CASE/0253/08/24

COMPLAINANT v AMGEN

Allegations about a company website and a booklet for health professionals

CASE SUMMARY

This case was in relation to a promotional website for Amgen's product, Xgeva (denosumab). The complainant alleged that there was no "screen" to prevent patients or the general public accessing the website and further, that a booklet on Xgeva, which could be downloaded from the website, omitted wording from the NICE approval guidance.

The outcome under the 2021 Code was:

Breach of Clause 6.1	**Making a misleading claim**
Breach of Clause 16.1	**Failing to comply with all relevant requirements of the Code**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1(x2)	**Requirement to maintain high standards at all times**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

A complaint was received from an anonymous, contactable complainant about Amgen.

COMPLAINT

The complaint wording is reproduced below:

> "Dear PMCPA,
>
> The following website has no screen to prevent patients or the general public accessing a promotional website for HCPs: [URL provided]
>
> Along with the fact there is a patient resource tab it would not be at all clear that this is for at least patients:
>
> [screenshot provided of the webpage]
>
> On page 6 of the document attached there is the following:

[screenshot provided of part of page 6 of the booklet]

What NICE states [URL provided]:

[screenshot of an extract from NICE guidance]

In essence the caveat regarding bisphosphonate has been omitted.

Please investigate."

When writing to Amgen, the PMCPA asked it to consider the requirements of Clauses 16.1, 6.1, 5.1 and 2 of the 2021 Code.

AMGEN'S RESPONSE

The response from Amgen is reproduced below:

"Thank you for your letter dated August 2, 2024. Amgen Limited ("Amgen") places the utmost importance on adhering to the ABPI Code of Practice (the "Code") and is committed to conducting its business in a responsible, ethical, and professional manner at all times.

Xgeva Website
We have thoroughly investigated the details of this case, including the screenshots and attachments provided by the complainant concerning our Xgeva website: [URL provided] ("Website"), to assess compliance with the ABPI Code. Below are our detailed responses to the complainant's email.

In June 2024, we revised the Website, a promotional platform aimed at UK healthcare professionals only. These revisions were approved [job code], including testing on the staging website (an offline testing area which isn't accessible to the public) for the honesty box/self-attestation [job code] before the Website went live. The page referenced by the complainant whilst on the staging website and prior to the launch of the revised Website was only accessible by clicking on the "I am a healthcare professional" button.

Unfortunately, during the process of relaunching the Website, our digital service provider published the honesty box but failed to configure it correctly to display when visitors accessed the Website referenced by the complainant. Whilst we also have vigorous testing procedures in place, our procedures were not correctly followed. Therefore, from 17 June 2024 the honesty box no longer appeared when visitors accessed the Website. We regret any confusion or inconvenience this may have caused and are taking steps to address the issue to prevent any recurrence in the future.

Regarding the remaining content of the Website, Amgen has strictly adhered to all code requirements. This is a promotional Website for UK healthcare professionals ("HCPs") and, despite the brief absence of the honesty box, once the HCP accesses the Website there is also a prominent banner at the very top of the landing page making it clear that the Website is only intended for HCPs only. It states:

'This is a promotional website intended for UK healthcare professional only. XGEVA® (denosumab) is indicated for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone'.

Once a user accesses the Resources page, it automatically opens on the Healthcare Professional Resources tab. The Website hosts educational resources (written and video) for HCPs on Xgeva, as well as patient resources that HCPs can download and provide to their patients. The information that an HCP can provide to their patients is housed in the 'Patient Resources' and 'Video/Webinar' tabs. The same banner, as mentioned above, also appears when the user clicks onto the Patient Resources tab and the same is true of the 'Videos/Webinars' tab. Furthermore, it is clear from the terminology used throughout the Website that this content is speaking to HCPs rather than patients directly. We are confident that the remaining content displayed aligns with our testing, approvals and the expectations under the Code.

Although it is still clear from the content of the Website (even in the absence of the honest box) that the Website is intended only for HCPs we accept that, for a brief period, we were in breach of clause 16.1 as our service provider did not link the honesty box/attestation page with the Website.

Xgeva Booklet

The Xgeva booklet [job code], is designed to educate and support healthcare professionals in prescribing and administering Xgeva. It serves as a comprehensive resource on efficacy and safety data, primarily derived from the SmPC, and includes detailed instructions on how to administer Xgeva. The booklet is available for HCPs to download from our Website, within the Healthcare Professional Resources tab.

