CASE AUTH/3659/6/22

COMPLAINANT v TEVA

Allegations about the promotion of Ajovy on a Teva website

CASE SUMMARY

This case was in relation to a Teva registration website for health professionals to register for access to recorded webinar highlights videos from a meeting in relation to Ajovy (fremanezumab).

The Panel ruled a breach of the following Clauses of the 2021 Code for having a link to the prescribing information that was not sufficiently prominent thereby failing to maintain high standards, and failing to include the black triangle adjacent to the first mention of Ajovy on two separate pages of the website.

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.6	**Failing to include a clear, prominent statement as to where prescribing information could be found**
Breach of Clause 12.10	**Failing to include a black triangle adjacent to the first mention of the product in digital material**
Breach of Clause 16.1	**Producing a website that contained promotional material which did not comply with all relevant requirements of the Code**

The Panel ruled no breach of the following Clauses of the 2021 Code on the basis that in the particular circumstances of this case, the landing page had not disguised the promotional nature of the registration website homepage and the complainant had not established that:

- **the claim 'Less migraine. More moments' was a hanging comparison and had not made out their allegation that it was incapable of substantiation**
- **the homepage and contents page of the website promoted Ajovy outside the licensed indication, and**
- **in the particular circumstances of this case the absence of an option for members of the public on the landing page meant that members of the public had accessed information not intended for them**

No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 6.1	**Requirement that claims must not be misleading**

No Breach of Clause 6.2	**Requirement that claims must be capable of substantiation**
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**
No Breach of Clause 26.2	**Requirement that information about prescription only" medicines which is made available to the public must be" factual, balanced, must not raise unfounded hopes of" successful treatment or encourage the public to ask" their health professional to prescribe a specific" prescription only medicine.**

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

FULL CASE REPORT

An anonymous, contactable complainant who described themselves as a health professional alleged that there were a number of breaches on a Teva UK Limited website for Ajovy. The website with compliance failings was:lessmigraine.co.uk (ref AJO-UK-00016 Date of Preparation: October 2020).

COMPLAINT

Landing page (https://lessmigraine.co.uk/)

The complainant alleged that there was no separate option for members of the public on the landing page, the access was provided only for health professionals or patients. The complainant alleged breaches of Clauses 26.2, 5.1 and 2 as there should have been a section dedicated to the public so members of the public did not access content not intended for them when arriving at the landing page.

The complainant further alleged that the landing page did not mention that the content of the website would be about product as there would be the expectation that the website would just be migraine information that was educational and not promotional. This was disguised promotion as the landing page should have made clear that there was promotional content on the website and breaches of Clauses 3.6, 5.1 and 2 were alleged.

Homepage (https://lessmigraine.co.uk/home/)

The complainant alleged that the homepage promoted Ajovy outside the licensed indication. The wording read as follows: 'We are pleased to have held the AJOVY Webinar in May 2020, a promotional webinar for the management of difficult-to-treat migraine, via live stream'. Ajovy was not licensed for difficult-to-treat migraine, the actual indication was for prophylaxis of migraine in adults who have at least 4 migraine days per month. The complainant alleged a breach of Clauses 11.2, 5.1 and 2. Inconsistency with the summary of product characteristics

(SPC) was very concerning, considering this was a black triangle product. The actual licence had not been presented anywhere on the homepage.

On the homepage, the first and most prominent mention of Ajovy was at the top of the page which read 'Welcome to the registration website for the recorded 2020 AJOVY Webinar highlights'. However, there was no black triangle mentioned next to this first and prominent mention of the product in breach of Clauses 12.10, 5.1 and 2.

Contents page (https://lessmigraine.co.uk/content/)

The complainant stated that the contents page of the website also had the incorrect indication. There was reference to video 2 title as 'AJOVY for the management of patients with difficult-to-treat migraine'. The complainant alleged that this was a breach of Clauses 11.2, 5.1 and 2 as Ajovy was not licensed for difficult-to-treat migraine and there needed to have been 4 migraine days for treatment.

