CASE AUTH/3656/6/22

HEALTH PROFESSIONAL V TEVA

Alleged promotion of Ajovy and Copaxone in an P3 Pharmacy article

CASE SUMMARY

This case was in relation to an article in P3 Pharmacy, relating to an interview with a senior leader at Teva.

In the Panel's view, the article for which Teva was responsible was promotional and it ruled a breach of the following Clause(s) of the 2019 Code because:

- **Prescribing information for both Ajovy and Copaxone had not been included**
- **An adverse event reporting statement had not been included**
- **The article had not been certified**
- **The word 'new' was used to describe Copaxone when it had been available for more than 12 months in the UK**
- **A statement in the article implied that Copaxone was licensed for all types of multiple sclerosis which was not so, and thus the statement at issue was inconsistent with the SPC as alleged**

Breach of Clause 3.2	**Promoting a medicine in a manner that was inconsistent with the particulars listed in its summary of product characteristics.**
Breach of Clause 4.1	**Failing to include prescribing information**
Breach of Clause 4.9	**Failing to include the prominent adverse event reporting statement**
Breach of Clause 4.10	**Failing to include a black triangle**
Breach of Clause 7.11	**Referring to a product as 'new' when it has generally been available for more than twelve months in the UK**
Breach of Clause 9.1	**Failing to maintain high standards**
Breach of Clause 14.1	**Failing to certify promotional material**

The Panel ruled a breach of the following Clause of the 2019 Code because the black triangle for Ajovy had not been included and it considered that failure to also include an adverse event reporting statement compounded its concerns in this regard.

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**

The Panel ruled no breach of the following Clause of the 2019 Code in relation to the lack of prescribing information, lack of certification of the article and the promotion of Copaxone in a manner that was inconsistent with its SPC because it considered that an

additional breach of Clause 2 was not warranted and/or that the rulings of breaches above adequately covered the matter:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

The Panel ruled no breach of the following Clauses of the 2019 Code because:

- **It did not consider that the complainant had provided evidence to establish that the statement 'Our product is for those people who are suffering with chronic migraine, who may be bedbound for 15 to 20 days a month' was inconsistent with the Ajovy license indication as alleged**
- **It did not consider that it had been established that the claim 'The pen just makes it easier for patients to inject the product and continue to live their lives. That's the important thing' was misleading or incapable of substantiation as alleged**

No Breach of Clause 3.2	**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**
No Breach of Clause 7.2	**Requirement that claims/information/comparisons must not be misleading**
No Breach of Clause 7.4	**Requirement that claims/information/comparisons must be capable of substantiation**
No Breach of Clause 9.1	**Requirement to maintain high standards at all times.**
No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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

FULL CASE REPORT

COMPLAINT

The complainant alleged that Teva had a promotional article which was not certified and did not contain the mandatory promotional requirements. The complainant was concerned that the article was done in conjunction with a senior leader of Teva. The complainant alleged that the following parts of the article were non-compliant:

1 ‘We’re speaking days after the launch of the pre-filled pen presentation of AJOVY® (fremanezumab). The pen offers added convenience and flexibility to sufferers of chronic migraine responsive to anti-CGRP (calcitonin gene-related peptide) drugs.’

The complainant noted this sentence did not have the black triangle that was required for Ajovy and alleged breaches of Clauses 12.10, 5.1 and 2.

2 ‘We are one of the largest suppliers to the NHS and while our heart and soul is that of a generic manufacturer – it’s what the company history is about – we are also known for our new chemical entities, including Copaxone® (glatiramer acetate) for multiple sclerosis.’

The complainant alleged that no prescribing information was provided for Copaxone and that Copaxone had a very specific licence for multiple sclerosis (MS) as opposed to being ‘for multiple sclerosis’ as mentioned in the article. The actual licence was for the treatment of relapsing forms of MS (the complainant referred to Section 5.1 for important information on the population for which efficacy had been established). Copaxone was not indicated in primary or secondary progressive MS. The complainant alleged breaches of Clauses 11.2, 12.1, 5.1 and 2.

