

VOLUNTARY ADMISSION BY ASTELLAS EUROPE

Promotion of Betmiga to the public via social media and the Internet

Astellas Pharma Europe voluntarily admitted breaches of the Code in that three Betmiga (mirabegron) videos had been posted online by third parties. The videos included a number of product claims and thus Betmiga, a prescription only medicine, had been promoted to the public.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Astellas.

Astellas Pharma Europe explained that a member of staff received alerts relating to Betmiga content changes on the web when certain key words were detected. From an alert (1 November 2016) accessed on 2 November it appeared that two videos which contained multiple references to Betmiga and various product claims were available on the social media site, Vimeo. Medical colleagues and other staff were informed.

A third video, of an internal Astellas launch event, was then identified via a UK events awards website by the Astellas Pharma Europe compliance team on 14 November 2016.

Astellas Pharma Europe explained that videos 1 and 2 were initially created by a UK based agency contracted to provide support for the launch of Betmiga.

The objective of video 1 was to motivate and grow the interest of Betmiga for brand teams involved in the product launch. The video was for internal use only and at that time, could only be viewed on a secure, internal intranet. This secure site was password protected and only the brand manager/medical managers for Betmiga in EMEA affiliates had access to it.

The objective of video 2 was to demonstrate the quality of the Betmiga launch campaign for a pharmaceutical industry advertising awards submission. The agency submitted the video on its own behalf but received permission from Astellas Pharma Europe to do so. This video was intended to be viewed by the competition judges only.

Video 3 contained excerpts of an internal Betmiga launch event filmed by another third party agency which created video 3 specifically for another award.

Neither Astellas Pharma Europe nor the agency knew that videos 1 and 2 had been posted by an ex-employee of the agency to demonstrate past work experience for future employment opportunities.

Video 3 was found on an awards website where it appeared that it was linked to YouTube which hosted the video in an area that could only be accessed via a secure link rather than by searching YouTube or the wider internet. The secure link had

now been deleted. Astellas Pharma Europe could not confirm if the video was taken down at source as the agency no longer existed.

Given the above, Astellas Pharma Europe fully accepted that it had breached the Code as prescription only medicines were advertised to the public. In addition, it might have encouraged members of the public to ask their health professional to prescribe a specific prescription only product. Given that promotion of a prescription only medicine to the public was a serious matter, Astellas understood that the Panel might wish to consider whether high standards had been maintained and the requirements of Clause 2.

Detailed information from Astellas Pharma Europe appears below.

The Panel noted that Vimeo was an open access website and was not limited to professional use. The Panel considered that there was a difference between putting examples of pharmaceutical promotional material on an advertising agency's website, in a section clearly labelled in that regard and putting the same on Vimeo. The Panel considered that placing videos 1 and 2 on Vimeo promoted a prescription only medicine to the public and statements had thus been made in a public forum which would encourage members of the public to ask their health professional to prescribe Betmiga. Breaches of the Code were ruled including that high standards had not been maintained. The Panel noted that Astellas Pharma Europe had taken immediate steps to ensure removal of the material from the websites as soon as it was discovered. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such.

The Panel noted that video 3, which also contained claims for Betmiga, was filmed by a second agency, specifically for entry into an awards event in 2013 and contained excerpts of an internal Betmiga launch event. The agency had ceased trading. Astellas Pharma Europe knew of no correspondence requesting permission to create and use video 3 in the way described.

The Panel acknowledged that creative agencies would want to enter their work for awards and that as a result, examples of such work might appear, *inter alia*, on open access websites. The website in this case was directed specifically at the creative media and although anyone could access it, it was not aimed at the general public. In addition it appeared that whilst the video could be viewed from the event awards website, the video could only be accessed on YouTube via a secure link rather than by searching YouTube or the wider internet.

The Panel considered that in the particular circumstances of this case, Betmiga had not been promoted to the public. No breaches of the Code were ruled including no breach of Clause 2.

Astellas Pharma Europe Ltd (Astellas Pharma Europe) voluntarily admitted breaches of the Code in that three Betmiga (mirabegron) videos had been posted online by two third parties.

The videos included a number of product claims. The company considered that Betmiga, a prescription only medicine, had thus been promoted to the public. Betmiga was indicated for the symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as might occur in adults with overactive bladder (OAB) syndrome.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Astellas.

VOLUNTARY ADMISSION

Astellas Pharma Europe explained that a member of staff received alerts relating to Betmiga when content changes on the web in relation to certain key words were detected. From an alert delivered on 1 November and accessed on 2 November 2016 it appeared that two videos which contained multiple references to Betmiga and various product claims were available on the social media site, Vimeo. Medical colleagues and other staff were informed.