Registration page (https://lessmigraine.co.uk/registration/)

The complainant alleged that there was no black triangle next to the first and prominent display of Ajovy on the registration page in breach of Clauses 12.10, 5.1 and 2.

Overall

The complainant alleged that the claim on every single page of this website at the top was 'less migraine, more moments' and that this was a hanging comparison as it was not qualified as to what the 'less migraine, more moments' was actually against in breach of Clauses 6.1, 6.2, 5.1 and 2.

The complainant further alleged that none of the pages on the website had a prominent statement as to where the prescribing information could be found, in breach of Clause 12.6 multiple times as well as Clauses 5.1 and 2.

The complainant stated that these were serious errors for a black triangle product. The competency of the medical Central Nervous System (CNS) team and leadership at Teva was doubtful and concerning, considering the failings of this website.

When writing to Teva, the Authority asked it to consider the requirements of Clauses 2, 3.6, 5.1, 6.1, 6.2, 11.2, 12.6, 12.10 and 26.2 of the 2021 Code as cited by the complainant. In addition, the Case Preparation Manager asked Teva to respond in relation to Clause 16.1.

RESPONSE

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

Teva stated that it would address the matter in the letter of complaint and bear in mind the requirements of Clauses 2, 3.6, 5.1, 6.1, 6.2, 11.2, 12.6, 12.10, 16.1 and 26.2 of the 2021 Code as cited by the complainant but noted that the website was published in October 2020 and therefore at the time of approval it had been reviewed and certified as per the 2019 Code that was in place at the time of publication.

Teva explained that the website was a registration website to enable health professionals to access a recording of a promotional webinar that had been held earlier in 2020 around the launch of Ajovy (fremanezumab) and post NICE (The National Institute for Health and Care Excellence) recommendation for its use. Health professionals were signposted to the website through the Teva Key Account Manager sales team – it was not promoted in any other way or on any other Ajovy material, nor promoted via search engines.

Teva submitted that the website was not detailed on other promotional items such as Ajovy campaign leavepieces and other health professional-facing material used by the sales team or on the internet and could only be found if signposted to the website following awareness from the Sales Team, as above, or found inadvertently via search engines.

The allegations were considered as follows.

Landing page (https://lessmigraine.co.uk/)

Teva stated that the website was a registration website to enable access to promotional material, and, as such, was only intended for health professionals to enable them to see details of the agenda of the recorded webinar and then request access once they had been made aware of its existence through the Sales Team, with that access restricted, moderated and limited to health professionals.

Teva stated that there was no Code requirement for information to be available for members of the public on a promotional website. Teva referred to Case AUTH/3271/10/19 – Complainant v Napp, when the Panel ruled a breach because the user could select if they were 'a patient or a member of the general public' but the content was aimed specifically at patients who had been prescribed the medication. As the website did not state it provided information for the public nor did it contain content that was suitable for members of the public, Teva believed there was no breach of the Code. On the contrary, having a 'Members of the Public' section on a promotional website would contravene Clause 26.1 and case precedent by indicating medicine information was relevant to those who had not been prescribed a prescription only medicine. The website clearly stated that it was a registration website for accessing recorded webinar highlight videos for Consultants, Nurses and GPs with an interest in headache and migraine, funded and organised by Teva UK Limited, and further asking for confirmation of such or if a patient, then directing to an alternative website as was described by the Code.

The supplementary information to Clause 16.1 states:

> *'**Clause 16.1 (28.1) Website Access***
> *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 MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.'*

It was clear that the promotional content was only accessible to health professionals in that they had to complete a registration page and then have their registration status checked and secure login details provided by the Secretariat of the meeting once that status had been confirmed:

> *'Clause 26.2 (26.2) Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.'*

It was clear therefore that there should have been no information for members of the public, and there was no information presented to the public and furthermore no information that might have raised unfounded hope of successful treatment or be misleading and Teva therefore refuted a breach of Clauses 26.2, 5.1 and 2 of the Code as alleged and Clause 16.1 as raised by the Case Preparation Manager.

