

SECTIONS OF THE CODE (EDITION 20)

- **Overarching 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.
- **Overarching 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 1.1(a):** Balance
- **Section 1.2:** Substantiating Data

RESPONSE TO THE COMPLAINT

AstraZeneca disagreed that the Materials breached the Code, and maintained that the purpose of the Materials was to provide a PBS update, aligned with an earlier TGA decision to remove strict uACR thresholds.

They argued that the Materials should be assessed as a whole and in context, with its overall intent considered. In particular, they clarified that the phrase “irrespective of uACR” referred to the removal of a fixed uACR threshold for PBS access, rather than suggesting that uACR should be disregarded in clinical diagnosis. They maintained that the Materials did not promote prescribing in non-proteinuric CKD, but instead reflected the updated reimbursement criteria.

CODE COMMITTEE DECISIONS

The Code Committee considered the complaint and determined that breaches of the Code had occurred. Sanctions were applied by the Code Committee. See the table of Committee Decisions below, and the Code Committee Reasons on pages 4-7.

APPEAL

The subject company appealed all findings of the Code Committee where breaches had been determined, and sought to have the sanctions withdrawn. The finding in relation to Section 1.2 was not appealed. The complainant did not appeal any findings of the Code Committee but submitted that the appeal should be dismissed and the sanctions maintained.

APPEAL COMMITTEE DECISIONS

The Appeals Committee upheld all findings of the Code Committee, reconfirming breaches of the Code. The sanctions were upheld. The Reasons for their Decisions are on pages 7-10.

Summary of Decisions

Area of the Code	Code Committee Decision	Appeals Committee Decision	Code Committee Sanctions	Appeals Committee Sanctions
Overarching Principle 3	Breach (unanimous)	Breach (unanimous)	• \$120,000 fine (moderate breach) • Withdrawal of the material found in breach and any other promotional material containing the claim found in breach • The claim found in breach must not be used in the same or similar form • No corrective action	Code Committee decision upheld Due to the decisions of the Code Committee being upheld in their entirety, Medicines Australia retained the appeal bond.
Overarching Principle 8	Breach (unanimous)	Breach (unanimous)		
Section 1.1(a)	Breach (unanimous)	Breach (unanimous)		
Section 1.2	No Breach (majority)	Not appealed		

CONTEXT

Forxiga® is indicated to reduce the risk of progressive decline in kidney function in adults with proteinuric chronic kidney disease (CKD).

Both materials contained prominent statements, including:

- Forxiga® can now be initiated “irrespective of uACR” (“**the Claim**”)
- Broader positioning statements such as “Forxiga® in CKD has been simplified” and “New simplified protection for your CKD patients”.

CONTEXT (continued)

The Committee considered the term “proteinuric CKD” and noted that this requires a clinician to assess for, and confirm, the presence of abnormal protein in the urine prior to prescribing. The urinary albumin-to-creatinine ratio (**uACR**) is used as a screening test for proteinuria, with a value above the established reference range considered abnormal.

Against this clinical framework, the Committee noted that the descriptor “proteinuric CKD” remained a defining element of the TGA-approved indication.

The PBS eligibility criteria were updated, effective 1 February 2026. These changes were implemented as a class-aligned approach across SGLT2 inhibitors, including Forxiga®.

The revised criteria removed a minimum uACR requirement for certain patients and instead linked eligibility more broadly to eGFR ranges, including patients with any level of uACR where eGFR is between 20 and <45 mL/min/1.73m², and those with higher uACR thresholds at higher eGFR ranges.

The Committee considered the submission that the PBS update did not occur in a regulatory vacuum but rather followed the April 2025 change to the approved indication, with the effect of streamlining patient access criteria in a manner said to be consistent with the TGA indication. However, the Committee was not satisfied that this linkage had been adequately demonstrated and noted that it was not in a position to determine regulatory intent.

In any event, this did not alter the Committee's focus, which was on how these changes were communicated to healthcare professionals in the Materials, rather than the intent underpinning them.

CONSIDERATION OF PROCEDURE & SCOPE BY THE CODE COMMITTEE

The complaint initially comprised three concerns raised by the complainant; however, two were resolved through intercompany dialogue. As a result, only the remaining allegation proceeded to adjudication as Complaint 1185.

