Medicines Australia

Better health through research & innovation

COMPLAINT OUTCOME

1172 - Media Statement re NUBEQA

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 Reasons) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties.

This report is an extract of the minutes of the complaint heard on 20 November 2023.

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DOWNLOAD THE CODE

The Code of Conduct and all associated materials are available on the Medicines Australia Website

COMPLAINT 1172 - Media Statement re Nubeqa

SUBJECT COMPANY	PRODUCT	COMPLAINANT
Bayer	**Nubeqa (darolutamide)**	Astellas

SECTIONS OF THE CODE

Astellas alleged that Bayer had breached Section 13.2: Educational Information and Disease Awareness.

In response, Bayer alleged that Astellas had breached Section 16.4: Abuse of the Code.

COMPLAINT (by Astellas)

Astellas alleged that the media statement Bayer published on their website contravenes the Code and the Therapeutic Goods Act because "*a reasonable person would regard the statement (or at least parts of it) as an intention by Bayer to 'advertise' its new combination prostate cancer therapy to the general public*".

Astellas asserted the media statement went beyond informing the general public of the availability of NUBEQA, and took the view that it "*incited hope in a vulnerable population by positioning NUBEQA as an effective and accessible new treatment*" and "*was likely to stimulate demand for NUBEQA and drive inappropriate patient-led prescribing.*" They also believed that promoting a compassionate access program to the general public was inappropriate.

The media statement was published on the Bayer Australia website, dated 22 March 2023 and accessible by the general public. Astellas raised their concerns with Bayer on 20 June 2023. In response, Bayer removed the statement from their website and acknowledged it should have included a statement that the appropriate treatment for each patient is for their healthcare professional to decide. Intercompany dialogue (ICD) was held on 10 August to resolve the other aspects of the complaint, after which resolution was not achieved and Astellas sought the Code Committee to adjudicate on the matter.

RESPONSE (by Bayer)

Bayer expressed their disappointment with the complaint having been escalated to the Code Committee as they took the view "*that inter-company dialogue was ongoing and on-track for complete resolution at the intercompany level. This is not evident from the Astellas submission.*"

In conceiving the media statement, Bayer believed it to be consistent with Code requirements, which was communicated to Astellas in the ICD. However, in internal discussions post-ICD, Bayer re-reviewed and agreed it could undertake the actions requested by Astellas in their "*commitment to resolve disputes where possible at the intercompany level.*" Additionally, Bayer asserts that Astellas had misinterpreted the Code and Section 13.2 is not intended to prohibit companies from issuing product-specific media statements to inform the general public of the availability of new products or indications.

Bayer offered verbally and in writing to undertake these actions and requested a further ICD meeting. These were omitted from the complaint submitted by

Astellas. Hence, Bayer requested that Medicines Australia not accept the complaint and re-direct Astellas back to ICD. This request was not granted.

Bayer requested the Committee consider if the complaint had effectively already been resolved given the actions undertaken by Bayer, and whether Astellas has abused the Code (16.4) because they failed to disclose critical details of ICD and failed to respond to Bayer's requests for further ICD.

RESPONSE TO 'ABUSE OF THE CODE' (by Astellas)

Astellas maintained that the ICD undertaken on 10 August had concluded without resolution, and both parties maintained two very different opinions. Astellas understood that Bayer continued to maintain that its actions were not in breach of the Code and as such, Bayer's proposed undertakings "were *not sufficient to resolve this matter*". Astellas considered that the allegation that the ICD process was ongoing was both mischievous and misleading.

Astellas acknowledged the omission of 2 subsequent correspondence pieces but stated this was inadvertent and rectified this as soon as it was made known.

CODE COMMITTEE DECISIONS

Company	Code	Decision	Sanction
Bayer	Section 13.2	Breach (majority decision)	$120,000 fine (moderate breach)
Astellas	Section 16.4	No breach (unanimous decision)	N/A

CONSIDERATION OF THE COMPLAINT

The complaint concerned a media statement the subject company published on their website in March 2023, relating to a new TGA-approved indication for NUBEQA, as a combination therapy for an advanced form of prostate cancer (‘**the Statement**’). This material was alleged to breach Section 13.2 of Edition 19 of the Code. The Statement had been referenced by the Prostate Cancer Foundation Australia in social media posts.