Teva submitted that the website was clear in what it was, in that it was a website to enable registration to access recordings of a webinar. The registration website landing page itself was not promotional and did not mislead in stating it was migraine information, it merely identified the appropriate audience for the content post-registration, once a health professional had been signposted to the website following contact with the sales team.

Teva therefore refuted allegations of disguised promotion (Clause 3.6) on the landing page or subsequent pages which had the product name to enable the reader to decide whether they wished to register to access the content and therefore refuted a breach of Clauses 3.6, 5.1 and 2.

Homepage (https://lessmigraine.co.uk/home/)

Teva submitted that as was clear from the page, the promotional Ajovy Webinar was for the management of difficult-to-treat migraine, and this was not a claim directed at the attributes of Ajovy. However, for clarity, the licensed indication for Ajovy was for the prophylaxis of migraine in adults who had at least 4 migraine days per month. This indication covered a broad spectrum of patients that had a primary headache diagnosis of migraine, with a restriction on the minimum frequency of attacks per month. Within the population of migraine patients, variability existed in terms of migraine severity, frequency and response to therapies. A sub-population of migraine patients might have attacks that occur at a high frequency (chronic migraine patients defined by at least 8 migraine days per month) or had at least 4 migraine days per month where attacks were very severe and highly disabling. Additionally, these patients might not respond to first-, second- or third-line treatments. This subpopulation was described as having difficult-to-treat migraine.

Difficult-to-treat migraine patients had a primary diagnosis of migraine and experienced at least 4 migraine days per month, therefore this sub-population was contained within the licensing indication of Ajovy. Furthermore, it was this population where Ajovy was reimbursed in the UK; within its licensed indication for patients with a diagnosis of migraine that had failed at least three prior preventive therapies. Difficult-to-treat Migraine was, indeed, referred to in the Ajovy SPC.

The recorded webinar on the website focussed on the management of this difficult-to-treat sub-population of migraine patients, and this was where the product was licensed and reimbursed and was therefore not inconsistent with the SPC.

Teva therefore refuted breaches of Clauses 11.2, 5.1 and 2 as the website did not promote Ajovy outside of its licensed indication.

Teva submitted that as could be clearly seen on the homepage, as provided by the case preparation manager and Teva, the brand name was located on the homepage with the most prominent version detailing generic name and black triangle.

Teva therefore refuted breaches of Clauses 12.10, 5.1 and 2.

Contents page (https://lessmigraine.co.uk/content/)

Teva repeated that the licensed indication for Ajovy was for the prophylaxis of migraine in adults who had at least 4 migraine days *per* month. This indication covered a broad spectrum of patients that had a primary headache diagnosis of migraine, with a restriction on the minimum frequency of attacks per month. Within the population of migraine patients, variability existed in terms of migraine severity, frequency and response to therapies. A sub-population of migraine patients might have attacks that occur at a high frequency (chronic migraine patients defined by at least 8 migraine days per month) or have at least 4 migraine days per month where attacks were very severe and highly disabling. Additionally, these patients might not have responded to first-, second- or third-line treatments. This sub-population was described as having difficult-to-treat migraine.

Difficult-to-treat migraine patients had a primary diagnosis of migraine and experienced at least 4 migraine days per month, therefore this sub-population was contained within the licensing indication of Ajovy. Furthermore, it was this population where Ajovy was reimbursed in the UK; within its licensed indication for patients with a diagnosis of migraine that had failed at least three prior preventive therapies. Difficult-to-treat Migraine was, indeed, referred to in the Ajovy SPC.

The recorded webinar on the website focussed on the management of this difficult-to-treat sub-population of migraine patients, and this was where the product was licensed and reimbursed and was therefore not inconsistent with the SPC.

Teva therefore refuted allegations of breaches of Clauses 11.2, 5.1 and 2 as the website had not promoted Ajovy outside of its licensed indication.

Registration page (https://lessmigraine.co.uk/registration/)

Teva reiterated its statement above and earlier that it could be clearly seen on the homepage provided by Teva and in the screenshot provided by the case preparation manager, that the brand name was located on the homepage with the most prominent version detailing the generic name and black triangle.