The complaint also alleged a breach of the Therapeutic Goods Act in relation to off-label promotion. The Committee noted that its role was not to assess compliance with the Therapeutic Goods Act, but to adjudicate on matters under the Medicines Australia Code of Conduct. Accordingly, the Committee did not consider this aspect of the complaint, as it fell outside scope.

The subject company submitted that a press release referenced in the complaint had not been included in inter-company dialogue (“**ICD**”) and therefore constituted ‘new material’ to which it had no prior opportunity to respond. The Committee agreed and determined it was not appropriate to consider the material. While noting the complainant’s position that the press release was provided for contextual purposes only, the Committee considered that it should have been included in ICD.

The complainant submitted that references to their own materials promoting Jardiance® fell outside the scope of the complaint and risked broadening the issues. The Committee noted that no adjudication was sought on this material but accepted it was included to support the subject company’s arguments, was raised during ICD, and that the complainant had an adequate opportunity to respond; accordingly, it was not disregarded.

The subject company raised concerns regarding the complainant’s conduct in finalising ICD minutes and related matters and requested that the Committee have regard to this conduct as inconsistent with good faith obligations under the ICD Standards. The Committee noted that, in the absence of a formal counter-complaint regarding a potential breach of clause 15.5, they were not relevant to its consideration.

CONSIDERATION OF THE COMPLAINT by the CODE COMMITTEE

- The Committee accepted that the purpose of the materials was to communicate a PBS update to healthcare professionals, noting that the EDM clearly conveyed this intent through the subject line “PBS update.”
- In response to concerns raised by the subject company, the Committee noted that communicating a PBS update is not, of itself, necessarily promotional or involving ‘off label’ promotion. However, where PBS eligibility extends beyond the approved indication, there is an inherent risk that such communication may be understood as promoting off-label use - an issue addressed in Medicines Australia’s Developing Compliant Promotional Claims Guidance, warranting heightened scrutiny and careful framing to mitigate that risk. In this case, the PBS update was conveyed through promotional material, which further elevated that risk.
- The Committee considered the combined presentation of the claims “New simplified protection” and “irrespective of uACR (NEW)” both highlighted in bold red and positioned in close proximity within the headline structure of the page. The use of identical visual emphasis draws the reader’s eye between the two phrases, reinforcing them as a single, linked message. In the context of this efficacy-focused promotional material, the Committee considered it reasonable that this combined presentation could be interpreted as encouraging prescribing aligned with PBS criteria rather than the approved indication. The resulting message was inconsistent with the approved Product Information.
- As presented, the Committee observed that a healthcare professional could reasonably prescribe in line with the material without appreciating that such use may be off-label. The Committee considered that the material did not adequately clarify this distinction and instead emphasised the PBS criteria, which contributed to its overall view that the communication encouraged prescribing aligned with the PBS update rather than the approved indication.
- The Committee considered the use of the phrase “irrespective of uACR”. The Claim may not have been intended to suggest prescribing in patients with non-proteinuric CKD; however, the ordinary and practical meaning of the phrase, particularly in the way it was presented, is that Forxiga® may be used regardless of protein status. In this context, the Committee considered the Claim was likely to imply suitability in a range of CKD patients including those without proteinuria, which falls outside the approved indication.
- Building on this, the Committee confirmed that the phrase “irrespective of uACR” could be understood by a healthcare professional as providing a ‘green light’ to initiate treatment without first undertaking uACR assessment. The Committee emphasised that “irrespective of uACR” is not equivalent to “any level of uACR,” which more accurately reflects the intent of the PBS eligibility criteria. Rather, the use of “irrespective” may be interpreted as removing the need for uACR testing altogether notwithstanding that uACR assessment remains the key determinant of whether a patient has proteinuric CKD.
- The Committee noted that the EDM states “Forxiga® can now be initiated irrespective of uACR”. The use of “initiated” was considered to relate to prescribing, rather than PBS access. As the PBS update concerns access criteria, this wording was considered to blur the distinction between access and use, contributing to a broader prescribing message than was appropriate.
- The Committee considered the Claim in context, including the surrounding material and intended audience. Although the materials made repeated reference to “proteinuric CKD,” the Committee was not satisfied that the placement of these qualifications adequately mitigated the practical effect of inviting prescribers to consider Forxiga® “irrespective of uACR”, which by extension includes patients with a uACR <3 mg/mmol (and therefore with non-proteinuric CKD; see point 21). This was particularly the case where the Claim appeared in bolded text and was therefore highlighted, such that it could be inferred a busy healthcare professional reading the materials would focus on the headline claims and less on the further explanatory text appearing in less prominent terms elsewhere in the materials.