In response to the complainant's objection regarding page 6 of the booklet and its reference to NICE guidance, the standard of care for patients with bone metastasis at risk of skeletal-related events is bisphosphonates. This is well established practice and the booklet clearly states*:*

"XGEVA® is a NICE-recommended treatment option for preventing SREs in adults with bone metastases from breast cancer and from solid tumours. XGEVA® is not NICE-recommended for preventing SREs in adults with bone metastases from prostate cancer."

This clarification explicitly outlines when Xgeva can and cannot be used. None of the information in the booklet has been distorted, exaggerated, or given undue emphasis. The data includes all the pivotal clinical trials all of which have bisphosphonates as the comparator, as this is the standard of care. The information in the booklet is consistent with the SmPC, and the claims and comparisons are accurate, up-to-date, and not misleading. Therefore, we deny a breach of clause 6.1.

At all stages of the process, we have strived to maintain the highest standards and compliance with the ABPI Code of Practice. Our goal has always been to create high-quality educational resources for healthcare professionals, ensuring that the information provided is accurate, relevant, and adheres to the guidelines. We remain dedicated to

maintaining the integrity and trust that healthcare professionals place in our resources. We are committed to upholding these principles and, as such, deny breaches of clause 5.1 and clause 2.

Amgen signatories
The signatories of these materials are:
[signatory names and qualifications]"

PANEL RULING

A complaint was received about a promotional website for Amgen's product, Xgeva (denosumab). The complainant alleged that there was no "screen" to prevent patients or the general public accessing the website and further, that a booklet on Xgeva, which could be downloaded from the website, omitted wording from the NICE approval guidance.

Xgeva Website
Amgen submitted that the Xgeva website was a promotional platform aimed at UK health professionals only. In June 2024, revisions were made to the website and despite successful testing on the staging website, the self-attestation box which required visitors to confirm they were a health professional before accessing the platform, did not display correctly when the website was relaunched. Amgen accepted that for a brief period, the self-attestation box did not appear when visitors accessed the website.

The complainant had provided a screenshot of the 'Resources page' in support of the allegation. Amgen submitted that despite the self-attestation not appearing, the banner which appeared at the top of the website made it clear who the intended audience was. The Panel noted the wording as follows,

> "This is a promotional website intended for UK healthcare professional only. XGEVA® (denosumab) is indicated for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone."

The Panel noted that this was the licensed indication in line with the Summary of Product Characteristics (SPC).

The Panel observed the content of the Resources page which included the logos for both Xgeva and Amgen in the top corners of the page followed by signposting for prescribing information and adverse event reporting. The page was mostly taken up by three columns under the title 'Resources' which it appeared a user could select for further details. These were named 'Healthcare Professional Resources (1)', 'Patient Resources (4)' and 'Videos/Webinar Recordings (4)' and appeared to direct users to specific content. The complainant had identified the 'patient resources' tab as unclear. The Panel took this to mean that without a self-attestation page in place, the column titled 'Patient Resources' could be confusing for a member of the public who could have accessed the webpage and believed it was intended for them. The Panel agreed that despite the wording at the top of the page stating the website was for UK health professionals, this could cause confusion.

The Panel noted that the supplementary information to Clause 16.1, Website Access, stated:

> *"*Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to".

The Panel noted Amgen's submission that the webpage in question was directed at health professionals and considered that the open access nature of the webpage at the time of complaint failed to satisfy the requirements set out in the supplementary information to Clause 16.1. The Panel **ruled a breach of Clause 16.1** as accepted by Amgen.

In their response Amgen explained that the restricted offline testing area correctly displayed the self-attestation box and that the resources page was only accessible by clicking on the "I am a healthcare professional" button. The Panel noted Amgen's submission that their digital service provider published the self-attestation box on relaunch but did not configure it correctly resulting in it not appearing and considered that in this regard Amgen had been let down by a third party. Despite Amgen's assertion that they have rigorous testing in place, it appeared that the live website had not been checked, such that the absence of the self-attestation box was not identified.

Amgen submitted that a self-attestation page did appear on the testing site indicating the intention was for one to be displayed on the live website. Amgen provided a copy of the certification confirming this. In addition, the 'Resources' page of the website did state who the intended audience was. Accordingly, the Panel considered the ruling in relation to Clause 16.1 above to adequately cover the matters raised and ruled **no breach of Clause 5.1**.