3 ‘Migraine is often seen by people who don’t understand it as just another type of headache, but it can be a debilitating illness,’ …‘Our product is for those people who are suffering with chronic migraine, who may be bedbound for 15 to 20 days a month.’

The complainant noted that Ajovy was actually licenced for prophylaxis of migraine in adults who have at least 4 migraine days per month as opposed to what was written in the article; The complainant alleged breaches of Clauses 11.2, 5.1 and 2 as promotion was outside of the licence.

4 The complainant alleged that no prescribing information was provided for Ajovy in breach of Clauses 12.1, 5.1 and 2.

5 The complainant alleged that no adverse event reporting was provided for the article in breach of Clause 12.9.

6 The complainant stated that the promotional article should have been certified but clearly had not been and alleged breaches of Clauses 8.1, 5.1 and 2.

7 ‘“The pen just makes it easier for patients to inject the product and continue to live their lives. That’s the important thing,” [senior leader] says.’

The complainant alleged that there was no evidence that the pen made it easier for patients to inject and live normal life and it was a false and misleading claim in breach of Clauses 6.1, 6.2, 5.1 and 2.

8 ‘We are also known for our new chemical entities, including Copaxone® (glatiramer acetate) for multiple sclerosis.’

The complainant stated that the word 'new' should not be used in context of Copaxone as the product was ancient and alleged a breach of Clause 6.5.

The complainant submitted it was concerning that a senior employee had not intervened and prevented this uncompliant article. There was clearly very poor knowledge and understanding.

When writing to Teva, the Authority asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.5, 8.1, 11.2, 12.1, 12.9 and 12.10 of the 2021 Code as cited by the complainant.

RESPONSE

Teva submitted that, as an organisation, it took compliance with the ABPI Code of Practice extremely seriously and had fully investigated this matter.

Teva submitted that it would address the matter in the letter of complaint and bore in mind the requirements of Clauses 2, 5.1, 6.1, 6.2, 6.5, 8.1, 11.2, 12.1, 12.9 and 12.10 of the 2021 Code, however, it noted that the article was published by p3 Pharmacy in September 2020 and therefore if it was, indeed, covered by the Code, it should be the 2019 Code that was in place at the time of publication by p3 Pharmacy.

Teva submitted that the article was described to it as 'a biographical profile item on [a senior leader at Teva]'. The website where the article was published clearly detailed that it was a p3 Pharmacy item and the article itself was located in the interview section of the website. An interview was set up by p3 Pharmacy magazine upon its request and initiation. The questions to be used in the interview were shared with Teva in advance. These were not on product-related items but were with regard to the senior leader's experience in the industry and 'hot topics' around pharmacy and reimbursement (copy provided). The timing of the interview was after a recent launch of a new device for Ajovy (fremanezumab), which was detailed in the set-up of the article, but the launch was not part of the direct questions asked during the interview. A photographer arranged by p3 Pharmacy attended Teva's Head Office in West Yorkshire the day before the interview (which was held on Microsoft (MS) Teams) to take photographs which were ultimately used in the published article facilitated through Teva's Corporate Communications Department, as was the whole p3 Pharmacy article and arrangements. No payments were made for the article, or its publication and no advertising space was secured alongside it or paid for. In the set-up of the interview and questions proposed, p3 Pharmacy advised that they would send the article for factual checking, which was done again through the Teva Corporate Communications Department and referred to 'providing context to the magazine's readers about the environment in which they operate, community pharmacy and explanations around the national contract in order to inform them on such matters'. The Final item was not provided to Teva Corporate Communications in advance of publishing.

Teva, therefore, believed that the article was outside of the scope of the Code as it was: (i) not organised by Teva; (ii) neither a Teva nor a Teva third party item; and (iii) a p3 Pharmacy publication in print and online by p3 Pharmacy with the intention to inform Community Pharmacy and the magazine's readers on Teva and the senior leader at Teva as a biographical item.

Teva, therefore, refuted all allegations of a breach of all the clauses cited in the complaint by the complainant and that the article and its publication was not by Teva or a third party under its instruction or payment and therefore not covered by the Code.

