CASE/0276/08/24 ***NO BREACH OF THE CODE***

COMPLAINANT v ASTRAZENECA

Allegations about an advertisement

CASE SUMMARY

This case was in relation to an advert for Ondexxya (andexanet alfa) on a website intended only for health professionals. The headline of the advert included a statement that Ondexxya was "NICE recommended". The complainant alleged that this was misleading because it did not contain the full wording of the recommendation, which was that it was "recommended as an option".

The outcome under the 2021 Code was:

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	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1	**Requirement that information/ claims/ comparisons must not be misleading**

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

FULL CASE REPORT

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

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "I write to make a complaint about an advertisement that is currently on [link provided] for Andexanet alpha. The web address for the advert is [link provided]. As this page can only be accessed by subscribers, I attach a screenshot for ease of reference.
>
> The advert states '*For managing apixaban- and rivaroxaban-related life-threatening or uncontrolled bleeds, Ondexxya® is NICE recommended (GI bleeds)1'*. The reference is NICE TA697 which actually states at recommendation 1.1 '*Andexanet alfa is recommended as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life-threatening or uncontrolled bleeding'*. There is an important difference between 'recommended' and 'recommended as an option'. NICE is careful in its choice of words because recommending a treatment when no other treatments are

recommended, implies superiority, whereas addition of the qualifying term 'as an option' informs the reader that other treatment options should be considered and may be more appropriate. In my view it is imperative that in adverts for this drug the phrase 'recommended as an option' should always be used and not shortened to 'recommended'. On the drugs actual website [link provided] the full phrase 'recommended as an option' is used.

This advert is on a site for healthcare professionals. Failure to include the qualifying phrase 'as an option' can mislead doctors who have not read TA697. This is not a new issue with this particular drug. There have been other instances for which the company may not be responsible. For example a report at [link provided] in 2021 has as its title 'UK's NICE recommends Ondexxya.' This has led to a misunderstanding of the strength of the NICE recommendation. I am sure that is not the company's intention. All I ask is that they correct all existing adverts and moving forwards always use the exact wording in the applicable NICE technology appraisal. Otherwise misinformation amongst healthcare professionals about this drug will continue to spread."

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

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"We are writing in response to your letter dated 21 August 2024, concerning a complaint from a healthcare professional (HCP) regarding an advertisement on [link provided]. The complainant's allegations can be broken down as follows:

1. In the advert, a webpage advert for Ondexxya (andexanet alfa) states *'For managing apixaban- and rivaroxaban-related life threatening or uncontrolled bleeds, Ondexxya is NICE recommended (GI Bleeds).'* The complainant asserts that 'recommended as an option', as per NICE TA697(1), should be stated so as not to mislead health care professionals. The complainant alleges that this Ondexxya advert is therefore misleading.
2. The complainant asserts that by omitting that Ondexxya is 'recommended as an option' implies superiority over other treatment options.

In our response to these allegations, this letter will establish that:

- The statement 'Ondexxya is NICE recommended' does not indicate or imply that Ondexxya is the **only** NICE recommended treatment option for apixaban- and rivaroxaban-related life threatening or uncontrolled bleeds. It is a factual statement and does not indicate that HCPs should not consider other treatment options. It is therefore not misleading.
- The omission of 'recommended as an option' does not indicate or imply that Ondexxya is a superior treatment option.

AstraZeneca have been asked to consider clause 6.1, 5.1 and 2 of the 2021 ABPI Code (the "Code"). We will address each of the complainant's allegations below.

AstraZeneca Response

Background

The advert subject to complaint (GB-55802) was hosted on a website that can only be accessed only by GMC-registered doctors. The advert was certified in its final form by a Nominated Signatory (UK GPhC registered pharmacist). The target audience was gastroenterologists, haematologists, emergency specialists and stroke specialists, in keeping with HCPs who are familiar with managing life threatening/uncontrolled bleeds associated with apixaban or rivaroxaban. These HCPs were driven to this advert by clicking through a clinical bulletin sent by email.

Ondexxya is indicated for use in adult patients treated with apixaban or rivaroxaban when anticoagulation reversal is required due to life-threatening or uncontrolled bleeds. It is the only licensed reversal agent for this indication.

AZ Response to the allegations

1. *In the advert appearing on [link provided], a webpage advert for Ondexxya states 'For managing apixaban- and rivaroxaban-related life threatening or uncontrolled bleeds, Ondexxya is NICE recommended (GI Bleeds).' The complainant asserts that 'recommended as an option', as per the NICE TA697, should be stated so as not to mislead HCPs. The complainant asserts that by omitting that Ondexxya is recommended as an option implies superiority over other treatment options.*

Ondexxya underwent assessment by NICE technology appraisal, which was published as TA697 in 2021. This states that:

Andexanet alfa is recommended as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life-threatening or uncontrolled bleeding, only if:

- *the bleed is in the gastrointestinal tract, and*
- *the company provides andexanet alfa according to the commercial arrangement.*

The headline of the advert states '*For managing apixaban- and rivaroxaban-related life-threatening or uncontrolled bleeds, Ondexxya is NICE recommended (GI bleeds) and SMC accepted*'. The full NICE recommendation (including wording '*as an option*') is prominently included on the same page, for completeness.

By stating 'NICE recommended', there is no indication that other treatment options should not be considered when managing these bleeds, nor does it denote superiority of Ondexxya over other potential options. The headline is referenced with NICE TA697 which clearly demonstrates the recommendation from NICE. The statement is factual and does not include language such as 'only', which would indicate that Ondexxya is the single or superior treatment option. AstraZeneca ascertains that the headline stands alone, however for completeness as mentioned above, the full NICE recommendation is also included in the advert, approximately half way down on the same page.

