CASE/0681/08/25 ***NO BREACH OF THE CODE***

COMPLAINANT v ABBVIE

Alleged misleading and off-licence promotion

CASE SUMMARY

This case related to a promotional advertisement for Aquipta (atogepant) which appeared as a tile on a website that was a closed network for UK medical doctors. It was alleged that the promotion of Aquipta for "migraine prevention" was off-licence because the licensed indication, "for prophylaxis of migraine in adults who have at least 4 migraine days per month", was narrower and that the material was misleading in its references to National Institute for Health & Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) by omitting information.

The outcome under the 2024 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 6.1 (x2)	**Requirement that information must not be misleading**
No Breach of Clause 11.2	**Requirement that a medicine must be promoted in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics**

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 was received from a contactable complainant, who described themselves as a concerned healthcare professional, about AbbVie Ltd.

COMPLAINT

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

> "The following advert has been present on [URL provided].
>
> This advert states that the product is for migraine "prevention", yet the indication is "for prophylaxis of migraine in adults who have at least 4 migraine days per month" - so this is promoting off-licence as the licence is a much narrower indication.
>
> This states it is recommended as an option by NICE. The statement is in fact:

AQUIPTA is recommended by NICE as an option for preventing migraine in adults who have at least 4 migraine days per month, only if at least 3 preventive medicines have failed.

Stop AQUIPTA® after 12 weeks if the frequency of migraines does not reduce by:

at least 50% in episodic migraine (defined as fewer than 15 headache days per month) at least 30% in chronic migraine (defined as 15 or more headache days per month, with at least 8 of those having features of migraine).

It also states it is accepted by the SMC for restricted use. The statement is in fact:

AQUIPTA® is accepted by SMC for restricted use within NHSScotland for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

SMC restriction: for patients with chronic and episodic migraine who have had prior failure on three or more migraine preventative treatments.

As such, the advertisement is misleading both what the NICE and what the SMC have said."

When writing to AbbVie, the PMCPA asked it to consider the requirements of Clauses 5.1, 6.1 and 11.2 of the 2024 Code.

ABBVIE'S RESPONSE

The response from AbbVie is reproduced below:

"Thank you for your letter dated 6th August 2025 regarding a complaint received by the PMCPA related to concerns about the information included in a promotional advertisement for one of our products on [named website].

We take our responsibility for compliance with all applicable laws and regulations including the ABPI Code of Practice (ABPI Code) very seriously and we continuously endeavor to maintain these high standards in all our activities.

Complaint
The complainant, who identified themselves as a concerned HCP, has expressed concern about the indication and NICE/SMC wording included in the promotional advertisement for AbbVie's product, AQUIPTA®.

The Case Manager has requested AbbVie to consider the requirements of Clauses 5.1, 6.1 and 11.2 of the ABPI Code in our response.

Context
AQUIPTA® is indicated for prophylaxis of migraine in adults who have at least 4 migraine days/month. It is a selective Calcitonin Gene-Related Peptide (CGRP) receptor antagonist that blocks the binding of CGRP to the receptor and antagonises CGRP receptor function. By blocking the CGRP receptor- interaction, AQUIPTA® prevents migraine attacks.

The platform
[Named website] is a free and exclusive online platform for medical doctors to communicate and connect, keep up to date with the latest news and Continuing Professional Development (CPD) resources, find career advice and support and more.

The advertisement/material
The material subject to this complaint is a digital bulletin that appears as a tile on the [named website] homepage. The purpose of this bulletin is to inform Neurologist HCPs and GPs that there is a CGRP receptor antagonist available for migraine prevention (mechanism of action for AQUIPTA®) that has been recommended as an option by NICE and accepted by SMC for restricted use. The bulletin includes a short and succinct promotional message with the intention of the user clicking through for more in-depth educational content. By clicking the link within this tile, users are directed to the AQUIPTA® homepage within the Migraine Hub on [named website].

Definition of Migraine Preventative Treatment
In the United Kingdom, scientific organisations provide guidance and education on the management of headache and migraine. The British Association for the Study of Headache (BASH) 2019 guidelines recommend that preventative treatment should be offered to patients experiencing four or more migraine days per month, as this frequency is linked to significant disability. BASH guidelines are well recognised guidelines used within the migraine community and is referenced within the NICE migraine clinical knowledge summary.

This threshold of four or more migraine days a month is also reflected in other respected sources. GPnotebook, a clinical reference tool used by over 19,000 UK GPs each month, advises that migraines occurring four or more times per month should be managed with prophylactic treatment. Similarly, The Migraine Trust, a leading UK patient organisation, states that preventative medicines may be helpful for individuals suffering frequent attacks, often defined as four or more migraine days per month. Their website offers trusted information for both healthcare professionals and patients, reinforcing expectations around when to consider preventative therapy for migraine.