Teva noted that Clause 1.24 of the 2021 Code states:

> *'"Third party" means a legal person/entity or individual that represents a company or interacts with other parties on behalf of a company or relating to a company's medicine, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, media buyers, providers of services related to events, public relations services, non-clinical services, non-interventional studies management services etc.*
>
> *Companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given.'*

P3 Pharmacy was not a third party as defined by the Code as detailed above. There was no Teva responsibility with regard to the article and therefore there was no *prima facie* case to answer as the article and its publication was not covered by the Code.

Request for further information from the Panel

Following a request for further information, Teva provided correspondence it had had with p3 Pharmacy in relation to the list of questions or the reference to Ajovy in the set-up of the article including email trails on the set-up dates 4 Feb 2020, 3 July 2020 and the email trail with questions for the senior leader at Teva.

When asked to clarify whether or not it saw any version of the article for factual checking Teva provided several emails between p3 Pharmacy and Teva following the interview. This also included changes to the draft article suggested by Teva.

Teva also provided correspondence between Teva and p3 Pharmacy in relation to the interview and article in question and explained that they did not have a transcript of the interview.

PANEL RULING

The Panel noted Teva's explanation that the article at issue had been described to Teva as 'a biographical profile on [a senior leader at Teva] and was written by p3 Pharmacy following an interview which was set up at p3 Pharmacy's request and initiation. The Panel noted that complaints about articles in the press etc. were judged upon the acceptability of the information provided by the pharmaceutical company rather than the final published article. Whilst the Panel noted that the article was initiated and written by p3 Pharmacy, Teva had been provided with a proposed introduction to set context to the interview and a list of proposed questions to elicit the information p3 Pharmacy wanted to cover. Whilst the Panel did not have before it a transcript of the interview; it noted that Teva did not dispute that the quotes in the article attributed to the senior leader were made.

The Panel noted Teva's submission that the timing of the interview was after the recent launch of a new device for the administration of Ajovy (fremanezumab), which was detailed at the start of the article, but the launch was not part of the direct questions asked during the interview.

The Panel noted Teva's submission that it had been provided with a list of questions in advance of the interview, this document began with:

> 'We should perhaps start with the latest news, and the launch of Ajovy last week. It strikes me this is another continuation of Teva's investment in novel (and improved) treatments, where facilitating administration (especially for patients) is as strong an element in the innovation as the molecule itself.'

It thus appeared that Teva was aware from the outset that Ajovy would be referred to within the final article. The Panel noted that contrary to Teva's submission that the questions to be used in the interview were not on product-related items, one question did refer to Ajovy:

> 'What areas of this work are UK-based. Ajovy seems to have come out of the R&D based in Runcorn, but could you describe Teva's research and manufacturing investment in the UK?'

The Panel noted that the article in question which was titled 'Patient focus makes better business' opened with a comment from the senior leader at Teva as a way of introduction which stated:

> '[the senior leader at Teva] says that every day is a school day in their role ..... "As long as I'm learning, I'm happy. There are still so many things to do when we're focussing on patients. They are getting a stronger voice. They want to be treated the way they want to be treated. They want to access their medicines the way they want to access their medicines. Now 60 and 70-year olds are on Zoom and Face Time. Whatever we bring to the market has to have patients at the centre."'

and then included what appeared to be p3 Pharmacy's set up of the interview which stated:

> 'We're speaking days after the launch of the pre-filled pen presentation of AJOVY® (fremanezumab). The pen offers added convenience and flexibility to sufferers of chronic migraine responsive to anti-CGRP (calcitonin gene-related peptide) drugs. In June, it was the first anti-CGRP medicine approved by NICE (National Institute for Health and Care Excellence) for use in the NHS, having been previously approved by the Scottish Medicines Consortium (January). The pen device (AJOVY was initially available in a syringe) is the latest in the company's line of patient-friendly presentations that started in 2004 with the Qvar beclomethasone inhaler in the patented Easi-breathe device.'