CONSIDERATION OF THE COMPLAINT by the CODE COMMITTEE (continued)

- The Committee considered the defence that the Claim did not imply use in patients with no measurable proteinuria and would be reasonably interpreted as referring to the absence of a specific uACR threshold for PBS access within the relevant eGFR range. However, it was not satisfied that this was the only reasonable interpretation. The Committee, comprising experienced healthcare professionals, considered that the phrase 'irrespective of uACR', particularly in the context of prominent PBS-anchored messaging, was capable of broader interpretation. It could reasonably be understood by some healthcare professionals to suggest treatment without regard to proteinuria status, thereby extending beyond the limits of the approved indication.
- In evaluating how the Claim may be understood, the Committee also considered the perspective of the likely audience. While it was submitted that the materials were directed to specialist healthcare professionals experienced in managing proteinuric CKD, the Committee did not have sufficient evidence to conclude the audience was so limited. It therefore considered it reasonably likely that the materials may also have been received by general practitioners, whose broader scope of practice nonetheless includes management of CKD.
- The Committee understood that the clinical evidence does not support use in non-proteinuric CKD. In particular, it noted that the DAPA-CKD trial enrolled only patients with established proteinuria (uACR 22.6–565 mg/mmol [200–5000 mg/g]), and that there is no clinical trial evidence referred to in the clinical trial data section of the PI supporting the efficacy of Forxiga® in patients without proteinuria. The Committee considered that the primary concern was whether the Claim accurately reflected the approved indication and could be interpreted as promoting use beyond the approved proteinuric CKD population. Any absence of supporting evidence for use irrespective of uACR was secondary to this broader issue of ensuring that claims are consistent with both the approved Product Information and the relevant clinical evidence.
- The Committee determined that, because the approved indication is limited to proteinuric CKD -requiring evidence of proteinuria/albuminuria – promoting use 'irrespective' of a protein/albumin measure misrepresented the indicated population and conveyed a misleading implication.
 - On that basis, and by unanimous decision, the Committee determined the Material **breached** Overarching 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.*
- The Committee determined that recent changes to PBS reimbursement criteria were promoted in a manner that encouraged use of the product in a broader patient population than indicated and, in doing so, was inconsistent with the Product Information (PI), regardless of the source on which the Claim was based.
 - On that basis, and by unanimous decision, the Committee determined the material **breached** Overarching 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.*
- The material lacked balance, using claims in a manner not consistent with the PI, broader positioning statements, and presentation to overstate the approved use of Forxiga® without adequate context - for example, by suggesting that a uACR assessment was not required.
 - On that basis, and by unanimous decision, the Committee determined that the material **breached** Section 1.1(a): *Companies are responsible for ensuring they provide balanced information on products to support their appropriate use consistent with the Product Information (PI).*

CONSIDERATION OF THE COMPLAINT by the CODE COMMITTEE (continued)

- By majority decision, the Committee determined that there was **no breach** of Section 1.2. The complainant did not specify which subsection of Section 1.2 was alleged to have been breached, and while the Committee considered Section 1.2(c) (substantiating data should be consistent with the body of evidence), it was not satisfied that a breach had been established by reference to that provision because the complaint was not directed at substantiating data but rather off-label promotion by reference to the PI.