Teva therefore again refuted the further breaches of Clauses 12.10, 5.1 and 2.

Overall

Teva submitted, with regard to the statement 'less migraine, more moments', it was clearly annotated with a registered trademark. The statement was registered with the Intellectual Property Office (IPO) under trademark numbers UK00918021651, UK00917925545 and UK00003321840 and linked to class 16, printed materials related to the treatment of migraines, class 41 and 44 providing information relating to the treatment of migraines and class 5 pharmaceutical preparations for the treatment of neurological disease, migraines amongst others, all of which could be clearly found when searching on https://www.gov.uk/search-for-trademark for the phrase 'less migraine, more moments'. The registered trademark was not a claim for Ajovy, nor linked to Ajovy in its registration as was evident from above and the IPO website.

Teva therefore refuted breaches of Clauses 6.1, 6.2, 5.1 and 2.

Teva maintained that as could be clearly seen on each page directed at health professionals, there was a statement 'Prescribing Information' which provided a single click link to 'Abbreviated Prescribing Information'.

Teva therefore refuted allegations of breach of Clauses 12.6, 5.1 and 2 and there were no serious errors for a black triangle product as alleged.

Teva believed that the individual might have knowledge of Teva's Medical Department either through working for another pharmaceutical company, working for Teva or having recently left Teva, and/or was maliciously targeting Teva as the complaint was of almost identical wording and nature to previous complaints, disparaging and disrespectful in itself.

In addition, Teva noted that the complainant provided no supporting documents and therefore believed, as per the spurious and factually incorrect information stated in the complaint, that it should be dismissed as there was no *prima facie* evidence provided or case to consider.

Teva provided the certificate and details of the Medical Signatory who was no longer employed by Teva UK Limited.

PANEL RULING

Landing page (https://lessmigraine.co.uk/)

The Panel noted that, according to the landing page, the website was a registration website for accessing recorded webinar highlight videos; for Consultants, Nurses and GPs with an interest in headache and migraine, funded and organised by Teva UK Limited.

The Panel noted Teva's submission that the website was not detailed on promotional items such as Ajovy campaign leavepieces and other health professional-facing material used by the sales team, or on the internet and could only be found if signposted to the website following awareness from the sales team or found inadvertently via search engines.

The Panel noted that on the landing page, readers were asked to confirm that they were a health professional to enter the registration website and were then given the option to choose whether they were a health professional or a patient.

The Panel noted the supplementary information to Clause 26.2, Website Access, which referred to websites providing information for the public as well as promotion to health professionals and the need to have the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The Medicines and Healthcare products Regulatory Agency (MHRA) Blue Guide advised that the public should not be encouraged to access material which was not intended for them. The Panel noted that whilst this supplementary information did not specifically mention material for patients who had been prescribed a specific medicine, companies could, nonetheless, provide information about a specific medicine to patients for whom the prescribing decision had already been made so long as such information complied with the relevant requirements of the Code. In the Panel's view, the principles of the supplementary information to Clause 26.2 were relevant and the intended audience should be identified. When identifying the audience, companies should be clear about whether they were identifying patients in a broad sense or patients who had been prescribed a specific medicine.

The Panel did not agree with Teva's submission that there was no Code requirement for information to be available for members of the public on a promotional website. The Panel noted that the supplementary information to Clause 16.1, Website Access, stated that '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 was to avoid the public needing to access material for health professionals unless they chose to. In this regard, the Panel noted that promotional content was accessible prior to health professionals' registration status being checked and confirmed and secure login details being provided.

Whilst the Panel noted Teva's submission that the website did not state it provided information for the public nor did it contain content that was suitable for members of the public, it further noted Teva's submission that if 'I am a patient' on the landing page was selected, readers were directed to an alternative website. The Panel noted that the screen presented when 'I am a patient' was selected stated 'YOU ARE NOW LEAVING THE RECORDED WEBINAR WEBSITE Teva UK Limited and the meeting organisers are not responsible for the content of external sites' and asked the reader to confirm to 'Leave website'.