Following receipt of a complaint by the complainant, the Statement was removed from the subject company’s website. The subject company acknowledged the Statement should have included a comment that the appropriate treatment for each patient is for their healthcare professional to decide, in consultation with the patient. The Committee noted that the subject company had also, since the intercompany dialogue (‘ICD’) meeting and the filing of the complaint with Medicines Australia, re-reviewed the material and taken further actions with respect to the media statement including reviewing internal processes, undertaking training, offering an undertaking not to reference access programs in future media releases and others.

The Code Committee considered the complaint and determined, by majority decision, that the Statement breached 13.2 of the Code. Sanctions were applied by the Code Committee.

In their response to the complaint, the subject company counter-claimed that the complainant had abused the Code, largely because it had failed to re-engage in ICD, and also omitted critical ICD correspondence when submitting the complaint to Medicines Australia. The subject company also argued that the complaint had been resolved given the actions already undertaken by it in relation to the Statement.

The Code Committee considered this argument, as well as the complainant’s response to this allegation, and determined, by unanimous decision, that there was no breach of the Code in relation to Section 16.4.

I*n relation to whether the complaint had been effectively already resolved given the actions undertaken by the subject company:*

In relation to the subject company’s view that the “*complaint has effectively already been resolved given the actions undertaken*”, the Committee agreed the complaint had not been resolved to the satisfaction of both parties and therefore it was appropriate to hear the complaint.

The Committee reinforced previous views expressed by the Code Committee in 2023, specifically the reasons in Complaint 1169, that “*the Code does not prohibit the Committee from considering a matter where one company wishes the Committee to adjudicate and another does not*”, and “*the Code does not expressly preclude or prohibit the Committee from dealing with a complaint in circumstances where no consensus view has been reached by the parties about the resolution of the complaint*.”

The Committee clarified it was not in their remit to determine whether sufficient ICD had taken place. Instead, the Code provides that Medicines Australia makes the decision whether to accept a complaint based on whether “*clearly demonstrated intercompany dialogue had taken place and that, despite the reasonable efforts of the parties, the complaint has not been resolved.*” (Code Section 16.1). The Committee supported the decision made by Medicines Australia to accept

the complaint. It noted that both parties had participated in reasonable efforts at ICD and those minutes, to which both parties agreed, reflected the position of "we agree to disagree".

The Committee noted it would support a decision by Medicines Australia to develop threshold criteria concerning complaint acceptance and ICD, enabling companies and committees to understand clearly whether these thresholds have been met, and therefore allowing both parties to fully understand when a complaint may be made.

In relation to whether the complaint incorrectly applies Code Part D and Section 13.2 to a product-specific consumer-focused media release:

The complainant relied on Part D and Section 13.2 of the Code in its complaint. Part D is entitled "Ethical Interactions with Patients and the General Public". Section 13.2 appears in Part D and provides that, in summary, members of the public should have information on medical conditions and treatments which may be prescribed, that the purpose of such information should be educational and satisfy criteria - one of which is the information must not include reference to a specific prescription product.

In responding to the complaint, the subject company was of the view that the complainant misinterpreted the Code and "...Section 13.2 of the Code is not intended to prohibit Company from issuing product-specific media statements to inform the general public of the availability of new products or indications".

The Medicines Australia Secretariat confirmed the view put forward by the subject company that Section 11 of the Code is the more appropriate section of the Code that would apply to a consumer media release, by listing media as a relevant stakeholder, and that provision does not prohibit reference to a specific prescription product. This understanding has shaped educational advice given by Medicines Australia to the industry through webinars and emails. Similarly, the Code's Principle 6 also would apply to this activity. The Secretariat also confirmed the view put forward by the subject company that Code Section 13.2 is intended to govern disease awareness activities to the general public, and by its nature, educational information on the condition/disease rather than the treatment options.