The videos were entitled Manifesto (video 1) and an International launch campaign by a named third party (video 2). A third video, of an internal Astellas launch event, was then identified by Astellas Pharma Europe compliance team on 14 November 2016 via a UK event awards website. Video 3 was entitled Astellas Betmiga launch. All three videos and the transcript for video 1 were provided.

Background

Astellas Pharma Europe explained that videos 1 and 2 were initially created by a UK based agency contracted by Astellas Pharma Europe to provide support for the launch of Betmiga.

The objective of video 1 was to motivate and grow the interest of Betmiga for brand teams involved in the product launch. The video was for internal use only and was presented to internal marketing staff during a meeting of Astellas Europe, Middle East & Africa (EMEA) affiliate companies. At the time, it could only be viewed on a secure, internal only Betmiga intranet hub which was a repository of Betmiga material for EMEA affiliates. This secure site was password protected and only the brand manager/medical managers for Betmiga in EMEA affiliates had access. This video was not approved in Zinc as it was for internal use only. It was not for use with representatives or for training of any kind and was not intended to be used externally with health professionals or other relevant decision makers.

The objective of video 2 was to demonstrate the quality of the Betmiga launch campaign for a pharmaceutical industry advertising awards submission. The agency submitted the video on its own behalf but received permission from Astellas Pharma Europe to do so. This video was intended to be viewed by the competition judges only. The video was not approved in Zinc.

Video 3 contained excerpts of an internal Betmiga launch event. The launch event was filmed by a second third party agency which created video 3 specifically for entry into an event awards in 2013. However, the agency had ceased trading and Astellas Pharma Europe could not confirm its objective. Astellas Pharma Europe staff were unaware of any correspondence requesting permission from Astellas Pharma Europe to create and use video 3 in the ways described.

A brief description of the videos which included medicine related text/voiceover script only was provided as follows:

a) Video 1 (1 minute 53 seconds)

A male actor displays multiple images for the majority of video. Towards the end of the video the following voiceover and imagery was presented:

'We make more than just medicines. We make change happen for patients whose needs aren't being met ... all around the world ... and soon when we launch Betmiga ... we will be making a bit of history too... this is an entirely new approach to Overactive Bladder the first in 30 years ...'

A screen shot follows which contained the Betmiga brand and text which said; 'countdown to launch'.

b) Video 2 (2 minutes 9 seconds)

Opening screenshot with text: it's time to think of Betmiga- international launch by [agency name]'. There then followed screen shots of Betmiga marketing materials, shots of booths, congress and shots of an evening dinner. Much of the material stated that Betmiga was a new product – as it was at the time of launch in 2013.

c) Video 3 (35 seconds)

This video included snapshots of the internal Astellas audience, and a large cinematic screen could be seen in full view. The screen displays the following text at a specific timepoint in the video:

'Betmiga has a unique product profile which makes a real difference to patient's lives'

The following text appeared on the events awards website page in the same setting as the video but was not present in the video:

'Betmiga has redefined the competitive landscape in OAB'.

Astellas Pharma Europe submitted that it appeared that videos 1 and 2 were available on Vimeo, a video-sharing website (similar to YouTube) on which users could upload, share and view videos. The website was freely available for the public to use.

When it discovered videos 1 and 2 on Vimeo, Astellas Pharma Europe contacted its agency as part of its investigation. Neither Astellas Pharma Europe nor the agency knew that these videos had been posted. Upon further investigation it was noted that the video uploader was an ex-employee of the agency who when contacted confirmed his/her responsibility for the postings. The videos appeared to have been posted in order to demonstrate past work experience for future employment opportunities and access was not password protected. On learning of the error, the ex-employee apologised and immediately removed the videos. Astellas Pharma Europe confirmed that the videos were no longer available on Vimeo from 2 November 2016. Neither Astellas Pharma Europe nor its agency had received any request or correspondence from the ex-employee regarding the placing of these videos on the internet.

By taking the videos with him/her when he/she left the agency, the ex-employee had breached the terms of his/her employment contract and the agency had asked its ex-employee to destroy all copies of videos 1 and 2.

The exact dates that videos 1 and 2 were first posted to Vimeo were unknown. However, on 2 November 2016, Vimeo generated text stated that it was posted '3 years ago'. The agency confirmed that the individual had already left its employ when the videos appeared to have been first posted to Vimeo.

The agency was disappointed and assured Astellas Pharma Europe that as soon as rare situations such as this came to its attention, it acted swiftly to resolve them.

Video 3 was found on a UK event awards website. It appeared that the awards website did not receive or host the video itself but rather linked to YouTube which hosted the video in a secure section of that site ie an area of the site that could only be accessed via a secure link rather than by searching YouTube or the wider internet. The video itself could be viewed from the awards website.