Later the article included the following statements which were attributed to Teva's senior leader:

> 'We are one of the largest suppliers to the NHS and while our heart and soul is that of a generic manufacturer – it's what the company history is about – we are also known for our new chemical entities, including Copaxone (glatiramer acetate) for multiple sclerosis.'

and

> 'Treatment for chronic migraine had not changed for more than 20 years. We're getting loads of feedback from patients and headache specialists that it is really making a difference. The pen just makes it easier to inject the product and continue to live their lives. That's the important thing.'

Beneath the heading UK milestone for Teva the article stated:

> 'The pen breaks new ground for Teva's UK operation, it was developed at the company's research and development site in Runcorn, and will soon be filled there too. "As a homegrown product, it energises our employees, as do the patient stories we get back" [senior leader] says. "It really makes you feel that we are giving more than just a product to society."'

Noting its comments above, the Panel considered that the interview came within the scope of the Code.

The Panel noted that Clause 1.17 of the 2021 Code defined promotion broadly as any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicine.

The Panel noted that it was a well-established principle that, in general, the product name (brand or generic), particularly if alongside its indication, was likely to be seen as promotional and, depending on the context, a product could be promoted with either the product name or indication, or even without its name ever being mentioned.

The Panel noted Teva's submission that in the setup of the interview and questions proposed, p3 Pharmacy advised that it would send the article for factual checking, which was done through the Teva Corporate Communications Department. Whilst, according to Teva's initial response the final item was not provided to Teva Corporate Communications for factual checking in advance of publication, the Panel noted that, following a request for further information, communications between p3 Pharmacy and Teva, were provided which included a draft of the final article sent to Teva on 25 August 2020. Teva responded the same day with a few minor changes stating that it tried to limit them as much as possible. The Panel noted that the amendments/comments from Teva included that AJOVY is the first anti-CGRP approved by NICE, but not the first by the SMC and asked if information in relation to previous chronic migraine treatment could be removed as it sounded like Teva was disparaging its competition. It appeared therefore that Teva was aware that Ajovy (and Copaxone) would be mentioned in the final article and did not appear to recognise that reference to its medicines, including by Teva's senior leader meant that the article was promotional and for which Teva was responsible. Teva was aware of the content of the article prior to its publication and had had a chance to comment on it.

The Panel noted that the complainant and case preparation manager had referred to the clauses in the 2021 Code. The interview and resultant published article occurred in September 2020, so the Panel considered that the 2019 Code was thus relevant.

The Panel noted the article, which in its view promoted Ajovy and Copaxone, did not include prescribing information for either medicine as alleged. The Panel therefore ruled **a breach of Clause 4.1 of the 2019 Code** in relation to each. The Panel considered that failure to include the prescribing information meant that high standards had not been maintained and a **breach of Clause 9.1** was ruled in relation to each as alleged. The Panel did not consider that the specific circumstances warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. **No breach of Clause 2** was ruled in relation to each as alleged.

The Panel noted that the article did not include the obligatory adverse event report statement required in promotional material and therefore a **breach of Clause 4.9 of the 2019 Code** was ruled**.**

The Panel noted that Clause 4.10 of the 2019 Code stated that when required by the licensing authority, all promotional material must show an inverted black equilateral triangle to denote that additional monitoring was required in relation to adverse reactions. The Panel noted that according to the Ajovy SPC, accessed by the Panel on the electronic medicines compendium (emc) on 13 July 2023, Ajovy was a black triangle product. In the Panel's view, it thus was, on the balance of probabilities, likely that that was the case at the time of the interview and publication of the article but no black triangle had been included within the article in question. The Panel therefore ruled **a breach of Clause 4.10 of the 2019 Code.** The Panel considered that failure to include the black triangle, which denoted that additional monitoring was required in relation to adverse reactions meant that high standards had not been maintained and a **breach of Clause 9.1 of the 2019 Code** was ruled. The Panel considered that it was unacceptable to omit the black triangle; its appropriate use was an important part of medicines regulation and contributed towards patient safety. The Panel considered that failure to include an adverse event reporting statement compounded its concerns in this regard. The Panel therefore ruled a **breach of Clause 2** in relation to the failure to include the black triangle for Ajovy as alleged.