The Committee considered the arguments of both parties and the Secretariat's comments at length. The Committee considered that neither Section 13.2 nor Section 11 of the Code was directly referable to the conduct in issue in the complaint. Section 13.2 appeared to be directed to disease awareness and other educational campaigns (but was not expressly so limited). Section 11 referred to appropriate communications with relevant stakeholders, including regulators and the media, but did not refer to or provide that statements could be made on a member company's website which were available to members of the general public (not only the media). The Committee noted that Edition 18 of the Code had contained a specific provision dealing with "product specific media statements" (former Section 13.4.1) but that no equivalent provision was contained in Edition 19.

In circumstances where the Code does not explicitly address product-specific consumer media statements, the Committee accepted that there may be differing views on the most appropriate section to apply. Similarly, whilst the Committee agreed the purpose of the Statement in issue was

not to raise awareness of a disease, it acknowledged that the Statement contained information about a disease and therefore could be viewed as a blend of both a product announcement and disease education.

Some members of the Committee further noted that:

- Where the Statement had been made available to the general public it was important that the Code Committee not be restricted in dealing with the complaint because there was no one provision in the Code that clearly applied;
- Part D of the Code was directed to "ethical interactions with patients and the general public" whereas Part C was directed to "appropriate communications with relevant stakeholders" and this Statement had been available to the general public, not only the specified 'stakeholders' such that Section 11 also did not appear to be directly relevant;
- It was difficult to reconcile the content of the Statement with either Section 11 or Section 13.2, and the Code required some clarification;
- One of the reasons that the issue arose was because the Statement was a mixture of a disease awareness campaign and promotional information about the availability of a new indication; and
- The Statement was directed to the public and designed to capture public attention with a view to having patients approach their treating healthcare professionals about the product.

By majority, the Committee determined to address the complaint by reference to Section 13.2 of the Code. This view was reached because:

- This was the section expressly relied upon by the complainant;
- All parties therefore had sufficient notice of the complainant's allegations by reference to that particular provision; and
- Section 13.2 refers to interactions with the general public and in circumstances where the media statement at issue was available to the public, it was arguable that the section was appropriate.

However, given that there was scope for a different view to be taken in respect of the appropriate provision of the Code under which to assess the conduct, the Committee also determined to provide its views on whether a breach of Section 11 and Principle 6 of the Code would have been found had the Committee considered those provisions. For the reasons set out below, the Committee determined that regardless of which section was considered, the material was promotional in nature and therefore would breach both Section 11 and 13.2 of the Code.

The Committee recommended the upcoming 2024 Code Review consider whether it is appropriate for the Code to include a provision directed to the publication of consumer-focused statements (along the lines of Section 13.4.1 of Edition 18).

I*n relation to whether the Committee can consider complaints against sections of the Code not presented in the complaint:*

The Committee noted that, pursuant to Section 16.1 of the Code, the "Complainant has the burden of proving their complaint on the balance of probabilities". The Committee determined that it was not appropriate to adjudicate a complaint against alternative sections of the Code that were not presented in the complaint. The Committee considered that the principle of procedural fairness

requires that both parties have the opportunity to respond to the principles upon which the Code Committee adjudicates.

Related to the above, the Committee requested that the Medicines Australia Secretariat consider, on receiving a complaint where differing interpretations of the Code are being argued, proposing to both parties which provisions of the Code the Secretariat considers are appropriate to assess the conduct complained of, with a view to reaching agreement on this issue and otherwise direct the Code Committee to consider provisions in the alternative, if required and relevant to the matter.

The findings in relation to the Media Statement

It was not made clear to the Committee whether the Statement had been proactively sent to media, or whether it was solely posted on the company's website. What was clear was that the Statement had been published on the company's website and was available to the general public/ consumers. It was also clear that the Prostate Cancer Foundation Australia had seen the Statement and referenced it in the Association's social media posts (again, available to the general public/ consumers).

The Committee noted that as the material was on the company website, the company could not control whether it was shared, nor its audience. Given this, the Committee noted there is an increased onus on the company to ensuring its messaging is appropriate.

The complainant asserted the material promoted the use or supply of NUBEQA to the general public:

The Committee determined the Statement went beyond informing the public that the TGA had registered a second indication for NUBEQA, and that a reasonable person would regard the Statement as promoting a new combination prostate cancer therapy to the general public.