Following the discovery of video 3, the awards body confirmed that the second agency had sent the link to the video. Astellas Pharma Europe noted that the agency no longer existed so it could not verify any further information. According to YouTube generated text, the video was posted in September 2013. Video 3 was removed from the awards website in November 2016 following a request from Astellas Pharma Europe.

As noted above, Astellas Pharma Europe could not access the video directly via YouTube as it was only available via a secure link that had now been deleted. Astellas Pharma Europe could not confirm if the video was taken down at source as the agency no longer existed.

Agency Oversight

As part of the investigation in to these issues, Astellas Pharma Europe reviewed:

- The terms of engagement between Astellas Pharma Europe and the two agencies
- The compliance of the agency to terms of engagement (including training procedures)
- Astellas internal supplier vetting procedures.

Contract

Agency responsible for videos 1 and 2

Astellas Pharma Europe had a current master services agreement (MSA) with the agency, effective from January 2015. The previous MSA was effective between January 2012 and January 2014.

Both MSAs stipulated that:

- The agency complied with all applicable laws and codes including the ABPI Code
- The agency ensured its staff had the proper skills, expertise, knowledge, training and background necessary to accomplish the services required of them
- Astellas Pharma Europe did not expect or intend the agency to recommend or promote Astellas' pharmaceutical products.

In addition, the agency advised on 3 November 2016 that the standard agency employee contract contained two clauses relating to client confidentiality and intellectual property rights. These included sub-clauses which forbade the disclosure of client confidential information both during and post-employment at the agency. On the same date, the agency also advised that in their exit interviews, employees leaving the company were reminded of these clauses and specifically that their responsibilities continued after termination of their employment. The agency noted that, although it had appropriate protocols and training procedures in place, human error could occur as demonstrated in this case.

Agency training

The agency advised Astellas Pharma Europe on 7 November 2016 that it was standard practice that all new employees were required to complete the e-learning module provided by the PMCPA, regardless of prior experience or discipline. This formed part of their induction and must be completed within the first month of employment. Internal training might also be provided for major changes to the Code. All training was logged in individual employee continuing professional development (CPD) diaries on the Institute of Practitioners in Advertising (IPA) website. It did not have a record of the specific training received by the ex-employee. The agency itself held the Platinum Award for CPD for the last three years; in 2015 it recorded 3061 hours of training and 96% of employees did more than the industry average. A total of 48% of employees logged over 100 hours of training.

Agency vetting and monitoring

Astellas Pharma Europe submitted that it now had a process whereby third party suppliers were vetted in accordance with the Astellas Pharma Europe standard operating procedure (SOP) Working with suppliers (SOP-1479). This SOP required that a summary of key Astellas Pharma Europe SOPs (Rules of Engagement) was sent to all suppliers providing services that fell within the scope of the Code, and certain suppliers were also required to complete a supplier questionnaire designed to elicit information about Astellas Pharma Europe key compliance requirements. If this questionnaire was not satisfactorily completed, then further action was taken. Such actions might include training, audits of the supplier or removal from the list of approved suppliers to Astellas. This SOP was put in place in August 2016, the agency received a copy of the Rules of Engagement and recently completed the supplier questionnaire. Further clarification was being sought from the agency about its answers to the questionnaire.

Agency responsible for video 3

Agency Contract

Astellas Pharma Europe had an MSA with the agency from December 2012 to December 2015. The MSA stipulated that:

- The agency agreed to perform the due services in compliance with the applicable law, the Codes and good business ethics
- the agency ensured that any personnel assigned to provide the services or to create or deliver the project material would have the proper skills, expertise, knowledge, training and background necessary to accomplish the services
- Astellas Pharma Europe did not expect or intend the agency to recommend or promote Astellas' products.

However, as this agency no longer traded, additional information, including that about its training and procedures, was not available.

Given the above, Astellas Pharma Europe fully accepted that it had breached Clause 26.1 as prescription only medicines were advertised to the public in all three situations.

In addition, Astellas Pharma Europe submitted that as the promotional material was accessible to the public it might have encouraged members of the public to ask their health professional to prescribe a specific prescription only product. Astellas therefore acknowledged a breach of Clause 26.2.

Given that promotion of a prescription only medicine to the public was a serious matter, Astellas Pharma Europe understood that the Panel might wish to consider the requirements of Clauses 9.1 and 2.

Astellas Pharma Europe confirmed that it did not provide permission for videos 1 and 2 to be placed on the internet. Available Astellas Pharma Europe

staff who had worked on Betmiga, did not know about video 3 and so could not confirm whether Astellas Pharma Europe had given permission for video 3 to be placed on the internet.