The Panel further noted that the article, which in its view was promotional, and for which Teva was responsible had not been certified. The Panel therefore ruled **a breach of Clause 14.1 of the 2019 Code**. In the Panel's view, certification was an important element of self-regulation and the company's failure in this regard was such that high standards had not been maintained and a **breach of Clause 9.1 of the 2019 Code** was ruled. Whilst noting its comments above, the Panel considered that the rulings of breaches adequately covered this matter and an additional ruling of a breach of Clause 2 would be disproportionate in the particular circumstances of this case. A ruling of a breach of Clause 2 was used as a sign of particular censure and reserved for such use. The Panel, on balance, **ruled no breach of Clause 2.**

Clause 3.2 of the 2019 Code stated 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'.

The Panel noted the complainant's allegation that the statement in the article 'Our product is for those people who are suffering with chronic migraine, who may be bedbound for 15 to 20 days a month' was inconsistent with the Ajovy license indication. The Panel noted that the statement appeared to be referring to Ajovy and according to section 4.1 of the Ajovy (fremanezumab) 225 mg Pre-filled Pen for Injection▼ SPC, accessed by the Panel on 13 July 2023 on emc, it was indicated for the treatment of prophylaxis of migraine in adults who have at least 4 migraine days per month. The Panel noted that the complainant bore the burden of proof and did not consider that they had provided evidence to establish that the statement was inconsistent with the SPC as alleged and therefore the Panel ruled **no breach of Clause 3.2 of the 2019 Code**. The Panel, consequently, ruled **no breach of Clauses 9.1 and 2 of the 2019 Code**.

The Panel noted the complainant's allegation that the statement in the article 'we are also known for our new chemical entities, including Copaxone® (glatiramer acetate) for multiple sclerosis' was inconsistent with the Copaxone licenced indication. The Panel noted that according to Section 4.1 of the Copaxone SPC, accessed by the Panel on 13 July 2023 on the

emc, it was indicated for the treatment of relapsing forms of multiple sclerosis (MS) and not indicated in primary or secondary progressive MS. The statement in the article implied that Copaxone was licensed for all types of multiple sclerosis which was not so, and thus the statement at issue was inconsistent with the SPC as alleged and therefore the Panel ruled a **breach of Clause 3.2 of the 2019 Code**. The Panel considered that high standards had not been maintained in this regard and **a breach of Clause 9.1 of the 2019 Code** was ruled. The Panel considered that the rulings of breaches adequately covered this matter and in the particular circumstances of this case an additional ruling of a breach of Clause 2 was not warranted. **No breach of Clause 2** was ruled.

The Panel noted the complainant's allegation that there was no evidence to support the statement made by Teva's senior leader that 'The pen just makes it easier for patients to inject the product and continue to live their lives. That's the important thing' and the claim was false and misleading. The Panel noted that Teva had not commented or provided any evidence in this regard.

In the particular circumstances of this case, the complainant had submitted no material and had not identified any specific evidence to support their position. The Panel noted that the complainant bore the burden of proof and considered that they had not established their case on the balance of probabilities. In the absence of any evidence on this point, and on this very narrow ground alone, the Panel did not consider that it had been established that the claim was misleading or incapable of substantiation as alleged and the Panel therefore ruled **no breach of Clauses 7.2 and 7.4 of the 2019 Code**. The Panel consequently ruled **no breach of Clauses 9.1 and 2 of the 2019 Code** in this regard.

The Panel noted the word 'new' must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than 12 months in the UK. Given the date of first authorisation of Copaxone in the UK was according to the Copaxone SPC, accessed by the Panel on 13 July 2023 on the emc, was 7 April 2003 and a renewal of the authorisation was 11 September 2007, the Panel considered that use of the term 'new' in 'We are also known for our **new** (emphasis added by the Panel) chemical entities, including Copaxone® (glatiramer acetate) for multiple sclerosis' constituted a **breach of Clause 7.11 of the 2019 Code**.

Complaint received **6 June 2022**

Case completed **14 September 2023**