Xgeva Booklet

The complainant raised concerns about a booklet for Xgeva designed to educate and support health professionals in prescribing and administering Xgeva. Amgen submitted that the booklet served as a comprehensive resource on efficacy and safety data, primarily derived from the SPC, and included detailed instructions on how to administer Xgeva. The booklet was available for health professionals to download from the Xgeva website, within the Healthcare Professional Resources tab referred to above.

The complainant referred to page 6 of the booklet, titled 'What is Xgeva?' and alleged that the caveat regarding bisphosphonate had been omitted from the NICE recommendation section. The wording on page 6 of the booklet included that Xgeva was indicated for the prevention of skeletal related events (SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone)) in adults with advanced malignancies involving bone followed by,

> **NICE recommendation**: "XGEVA® is a NICE-recommended treatment option for preventing SREs in adults with bone metastases from breast cancer and from solid tumours. XGEVA® is not NICE-recommended for preventing SREs in adults with bone metastases from prostate cancer."

The remainder of page 6 included details of the presentation and administration of Xgeva.

The complainant also provided a screenshot from the NICE website of the Overview page for Technology Appraisal Guidance (TAG) (TA265) – 'Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours' as a comparison of the wording on page 6 of the booklet. The top of the Overview page read as follows,

> "**Adults with cancer that has spread to the bone from solid tumours except for prostate cancer**
>
> NICE recommends denosumab as a possible treatment for preventing complications that result from cancer spreading to the bone from solid tumours, except for prostate cancer, *if the person would otherwise be prescribed a type of drug called a bisphosphonate*.
>
> **Adults with cancer that has spread to the bone from prostate cancer**
>
> NICE does not recommend denosumab for preventing complications that result from prostate cancer spreading to the bone."

(Panel emphasis added)

Amgen submitted that the standard of care for patients with bone metastases at risk of skeletal-related events is bisphosphonates and that this is a well-established practice. It went on to state that "none of the information in the booklet has been distorted, exaggerated, or given undue emphasis. The data includes all the pivotal clinical trials all of which have bisphosphonates as the comparator, as this is the standard of care. The information in the booklet is consistent with the SPC, and the claims and comparisons are accurate, up-to-date, and not misleading".

The Panel accepted that this was a booklet aimed at UK health professionals to support prescribing decisions. It also accepted that page 6 of the booklet set out when Xgeva should and should not be used.

The Panel considered the 32 page booklet and its structure in full which was titled "XGEVA® (Denosumab) A guide for clinical practice for the prevention of skeletal-related events in adults with advanced malignancies involving bone". Pages 1 to 3 of the booklet were taken up by the front cover and contents. Pages 4 to 5, titled "Cancer and bone health" and "What are SREs?" discussed cancer and bone health and the prevalence and problems associated with skeletal related events before stating that bone targeted treatment should be initiated. The Panel interpreted pages 4 to 5 as setting out the issues that needed to be tackled for the reader but noted that there was no specific mention of bisphosphonates or any other treatment options. Page 6, as described above appeared to provide information on a treatment for the conditions outlined in the previous pages, followed by page 7 which detailed how Xgeva works.

The Panel considered that NICE guidelines served an important role in determining the pharma economic overview of a medicine which can make a difference in prescribing choices.

In this regard the Panel questioned whether the omission of "*if the person would otherwise be prescribed a type of drug called a bisphosphonate*" could be misleading. Whilst the Panel accepted that bisphosphonates were the standard of care in this disease area, in its view that did not mean they were the *only* possible treatment. The NICE recommendation was clear that denosumab was specifically recommended in instances where a patient would have alternatively been treated with a bisphosphonate. The wording on page 6 of the booklet made

no mention of bisphosphonate and although there were no positive claims about Xgeva being the only treatment option, the Panel considered that the omission meant that the recommendation was incomplete with regards to other treatment options available. As a "comprehensive overview" the Panel questioned why Amgen had omitted this wording from the booklet. The NICE recommendation had been used as part of the promotion of Xgeva and therefore should have been reproduced in a way so as not to mislead or create ambiguity. The Panel, on balance, ruled a **breach of Clause 6.1**.

The complainant had not made any specific allegations with respect to high standards or bringing discredit or reducing confidence in the pharmaceutical industry. In the absence of any further evidence, the Panel considered that the ruling above adequately covered this matter. It did not consider that the circumstances of this case indicated that high standards had not been maintained or that Amgen had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clause 5.1 and no breach of Clause 2**.

Complaint received **1 August 2024**

Case completed **31 October 2025**