Sanctions

- The Committee determined the material had no significant safety implications to patient wellbeing but would likely have a moderate effect on how the medical profession would prescribe the product. For these reasons, the Committee was satisfied the breaches arising from the material should be categorised as **moderate**.
- The Committee considered what sanctions were appropriate, having regard to the following factors:
 - Nature and extent of the material (including whether the breach should have been evident to the subject company)
 - Breadth and length of the activity (how widely the materials were distributed or promoted and how long the materials were in circulation)
 - Number and type of breaches
 - Context of the activity (including circumstances, ICD and any explanation provided by the company).
- The Committee noted that the subject company made reasonable concessions in its ICD during the process.
- The Committee also noted that the subject company had indicated that the EDM was used only once, and that it had already amended the Materials to add further explicit references to "proteinuric CKD" in and around the table containing the Claim.
- However, because the breaches related to promotion beyond the approved indication, the Committee considered that additional care should have been exercised when communicating changes to PBS criteria where these extend beyond the approved indication. In this context, the Committee regarded the breach as significant and one that should be taken seriously. For this reason, the fine was set at its determined level.
- The Committee also acknowledged the challenges arising where different Government frameworks are not aligned, and the complexity this creates for companies in communicating responsibly with healthcare professionals, while meeting compliance obligations. However, as demonstrated in this complaint, consistency with the Product Information remains critical in promotional contexts.
- The Committee did not impose corrective action, determining that a monetary fine coupled with the withdrawal and cessation of the use of the claims found in breach would be adequate.
- In determining the overall package of sanctions, the Committee considered that a mid-range fine was appropriate within the context of the moderate breach finding. The Committee imposed the following sanctions:
 - Single monetary fine of \$120,000.
 - Withdrawal of the material found in breach (where still in circulation) as well as any other promotional material containing the Claim found in breach.
 - The Claim found in breach must not be used in the same or similar form.

CONSIDERATION OF THE COMPLAINT by the CODE COMMITTEE (continued)

Sanctions (continued)

- In keeping with this decision, the Committee noted that future promotion of Forxiga must remain within the bounds of the approved Product Information (PI). This does not prevent appropriate and carefully balanced communication of relevant PBS reimbursement information.
- In this complaint, the Committee considered that the Claim breached the Code but also noted that the broader positioning statements and contextual messaging surrounding the Claim were relevant to its assessment of the overall promotional message conveyed. However, those statements were not themselves the subject of the breach finding, which related specifically to the Claim.

CONSIDERATION OF THE COMPLAINT by the APPEALS COMMITTEE

The Appeal Material and Process

- Section 15.7 of the Medicines Australia Code of Conduct provides that an appeal is a rehearing of the original complaint and that the Appeals Committee may affirm, set aside, or vary findings and/or sanctions of the Code Committee. The Appeals Committee shall not uphold an appeal unless it is “persuaded that the findings of the Code Committee, or the sanction imposed by it, involved an error on the basis of which they should be set aside or varied”.
- The subject company argued that the Code Committee made three key errors:
 - Incorrectly interpreted the phrase "irrespective of UACR", leading to an erroneous conclusion about how a reasonable HCP would understand the claim and materials,
 - Applied the incorrect standard for the interpretation of the claim, and
 - Incorrectly assumed that healthcare professionals would focus primarily on headline statements rather than explanatory content; and general practitioners would be more likely to misinterpret the materials than other healthcare professionals.
- In response, the complainant argued that the appeal identified no material error of fact, process, or principle, but merely repeated arguments already considered by the Code Committee. The complainant maintained that the key issue was whether the materials conveyed a promotional message inconsistent with the approved Product Information (PI) for Forxiga®, and that the Code Committee was entitled to conclude that they did so.
- The Appeals Committee was satisfied that it was appropriate, in determining the appeal, to consider the following material:
 - the original complaint materials from the complainant;
 - the original complaint materials from the subject company;
 - the appeal material submitted by the subject company;
 - the appeal material submitted by the complainant;
 - the oral submissions on behalf of the subject company and the complainant, including their responses to questions posed by members of the Committee; and
 - the Code Committee's reasons.