Astellas Pharma Europe took immediate steps to ensure removal of the material from the websites as soon as it was discovered. Whilst Astellas Pharma Europe did not consider there was any attempt or intention on its part to advertise to the public it fully recognised that under the Code it was responsible for any acts or omissions of its third party suppliers.

When writing to Astellas Pharma Europe, the Authority asked it to respond in relation to Clauses 26.1, 26.2, 9.1 and 2.

RESPONSE

Astellas Pharma Europe submitted that it had no further comments in relation to the requirements of Clauses 26.1, 26.2, 9.1 or 2 but provided USB sticks with the electronic versions of all enclosures including the three videos at issue.

PANEL RULING

The Panel noted Astellas Pharma Europe's submission that three videos relating to Betmiga had appeared on the internet. Videos 1 and 2 had been created for Astellas Pharma Europe by a UK based agency and both made claims about Betmiga. Video 1 was a motivational piece for internal use only and video 2 had been created to demonstrate the quality of the Betmiga launch campaign in an advertising awards submission. Both videos had been posted on Vimeo, a video-sharing website, similar to YouTube and available for the public to use. It appeared that neither Astellas nor the agency knew that either video had been posted on Vimeo; investigation showed that both had been posted by an ex-employee of the agency in order to demonstrate past work experience for future employment opportunities. Taking the videos when leaving the agency was a breach of his/her employment contract with the agency. Astellas Pharma Europe had taken immediate steps to ensure removal of the material from the website as soon as it was discovered.

The Panel understood that individuals might want to be able to show examples of their work. The Panel noted that both versions of the MSA between Astellas Pharma Europe and its agency stipulated that the agency must comply with all applicable laws and codes including the ABPI Code; ensure that staff members had the proper skills, expertise, knowledge, training and background necessary to accomplish the services required of them and that Astellas Pharma Europe did not expect or intend the agency to recommend or promote Astellas' pharmaceutical products. In addition, the Panel noted Astellas Pharma Europe's submission that the standard agency employee contract contained two clauses relating to client confidentiality and intellectual property rights. These included sub-clauses which forbade the disclosure of client confidential information both during and post-employment at the agency. The agency also

advised that in its exit interviews, employees leaving the company were reminded of these clauses specifically their responsibilities which continued after termination of their employment. Nonetheless, it was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. Pharmaceutical companies had to ensure that prescription only medicines were not advertised to the public. The Panel considered that Astellas Pharma Europe had been let down by an ex-employee of the third party working on its behalf.

The Panel noted that Vimeo was an open access website and was not limited to professional use. The Panel considered that there was a difference between putting examples of pharmaceutical promotional material on an advertising agency's website, in a section clearly labelled in that regard and putting the same on Vimeo. The Panel considered that placing videos 1 and 2 on Vimeo promoted a prescription only medicine to the public. A breach of Clause 26.1 was ruled. The Panel considered that statements had thus been made in a public forum which would encourage members of the public to ask their health professional to prescribe Betmiga. A breach of Clause 26.2 was ruled. The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel noted that Astellas Pharma Europe had taken immediate steps to ensure removal of the material from the websites as soon as it was discovered. The Panel noted its rulings and comments above and did not consider that the 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.

The Panel noted that video 3, which also contained claims for Betmiga, was filmed by a second agency specifically for entry into an awards event in 2013 and contained excerpts of an internal Betmiga launch event. The Panel noted Astellas Pharma Europe's

submission that the agency had ceased trading and so it could not be asked to confirm its objective. Astellas Pharma Europe staff members knew of no correspondence requesting permission from Astellas Pharma Europe to create and use video 3 in the way described. The Panel noted that the MSA between Astellas Pharma Europe and its second agency imposed closely similar requirements to those imposed between it and the first agency.

The Panel acknowledged that creative agencies would want to enter their work for awards and that as a result, examples of such work might appear, *inter alia*, on open access websites. The website in this case was directed specifically at the creative media and although anyone could access it, it was not aimed at the general public. In addition it appeared that whilst the video could be viewed from the event awards website, the video itself was hosted in a secure section of YouTube which could only be accessed via a secure link rather than by searching YouTube or the wider internet. The Panel noted that the secure link had now been deleted but Astellas Pharma Europe could not confirm if the video was taken down at the source as the agency no longer existed.

The Panel noted that the organisation was a network for marketing agencies and the annual event awards allowed event organisers, promoters, etc to showcase events they had organised. The Panel further noted that the video could only be viewed on a secure part of YouTube and considered that in the particular circumstances of this case, Betmiga had not been promoted to the public. No breach of Clause 26.1 and 26.2 was ruled. High standards had been maintained. No breach of Clause 9.1 was ruled. The Panel noted its rulings above and consequently ruled no breach of Clause 2.

Voluntary admission received	5 December 2016
Case completed	3 April 2017