Response
AbbVie would like to reassure the PMCPA that all the appropriate and relevant information has been included for HCPs to learn more about AQUIPTA® in the bulletin included in the HCP community platform.

We would like to take this opportunity to address the concerns raised by the complainant in relation to the following clauses:

Clause 6.1 Information, claims and comparisons must not be misleading
Clause 6.1 of the ABPI Code provides that 'Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.'

AbbVie believes that the bulletin complies with the requirements of Clause 6.1 of the ABPI Code.

The complainant claims that the reference to AQUIPTA® being recommended by NICE as an option and accepted by SMC for restricted use is not complete. However, the bulletin clearly states in bold in its title that AQUIPTA® is recommended by NICE as an option and accepted by SMC **for restricted use**. The bulletin therefore very clearly, accurately and unambiguously states that the AQUIPTA® is recommended by both NICE and SMC for restricted use only. The bulletin is therefore not misleading in any way, but to the contrary clearly acknowledges the restricted use of AQUIPTA® by both NICE and SMC. Additionally, the bulletin has a clear and visible click through option (Learn more' being the call to action) to the AQUIPTA® homepage on the DNUK migraine hub which includes links to the relevant NICE and SMC sites with full information on the restricted use of AQUIPTA®. Therefore, AbbVie maintains that there has been no breach of Clause 6.1 of the ABPI Code.

Clause 11.2 Unauthorised indications
Clause 11.2 of the ABPI Code provides that 'The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics subject to the provisions of Clause 11.3 below.'

AbbVie respectfully but strongly disagrees with the allegation that the bulletin promotes AQUIPTA® outside of its approved indication by describing it as a treatment for 'migraine prevention'. The Summary of Product Characteristics (SPC) states AQUIPTA® is indicated for the prophylaxis of migraine in adults with at least four migraine days per month. The terms 'prophylaxis' and 'prevention' are considered interchangeable in the management of migraine by the well established and authoritative scientific guidelines, including those from the British Association for the Study of Headache (BASH), GPnotebook, and the Migraine Trust. All these sources define preventative treatment as appropriate for patients with four or more monthly migraine days. UK clinicians are familiar with this standard, and the information provided in the bulletin, which is meant for UK clinicians only, is consequently consistent with accepted leading clinical practice.

AbbVie would also like to highlight that, in case AUTH/3856/11/23 – Complainant v Idorsia (regarding alleged off-licence promotion), there was a similar complaint relating to the use of the term 'chronic insomnia' in a web advert alleging that the SPC was more narrow than the term used in the banner advert. In this instance, the Panel found no breach of off license promotion as it was recognized the definitions from scientific bodies matched the recognised characterisation of chronic insomnia in the indication. AbbVie respectfully requests the Case Manager and the Panel to consider a similar principle when reviewing this case.

Finally, the bulletin includes clear links to the full product information and complies with mandatory ABPI Code requirements. It is therefore clear that high standards have been upheld, with the promotion of the medicine being fully in accordance with the marketing authorisation and entirely consistent with the SPC. Therefore, AbbVie maintains there has been no breach of Clause 11.2 of the ABPI Code.

Clause 5.1 High Standards
We believe that in this case high standards have been maintained at all times as the information included in the advertisement is sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine and is not misleading. In addition, the information is accurate, balanced, fair, objective and unambiguous and claims contained therein are capable of substantiation (referenced to the AQUIPTA® Summary of Product Characteristics, NICE and SMC).

Summary
In summary as outlined above, AbbVie does not believe that the bulletin has breached Clauses 5.1, 6.1 and 11.2 of the 2024 ABPI Code. We reiterate our continued commitment to operate consistently with the highest standards and all applicable laws, regulations and the ABPI Code.

AbbVie thanks the PMPCA for the opportunity to respond to this complaint. We remain available to answer any further questions you may have, but trust that our response is sufficient for the Panel to confirm AbbVie are not in breach of any of the Clauses of the ABPI Code that AbbVie have been asked to consider."

PANEL RULING

This case related to a promotional advertisement for Aquipta (atogepant) which appeared as a tile on a website that was a closed network for UK medical doctors. The complainant alleged that the advertisement promoted Aquipta off-licence because the indication was narrower than positioned and that the material was misleading in its references to National Institute for Health & Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) by omitting information. Aquipta was licensed for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

The Panel observed the advertisement included the headline statement "Introducing AQUIPTA▼ (atogepant) OD: an oral CGRP receptor antagonist for migraine prevention, recommended as an option by NICE and accepted by the SMC for restricted use" together with a call to action to click to visit the Aquipta migraine hub to "understand the need for preventative treatment in patients with migraine and how targeting the CGRP receptors could help". The advertisement included that the hub was promotional information from AbbVie for UK health professionals and included a link to prescribing information together with information about how to report adverse events.