In a similar case (AUTH/3552/8/21, Health professional v Roche), the complainant alleged that a company website claimed Polivy (polatuzumab) was recommended by NICE and SMC. The complainant deemed this to be misleading as Polivy was

recommended as an option only if it was provided according to the commercial arrangement. The Panel ruled that, *in this case, by only stating 'Recommended by NICE and SMC' was not misleading*. They did, however, consider that it would have been helpful to include the information that Polivy was only recommended if provided according to the commercial agreement. In the Ondexxya advert, 'NICE recommended' is included in the headline, in addition to the full NICE recommendation on the same page – including wording '*NICE recommended as an option*' - consistent with the Panel suggestion in this case.

AstraZeneca were not responsible for the [named website] article with link included in the complaint. As mentioned by the complainant "*There have been other instances for which the company may not be responsible".*

AstraZeneca asserts that stating Ondexxya is NICE recommended is not misleading nor does it imply superiority for the reasons outlined above. Additionally, In the case of the Ondexxya advert, the full NICE recommendation was included underneath for completeness.

AstraZeneca have maintained the high standards, and have not brought the industry into disrepute.

We therefore refute alleged breach of clauses 5.1, 6.1, and 2 of the Code.

Summary of AstraZeneca's position

It is AstraZeneca's position that the headline of the advert is factual and not misleading. The statement 'Ondexxya is NICE recommended' does not indicate or imply that Ondexxya is the only NICE recommended treatment option, or superior to other treatment options.

AstraZeneca subscribes fully to the high ethical and moral spirit of the ABPI Code of Practice and takes its responsibilities under the code very seriously."

PANEL RULING

This case was in relation to an advert for Ondexxya (andexanet alfa) on a website intended only for health professionals. The headline of the advert was the following statement: "*For managing apixaban- and rivaroxaban-related life-threatening or uncontrolled bleeds, Ondexxya® is NICE recommended (GI bleeds) and SMC accepted"*. The words "*NICE recommended*" and "*SMC accepted*" were highlighted by being in bold red font.

The actual wording of the NICE recommendation was "*Andexanet alfa is recommended as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life-threatening or uncontrolled bleeding*" (Panel's emphasis). The complainant also referred to the website for Ondexxya, which used the above wording from the NICE recommendation.

The complainant's allegation was that the reference to "*NICE recommended"*, in the headline of the advert, was misleading because it did not include the qualifier "*as an option*". The complainant also alleged that the advert implied superiority because the reader may mistakenly conclude that there were no other treatment options to consider.

The complainant also referred to a news article from a global news website that had as its title "*UK's NICE recommends Ondexxya.*" The complainant did not provide any evidence that this article was the responsibility of AstraZeneca.

In response to the complaint, AstraZeneca submitted that:

1. The phrase "*NICE recommended*" is factually accurate and does not imply superiority.
2. The full NICE recommendation (including the phrase "*recommended as an option*") was included on the same advert page.
3. The advert was certified by a qualified signatory and targeted at specialists familiar with managing such bleeds.
4. In a previous case (AUTH/3552/8/21), a similar phrase was not deemed misleading by the PMCPA.
5. AstraZeneca was not responsible for third-party misrepresentations, such as the article cited by the complainant.

The Panel noted that the screenshot provided by the complainant only showed the headline of the advert (which included the wording complained about), plus two sentences explaining Ondexxya's conditional marketing authorisation. However, the Panel also relied upon the *complete* version of the advert provided by AstraZeneca which was available on the health professional website, referred to by the complainant. In addition to the details in the screenshot provided by the complainant, the full advert also included, among other things, a case study involving a fictional patient, links to example protocols for emergency departments, and links to a dosing and administration guide. The middle section of the full advert contained further details on the NICE recommendation including the complete wording, "*as an option*", as well as signposting readers to the full NICE guidance. The Panel considered the complete NICE recommendation wording to be in a font size consistent with the rest of the advert.

The Panel's view in this case, was that the use of the term "*NICE recommended*" in the headline of the advert was not misleading because the full wording of the recommendation (which included the qualifier "*as an option*") *was* within the advert and was reasonably prominent. The Panel therefore did not consider that there was potential for a health professional to be misled by the headline, in the context of the advert as a whole, its layout, and its overall impression.

In addition, the Panel did not agree with the complainant that a health professional may be misled in interpreting "*NICE recommended*" to mean that there were no other options. In the Panel's view, that was not a logical interpretation of that wording because stating that a medicine is recommended does not mean (or imply) it is the only recommendation. For these reasons, the Panel ruled **no breach of Clause 6.1**.

Finally, the Panel considered the complainant's allegation that there were "*other instances*" related to their complaint about the advert. The Panel interpreted this as an allegation that AstraZeneca had failed to maintain high standards. The complainant themselves conceded that, in relation to the "*other instances*", including the news article they cited from a global news website, "*the company may not be responsible*". The Panel accepted AstraZeneca submission that it had no responsibility for the article in question. The Panel therefore concluded that the complainant had not made out their case in relation to this allegation. In the absence of any evidence from the complainant that the company was responsible for this article, or that there had been any other failure to maintain high standards by AstraZeneca in this case, the Panel ruled **no breach of Clause 5.1**. For the same reasons the Panel ruled **no breach of Clause 2**.

Complaint received	**20 August 2024**
Case completed	**07 July 2025**