The findings in relation to the first error: construction of the phrase “irrespective of UACR”

- The subject company submitted that, having regard to the Claim in the context of the Materials, healthcare professionals would understand the indication to be for proteinuric CKD and would not interpret the Materials as promoting the use of Forxiga® in patients where CKD is non-proteinuric or without albuminuria, or in circumstances where a UACR assessment has not been conducted.
- The Appeals Committee did not accept this submission and affirmed the findings of the Code Committee. In the Appeals Committee's view, the Claim, when considered in the context of the Materials as a whole, could reasonably imply that Forxiga® was suitable for a broader range of CKD patients, including those without proteinuria, and that treatment could be initiated without first undertaking a UACR assessment.
- The subject company submitted that no reasonable healthcare professional would interpret the Claim in this manner. However, no evidence was provided to support that submission. While the Committee understood that stakeholder feedback had informed the development of the Materials, no evidence was presented demonstrating that healthcare professionals consistently interpreted the Claim as being confined to patients with proteinuric CKD.
- The Appeals Committee also noted that both the Code Committee and the Appeals Committee included members with relevant healthcare expertise and experience. The unanimous conclusions reached by both Committees reinforced the view that a reasonable healthcare professional could have interpreted the Claim that way. For the reasons articulated by the Code Committee, the Appeals Committee found no reason to depart from that conclusion.
- Consistent with the approach adopted by the Code Committee, the Appeals Committee considered the Claim in the context of the Materials as a whole, rather than in isolation. The Appeals Committee accepted that “irrespective of uACR” is not synonymous with initiating treatment “without” assessing uACR. However, it considered that distinction to be of limited significance. The Appeals Committee noted that the Claim was prominently presented through its use of colour, placement and design elements and was linked to other promotional messages, including “New Simplified Protection”. In that context, the distinction was insufficient to prevent the Claim from being understood as conveying that Forxiga® may be initiated without first confirming proteinuric CKD. At best, the message was ambiguous and lacked the clarity required to ensure consistency with the Product Information.
- In relation to the leave-behind, the Appeals Committee noted that the Claim appeared prominently within the six-page roll-fold design and formed part of a single promotional piece. However, the Appeals Committee considered that the document could readily be folded so that only the page containing the Claim was visible. The Appeals Committee did not suggest that this was the intended or usual manner of use. Rather, it considered this possibility relevant when assessing whether the broader context of the material was sufficient to qualify or offset the message conveyed by the Claim. In those circumstances, the Appeals Committee was not persuaded that reliance could be placed solely on references to proteinuric CKD elsewhere in the leave-behind to clarify the Claim's meaning.
- The Appeals Committee also considered whether “irrespective of uACR” and “any level of uACR” meant the same thing. It noted the Code Committee's observation that “any level of uACR” more accurately reflected the PBS criteria. However, the issue was not whether better wording was available. Rather, the Appeals Committee considered that the Code Committee's observation highlighted the ambiguity of the Claim. In particular, the Claim did not clearly convey that Forxiga® is approved only for patients with proteinuric CKD and could reasonably be interpreted as implying that a UACR assessment was not required before treatment initiation. The Appeals Committee therefore concluded that the Claim was inconsistent with the Product Information.

The findings in relation to the first error: construction of the phrase “irrespective of UACR” (continued)

- The Appeals Committee considered the subject company’s submission that a UACR threshold of greater than 3.0 mg/mmol should not apply because it is inconsistent with the approved indication and may limit patient access to treatment. However, the Appeals Committee considered that this was not the substance of the complaint. Rather, the issue was whether the Claim clearly reflected the approved indication, which remains limited to patients with proteinuric CKD. Although the approved indication no longer specifies a minimum UACR threshold, it remains confined to patients with proteinuric CKD. The Appeals Committee did not consider that the Materials clearly communicated this limitation.