The assertion of ambition for the indication to be PBS-listed was also considered by the Committee to potentially cause indirect pressure on the PBAC in making a positive decision, and potentially raise hope for patients that it would be PBS-listed in the future, when this outcome is not yet known.

The Committee advised against using terminology that asserted the medicine was effective, as this is understood to be a promotional claim. It was also agreed that publicly referencing the access program was inappropriate in this context, and product-specific access programs should not be promoted to the general public. The Statement included two references to the availability of the access program, which the Committee believed could have the effect of driving inappropriate patient-led prescribing.

Therefore, it was determined by the Committee by majority that the Statement had breached Section 13.2, because:

- It was available to the general public;
- It was promotional, and not reflective of a purpose to provide information that was

educational and to encourage patients to seek further information from their healthcare professional. The Statement went well beyond letting the public know about the availability of a medicine or educating the public on a disease;
- It included a reference to the brand name of a specific prescription product;
- It did not present information in a comprehensive, balanced and fair manner that did not unduly emphasise particular product options;
- The emphasis of the information was not on the condition and its recognition, rather than treatment options;
- The tone of the material was presented in a way that could cause misunderstanding in the community and stimulate the demand for prescription of a particular product; and
- The Statement should have included a comment that treatment was a matter for a healthcare professional to decide, in consultation with the patient.

The Committee then discussed what its findings would be had it been asked to consider the complaint by reference to Sections 11 and Principle 6 of the Code. The Committee determined by majority that the Statement would breach:

- Section 11 because the communication was promotional in nature. The communication was not directed only to the 'media' or other stakeholders but was much broader and appeared to be directed to promoting an indication or medicine to the general public.
- Principle 6 because in promoting a prescription product to the public the company did not engage in interactions with stakeholders that were at all times professional, consistent with all legislative requirements and appropriate to the information needs of the respective audience.

<u>The findings in relation to Abuse of the Code, as alleged by the subject company.</u>

The subject company claimed ICD was ongoing and 'on-track for complete resolution at the inter-company level', which was not evident in the complaint because "critical communication … offering a clear pathway to resolution" was initially omitted by the complainant, but later rectified. For these reasons, the subject company claimed the complainant had abused the Code, as per Section 16.4, which may be found in circumstances where a complaint is frivolous (i.e., not having any serious purpose or value) or vexatious (i.e. a complaint that is made without sufficient grounds, purely to cause annoyance to the other party).

The Committee determined that there was no abuse of the Code.

<u>Sanctions:</u>

The Committee noted that the subject company had made meaningful concessions before and after ICD. The importance of this conduct was in relation to the determination of sanctions rather than any determination of breach. These concessions are namely:

- Withdrawal of the material when the complaint was made;
- Contacting the Prostate Cancer Foundation Australia and requesting removal of any posts related to the media statement;
- Committing not to include details of Patient Access Programs in future Product Specific Consumer Media Releases related to TGA registrations or PBS listings;
- Reviewing internal approval processes for consumer media statements; and
- Conducting further training with employees about the Code and TGA requirements in relation

to the creation, review and approval of consumer media materials.

The Committee was satisfied the breach arising from the Statement had the potential to affect how the medical profession may prescribe the product, and therefore the breach was categorised as moderate.

The Committee considered whether a sanction was appropriate, having regard to the following factors:

- Whether the breach should have been clearly evident to the subject company;
- Length of time that the materials have been in use;
- The number and type of alleged breach/es;
- Circumstances in which the activity took place – and whether any explanation was offered by the subject company;
- Whether a subject company engaged in ICD in good faith;
- Whether a subject company made reasonable concessions in response to ICD or the complaint itself; and
- Where prescribing behaviour may be affected, the likely degree of the effect.

The Committee determined that a fine was appropriate, on the medium end of the moderate category threshold (as imposed by the Code). The Committee imposed the following sanctions:

- Single monetary fine in the amount of $120,000.
- In circumstances where it was the Committee's understanding that the material found to be in breach had been withdrawn, the Committee did not consider it necessary to impose any sanction related to the withdrawal of material.

- end -