It appeared from the screenshots provided by Teva that the website readers were directed to was a Teva UK website which included tabs for 'Patients and Health Professionals' at the top of the page alongside the following tabs 'About Teva', 'support for pharmacists', 'Our impact', 'Your career', 'News & media', and 'Contact us'. Details of the contents of this website were not before the Panel so it was unclear whether its content within the 'Patients' section was aimed at patients who had been prescribed Ajovy or patients in a broad sense and whether there was content on the website suitable for members of the public.

The Panel considered it would have been helpful if the landing page was clear with regard to whether it was identifying patients in a broad sense or patients who had been prescribed Ajovy and if the latter had provided a third option for members of the public who had not been prescribed the medicine.

However, in the particular circumstances of this case, noting Teva's submission with regard to how health professionals were directed to the website and noting that there was no evidence

that the website 'patients' were directed to was not suitable for members of the public, the complainant had not established that the absence of an option for members of the public on the landing page meant that members of the public had accessed information not intended for them as alleged. The Panel, therefore, based on the complainant's allegation, ruled **no breach** of **Clause 26.2** and consequently **no breach of Clauses 5.1 and 2**.

The Panel noted that if readers selected 'I am a health professional' on the landing page they were directed to the registration website, the homepage of which was headed 'Welcome to the registration website for the recorded 2020 Ajovy webinar highlights' followed by 'We are pleased to have held the Ajovy webinar in May 2020, a promotional webinar for the management of difficult-to-treat migraine, via live stream. The recorded webinar highlights are open to Consultants, Nurses and GPs with an interest in headache and migraine'. Readers could view the content of the entire registration website which, in the Panel's view, was promotional; it included the brand name Ajovy and what it was used for as well as a link to the prescribing information. In this regard, the Panel noted that promotional content of the registration website was accessible prior to health professionals' registration status being checked and confirmed and secure login details being provided.

The Panel noted Teva's submission with regard to how health professionals were signposted to the registration website by Teva's sales team; there were, however, no details before the Panel with regard to how the sales team introduced the website.

In the Panel's view, it would have been helpful for the landing page to have included information that the registration website homepage contained promotional content or would include information on Teva's medicines so health professionals would be aware before they accessed the registration website homepage which, in the Panel's view, was promotional. Further, in the Panel's view, whilst the landing page referred to being for health professionals with an interest in headache and migraine which might imply that it would only contain disease information, it further stated that it was funded and organised by Teva UK Limited.

Nonetheless, noting the above, the Panel considered that health professionals accessing the landing page would be aware that the registration website was funded and organised by Teva and, on the balance of probabilities, would be likely to assume that it would include information on Teva's medicines in relation to headache and migraine and would therefore contain promotional content. The Panel did not consider, in the particular circumstances of this case, that the promotional nature of the registration website homepage had been disguised and, on balance, **no breach of Clause 3.6** was ruled. The Panel consequently ruled **no breach of Clauses 5.1 and 2**.

Homepage (https://lessmigraine.co.uk/home/)

The Panel noted that the allegation related solely to the homepage of the registration website; the Panel had no information before it related to the content of the webinar itself and it made its rulings on that basis.

The registration homepage included a welcome message from the meeting chair, 'Welcome to the registration website for the recorded 2020 Ajovy webinar highlights' followed by 'We are pleased to have held the Ajovy Webinar in May 2020, a promotional webinar for the management of difficult-to-treat migraine.', and indicated the target audience was 'consultants, nurses and GPs with an interest in headaches and migraine'.

The Panel disagreed with Teva's submission that '.for the management of difficult-to-treat migraine…' was not a claim directed at the attributes of Ajovy. The webinar was described as an Ajovy webinar and a promotional webinar for the management of difficult-to-treat migraine.

The Panel noted that the licensed indication for Ajovy, as stated in Section 4.1 of its SPC, was for prophylaxis of migraine in adults who have at least 4 migraine days per month.