Promotion of Aquipta for "migraine prevention"

The complainant alleged that the promotion of Aquipta for "migraine prevention" was off-licence because the licensed indication, "for prophylaxis of migraine in adults who have at least 4 migraine days per month", was narrower.

The Panel considered that the complaint could be reasonably interpreted differently as either:

- that the omission of any reference to the requirement for patients to have at least 4 migraine days per month meant that the medicine was promoted to a wider patient population than permitted by the licence; or
- that the term "prevention" used in the advertisement was wider than "prophylaxis" as included in Aquipta's licence; or

- a combination of both.

The Panel noted the NICE recommendation referred to “preventing migraine” while the SMC advice referred to “prophylaxis of migraine”. In this regard, the Panel accepted AbbVie’s submission that the terms prevention and prophylaxis were considered interchangeable in the management of migraine.

The Panel further noted AbbVie’s submission that a number of organisations defined preventative treatment as appropriate for patients with four or more monthly migraine days and that UK clinicians would be familiar with this standard.

The Panel considered the overall impression of the advertisement and that the material was a small tile, limited in content and that it included a link to further information on the Aquipta migraine hub which included the full licensed indication at the outset.

Based on the information before it, the Panel considered that the complainant had not established that use of the term “migraine prevention” promoted Aquipta to a broader population than that for which it was licensed such that its promotion was inconsistent with the particulars listed in its summary of product characteristics. The Panel ruled **no breach of Clause 11.2** accordingly.

Misleading references to NICE and SMC

The complainant further alleged that the advertisement was misleading in its references to NICE and SMC as each body’s guidance set out qualifying criteria for use of Aquipta which were not detailed in the advertisement.

The Panel did not accept AbbVie’s submission that the statement in the advertisement “recommended as an option by NICE and accepted by the SMC for restricted use” acknowledged the restricted use of Aquipta by both NICE and SMC. The Panel considered “restricted use” did not apply equally to both bodies and that it was a term generally used in SMC acceptance as opposed to NICE.

In the Panel’s view, the claim at issue comprised two distinct components: 1) that Aquipta was “recommended as an option by NICE” and 2) that it was “accepted by the SMC for restricted use”. The Panel considered each separately.

<u>NICE Guidance</u>

The NICE guidance (TA973), provided by AbbVie, stated atogepant was “recommended as an option for preventing migraine in adults who have at least 4 migraine days per month, only if at least 3 preventive medicines have failed”. It further included to stop atogepant “after 12 weeks if the frequency of migraines does not reduce by:

- at least 50% in episodic migraine (defined as fewer than 15 headache days per month)
- at least 30% in chronic migraine (defined as 15 or more headache days per month, with at least 8 of those having features of migraine)”.

The Panel noted its view above that reference to NICE in the advertisement was limited to Aquipta being “recommended as an option by NICE”. The Panel further noted that the linked

migraine hub included details of the NICE recommendation, in line with the above, with a link to read the full guidance document.

While the Panel acknowledged it might have been helpful to indicate that the recommendation included additional criteria and that this information could be found on the linked page, the Panel considered that the statement which appeared on a small tile, with limited content, was unlikely to mislead the reader. In the Panel's view, the wording "recommended as an option by NICE" did not misleadingly imply unconditional use of Aquipta for preventing migraines. The Panel considered, on balance, that the intended audience would likely be familiar with NICE recommendations being subject to criteria and ruled **no breach of Clause 6.1** in relation to the NICE recommendation.

SMC Advice

The SMC advice included that Aquipta was accepted for restricted use within NHSScotland for the prophylaxis of migraine in adults who have at least 4 migraine days per month. The restriction applied to patients with chronic and episodic migraine who had prior failure on three or more migraine preventative treatments.

The Panel noted reference to the SMC in the advertisement was in the context of "accepted by the SMC for restricted use" and that the linked migraine hub included details of the SMC acceptance with a link to read the full guidance document.

It was clear that the SMC acceptance was qualified as being subject to restriction(s) and the Panel therefore considered it had not been established that the statement, which appeared on a small tile with limited content, was misleading. The Panel ruled **no breach of Clause 6.1** in relation to the SMC acceptance.

High standards

Based on its rulings of no breaches above and in the absence of any further allegations or evidence from the complainant, the Panel did not consider it had been established that AbbVie had failed to maintain high standards and ruled **no breach of Clause 5.1**.

Complaint received **4 August 2025**

Case completed **25 February 2026**