The findings in relation to the second error: the Committee applied the wrong objective standard

- The subject company submitted that the Code Committee erred in applying the standard of a “busy healthcare professional” when assessing the Claim. It contended that the appropriate standard was that of a reasonable, suitably qualified and experienced healthcare professional treating patients with proteinuric CKD, and that the Code Committee had introduced unwarranted assumptions regarding the notional healthcare professional's attention to detail and the pressures on their time.
- The Appeals Committee did not accept this submission. In its view, the reference to a “busy healthcare professional” did not establish a different standard from that of a reasonable, suitably qualified and experienced healthcare professional treating patients with proteinuric CKD. Rather, it reflected the real-world circumstances in which promotional materials are ordinarily received and reviewed. A healthcare professional meeting that description may also be operating under clinical and administrative demands, and the Appeals Committee therefore regarded the concepts as compatible rather than mutually exclusive. The Appeals Committee further noted that references to busy healthcare professionals have appeared in other (unrelated) Committee decisions when assessing how promotional claims are likely to be understood in practice.
- The Appeals Committee considered that the reference to a "busy healthcare professional" did not reflect a different standard of assessment. Promotional materials are designed to communicate key messages efficiently through the use of colour, placement, font, emphasis and other design elements. The Appeals Committee considered that these features are relevant to how such materials are understood by healthcare professionals generally, irrespective of how busy they may be. Accordingly, the Appeals Committee had regard not only to the detailed content of the Materials, but also to the overall impression conveyed to a reasonable, suitably qualified and experienced healthcare professional treating patients with proteinuric CKD.

The findings in relation to the third error: the Committee operated under erroneous assumptions

- The subject company submitted that the Code Committee suggested that healthcare professionals would ignore diagnostic requirements or lacked knowledge regarding the diagnosis and management of CKD. The Appeals Committee did not accept that characterisation. Rather, it understood the reference to a “green light” as reflecting the concern that the Materials were capable of conveying that Forxiga® could be prescribed by reference to the broader PBS criteria, irrespective of uACR values or the confirmation of proteinuric CKD. In that sense, the Materials could be interpreted as signalling that treatment may be initiated irrespective of uACR values, and therefore without first confirming proteinuric CKD. The Appeals Committee considered that the obligation to communicate promotional messages clearly and consistently with the approved Product Information rests with the sponsor company. For the reasons set out above, the Appeals Committee did not consider that the Materials met that standard.
- The subject company submitted that the Code Committee had erred in assuming that general practitioners would be more likely to misinterpret the Materials. The Appeals Committee did not consider this issue material to its assessment. The Materials were directed to both general practitioners and specialists involved in CKD management, and therefore the Appeals Committee understood this to be a broader healthcare professional audience rather than a narrow group with specialist expertise in proteinuric CKD. In the Appeal Committee’s view, the breadth of the intended audience reinforced the need for the Claim to communicate the approved indication clearly and unambiguously.
- The Appeals Committee further considered that the relevant question was not whether healthcare professionals possessed sufficient knowledge to identify the limitations of the approved indication independently. Even healthcare professionals experienced in the management of CKD may reasonably take a prominent promotional claim at face value, particularly where it is framed as “new”, “simplified” and prescribing-focused. The Appeals Committee therefore did not accept that the knowledge or experience of the intended audience cured the ambiguity created by the Claim.

Summary, and the findings in relation to the sanctions

- The subject company submitted that it had proactively amended the leave-behind following concerns from the complainant, while maintaining that no breach had occurred. The Appeals Committee acknowledged these actions and the company’s willingness to reflect on and revise the Materials. However, the Appeals Committee noted that the scope of the appeal was confined to an assessment of the Materials as they existed at the time of the complaint and the Code Committee’s subsequent determination. Accordingly, the Appeals Committee did not consider the amended leave-behind further.
- The Appeals Committee agreed with the Code Committee’s conclusions.
- The subject company requested that the Appeals Committee overturn the Code Committee’s findings and withdraw the sanctions imposed. The subject company further submitted that the sanctions were disproportionate and failed to adequately recognise their cooperative approach throughout the process. The Appeals Committee noted that the sanction imposed was not at the upper end of the range of penalties available under the Code and that, on its face, the Code Committee’s reasons appeared to take into account the subject company’s cooperation and concessions during the intercompany dialogue process. Having unanimously affirmed all findings that were the subject of the appeal, the Appeals Committee was not persuaded that there was a basis to interfere with the sanctions imposed and therefore made no changes to them.
- With regards to the Appeal bond of \$20,000 paid by the subject company, the Appeals Committee instructed this appeal bond be retained by Medicines Australia, reflecting the outcome of the appeal.