The Panel noted the complainant's allegation that the wording 'We are pleased to have held the AJOVY Webinar in May 2020, a promotional webinar for the management of difficult-to-treat migraine, via live stream' on the website registration homepage promoted Ajovy outside the licensed indication because it was not licensed for difficult-to-treat migraine and the actual indication was for prophylaxis of migraine in adults who have at least 4 migraine days per month. The Panel noted the reasons given by the complainant in relation to the similar allegation on the contents page was that Ajovy was not licensed for difficult-to-treat migraine and there needed to have been 4 migraine days for treatment.

The Panel noted Teva's submission that a sub-population of migraine patients might have attacks that occur at a high frequency (chronic migraine patients defined by at least 8 migraine days per month) or have at least 4 migraine days per month where attacks were very severe and highly disabling. Additionally, these patients might not respond to first-, second- or third-line treatments; a subpopulation Teva described as having difficult-to-treat migraine.

The Panel further noted that Section 5.1 of the SPC, Pharmacodynamic Properties, included, among other things, summaries of evidence from relevant studies, one of which was titled 'Difficult to treat migraine' and described a 12 week study that included 838 episodic and chronic migraine patients with documented inadequate response to two to four classes of prior migraine preventive medicinal products.

The Panel noted Teva's submission that difficult-to-treat migraine patients had a primary diagnosis of migraine and experienced at least 4 migraine days per month and therefore this sub-population was contained within the licensed indication of Ajovy. The complainant had not provided any evidence to the contrary. The Panel noted that all complaints were judged on the evidence provided by both parties and that the complainant bore the burden of proof. The Panel noted that, on the evidence provided, the complainant had not established that the wording 'We are pleased to have held the AJOVY Webinar in May 2020, a promotional webinar for the management of difficult-to-treat migraine, via live stream' on the health professional registration website homepage promoted Ajovy outside the licensed indication, as alleged, and, based on the complainant's very narrow allegation, the Panel ruled **no breach of Clause 11.2** and consequently **no breach of Clauses 5.1 and 2**.

The Panel noted the complainant's allegation that there was no black triangle mentioned next to this first and prominent mention of Ajovy at top of the homepage in the heading which read 'Welcome to the registration website for the recorded 2020 AJOVY® Webinar highlights'. In relation to digital communications, Clause 12.10 required that the black triangle should be located adjacent to the first mention of the product as this was likely to be considered the most prominent display of the product. Whilst the Panel noted that the Ajovy brand logo, which included the black triangle, was located in the bottom right corner of the webpage, it was as part of the footer which appeared to the Panel would require scrolling to see. In the Panel's view, the black triangle should therefore have been included adjacent to the first mention of Ajovy on

the homepage and was not. The Panel therefore ruled a **breach of Clause 12.10**. In the particular circumstances of this case, the Panel did not consider that Teva had failed to maintain high standards in this regard, and it ruled **no breach of Clause 5.1** and consequently **no breach of Clause 2**.

Contents page (https://lessmigraine.co.uk/content/)

The Panel noted the complainant's allegation that the contents page of the registration website also had the incorrect indication. In this regard, the complainant referred to the title of video 2 'AJOVY for the management of patients with difficult-to-treat migraine' and alleged that Ajovy was not licensed for difficult-to-treat migraine and there needed to have been 4 migraine days for treatment.

The Panel noted that the allegation related solely to the title of Video 2 on the contents page of the website; the Panel had no information before it related to the content of the video itself and it made its rulings on that basis.

The Panel noted that the licensed indication for Ajovy, as stated in Section 4.1 of its SPC, was for prophylaxis of migraine in adults who have at least 4 migraine days per month.

The Panel noted Teva's submission that a sub-population of migraine patients might have attacks that occur at a high frequency (chronic migraine patients defined by at least 8 migraine days per month) or have at least 4 migraine days per month where attacks were very severe and highly disabling. Additionally, these patients might not respond to first-, second- or third-line treatments and this sub-population was described as having difficult-to-treat migraine.

The Panel further noted that Section 5.1 of the SPC, Pharmacodynamic properties which, included among other things, summaries of evidence from relevant studies, one of which was titled 'Difficult to treat migraine' and described a study that included 838 episodic and chronic migraine patients with documented inadequate response to two to four classes of prior migraine preventive medicinal products.

The Panel noted Teva's submission that difficult-to-treat migraine patients had a primary diagnosis of migraine and experienced at least 4 migraine days per month and therefore this sub-population was contained within the licensing indication of Ajovy. The complainant had not provided any evidence to the contrary. The Panel noted that all complaints were judged on the evidence provided by both parties and that the complainant bore the burden of proof. The Panel noted that on the evidence provided, the complainant had not established that the statement 'Ajovy for the management of patients with difficult-to-treat migraine' on the contents webpage promoted outside the licensed indication as alleged and based on the complainant's very narrow allegation, the Panel ruled **no breach of Clause 11.2** and consequently **no breach of Clauses 5.1 and 2**.

Registration page (https://lessmigraine.co.uk/registration/)

The Panel noted the complainant's allegation there was no black triangle next to this first and prominent mention of Ajovy on the health professional registration webpage of the registration website.

The Panel noted that the first mention of Ajovy on the health professional registration page was in the title 'Thank you for your interest in accessing the 2020 Ajovy recorded webinar' at the top of the page.

The Panel noted Teva's submission that the brand name was located on the homepage of the website with the most prominent version detailing the generic name and black triangle. It was not clear to the Panel whether the health professional registration webpage could be accessed without having to view the homepage. Nonetheless, the Panel noted its comments and rulings above with regard to the location of the black triangle on the homepage and considered that even if the homepage always had to be viewed prior to reaching the registration webpage, the black triangle and the apparent need for scrolling to see it in the footer of the homepage was such that it was likely to be missed before accessing the health professional registration webpage and thus the health professional registration webpage should have included the black triangle as required by Clause 12.10. The Panel ruled a **breach of Clause 12.10**. In the particular circumstances of this case, the Panel did not consider that Teva had failed to maintain high standards in this regard, and it ruled **no breach of Clause 5.1** and consequently **no breach of Clause 2**.

Overall

The Panel noted the complainant's allegation that the strapline 'Less migraine. More moments.' was a hanging comparison as it was not qualified as to what the 'less migraine, more moments' was actually against. The Panel noted Teva's comments that the statement was a registered trademark but disagreed that this meant it could not be considered a claim for Ajovy. In the Panel's view, the statement 'Less migraine. More moments' on an Ajovy promotional website was a claim for Ajovy and implied that patients would have 'less migraine' and therefore 'more moments' after taking Ajovy.

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel considered that, on the balance of probabilities, the complainant had not established that the claim was a hanging comparison, as alleged, and **no breach of Clause 6.1** was ruled.

The Panel noted that Clause 6.2 required that any information, claim or comparison must be capable of substantiation. The Panel did not consider that the complainant had made out his/her allegation in this regard; it was not for the Panel to make out a complainant's case for him/her. The Panel therefore ruled **no breach** of **Clause 6.2**. The Panel noted its rulings above and consequently ruled **no breach of Clauses 5.1 and 2**.

The Panel noted that Clause 12.6 required that promotional material provided on the internet must include a clear **prominent** statement as to where the prescribing information could be found.

The Panel noted that the link to the prescribing information was in the footer of each page of the website alongside the link to the company's privacy policy and terms and conditions, in smaller font size than the text in the main body of each webpage, and, in the Panel's view, was not sufficiently prominent and a **breach of Clause 12.6** was ruled in relation to each webpage. The Panel considered that Teva had failed to maintain high standards in this regard and **a breach of Clause 5.1** was ruled.

The Panel noted its rulings above but did not consider that the particular circumstances in this case 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.

The Panel noted that the case preparation manager had raised Clause 16.1 which required promotional material about prescription only medicines directed at a UK audience on the internet to comply with all the relevant requirements of the Code and, noting its rulings of breaches of the Code above, **ruled a breach of Clause 16.1**.

Complaint received **15 June 2022**

Case completed **19 June 2023**