

VOLUNTARY ADMISSION BY GRÜNENTHAL

Promotion to the public

Grünenthal voluntarily admitted breaches of the Code in that a video, certified for internal use only, relating to Palexia SR (tapentadol prolonged release), had been uploaded to YouTube without its knowledge. The company considered that the video constituted promotion of Palexia to the public or would encourage a member of the public to ask their health professional to prescribe Palexia. On being notified of the posting on YouTube, the company ensured that the video was taken down immediately.

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 Grünenthal.

Grünenthal stated that the video in question was originally used in January 2015 to reinforce key aspects relating to the Palexia SR 2015 brand plan to promotional field-based employees. The video was developed by Grünenthal's advertising agency using a third party production company.

With Grünenthal's consent, the advertising agency submitted a shortened version of the video (minus references to sales targets and promotional material) for a pharmaceutical marketing award in January 2016. On successfully winning an award, and without the knowledge of Grünenthal or the advertising agency, the director of the video provided a copy of the shortened version to the actor who subsequently uploaded this to YouTube.

Grünenthal fully accepted that it was wholly inappropriate for the video to appear on a publicly accessible Internet site but that it was ultimately responsible for the activities undertaken by third party service providers working on its behalf even when these occurred without its knowledge or instruction and constituted activities that the company would never sanction. Grünenthal therefore also accepted that on this occasion high standards had not been met. In view of the fact that information relating to a prescription only medicine, which was intended for internal company use only, had appeared on a publicly accessible Internet site, Grünenthal understood the seriousness of the situation and why the Panel might also wish to consider the requirements of Clause 2.

The detailed response from Grünenthal is given below.

The Panel understood that creative agencies and individuals would want to be able to show examples of their work. Whilst the video had not been uploaded by Grünenthal or its agency, it had been sent and uploaded by contractors of the agency. 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 Grünenthal had been let down by the third party working on its behalf.

The Panel noted that the shortened video was presented as a broadcast from 'Arthur Tapentadol' from the 'Ministry of Chronic Pain Control' who described Palexia as 'a jolly good medicine' and 'a darned good product'. It was also stated that Tapentadol was 'just the ticket' and that persuading a doctor to prescribe it would be a 'piece of cake'.

The Panel noted that YouTube 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 YouTube. The Panel considered that placing a video on YouTube which referred to Palexia as, *inter alia*, 'a jolly good medicine', promoted a prescription only medicine to the public. 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 Palexia. Breaches of the Code were ruled including that high standards had not been maintained. The Panel did not consider, however, that there had been a breach of Clause 2. Such a ruling was the sign of particular censure and reserved for such.

Grünenthal Ltd voluntarily admitted breaches of the Code in that a video for internal use only, relating to Palexia SR (tapentadol prolonged release), had been uploaded to YouTube without its knowledge. The company considered that the video constituted promotion of a prescription only medicine 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 Grünenthal.

VOLUNTARY ADMISSION

Grünenthal stated that the video in question was originally used in January 2015 to reinforce key aspects relating to the Palexia SR 2015 brand plan to promotional field-based employees. Palexia SR was a strong analgesic (Schedule II) indicated for the management of severe chronic pain in adults, which could be managed only with opioid analgesics.

The video was developed by Grünenthal's advertising agency using a third party production company. A master services agreement with the agency, covering the time period in question, documented that the agency was responsible for any sub-contractors engaged in the delivery of services under the agreement. The video content

was reviewed and certified for use as an internal company communication according to Grünenthal's standard operating procedure (SOP) for the approval of such material.

With Grünenthal's consent, the advertising agency submitted a shortened version of the video for a pharmaceutical marketing award in January 2016 where it received a Gold Award in the category for Corporate Communications. This shortened version omitted specific references to actual sales targets for 2015 and promotional material. The approved script for the original job (ref UK/P15 0001) was therefore different to the content of the actual video which appeared on YouTube.

Following receipt of the award, and without the knowledge of Grünenthal or the advertising agency, the director of the video from the production company contacted one of the actors to inform him of the award. The actor asked to see a copy of the video and the shortened version was sent to him by the director, again without the knowledge of Grünenthal or the advertising agency. The actor subsequently uploaded a copy of the shortened video to YouTube, presumably as an illustration of his work.

On 23 November 2016 (approximately 11am) Grünenthal received an email from a global headquarters colleague, based in Germany, informing the company that the video had been found on YouTube.

Grünenthal's procedures on the use of the Internet and social media did not allow staff to conduct routine Internet searches to find out information about Grünenthal's products. Grünenthal would therefore not routinely become aware of content relating to its products being available on social media sites. The presence of the video on YouTube was only picked up by global colleagues as Grünenthal GmbH was exploring options for the further use of digital media at a corporate level.

Upon notification of the presence of the video on YouTube, immediate action was taken to have it taken down by the actor through the third party video production company and this was achieved by 1pm the same day. During this process it was noted from the YouTube site that the video was posted in February 2016 and had been viewed 330 times.

Before addressing the issue of the presence of the video in the public domain, Grünenthal noted that it was important to be aware of the development and use of the video for its approved purpose.

Grünenthal explained that the video was intended to be a humorous parody of early television information broadcasts from the 1930s and was presented in black and white using a stereotypical character from that period. The video was one of the final pieces of communication to the sales force regarding the 2015 Palexia SR brand plan. Grünenthal realised that as a stand alone item, the video would not be appropriate as a representative briefing document. However, it followed a structured series of formal interactions with the representatives

in December 2014 and January 2015 to inform them of the brand plan and strategy for Palexia SR for the coming year. As such it was designed to remind staff of some of the key points from the brand plan (eg overall sales target and the importance of effective sales calls) in a more light-hearted and alternative manner. The business objective of this video was to drive internal engagement with the 2015 brand strategy and to motivate the sales force for the coming year; this was achieved through a high level of interaction from the intended internal audience. It was approved for internal use only in this context. The sequence of events in December 2014 and January 2015 relating to the brand plan introduction were as follows (all associated materials had at least one common final signatory to oversee consistency):

- 1 December 2014: Field Marketing Group (comprising Palexia SR brand manager and one representative from each business unit across the country) briefed on 2015 brand plan by Palexia SR brand manager using approved slide presentation at an online meeting
- Various dates in December 2014: Field Marketing Group present brand plan to their teams at local business unit meetings using approved material
- 6 January 2015: online business unit 'kick off' meeting for 2015 with Grünenthal's managing director. Head of marketing presented brief summary of Palexia SR brand plan for 2015
- 13 January 2015: Approved one page summary of the Palexia SR 2015 brand plan sent to field-based personnel
- 21 January 2015: Approved video in question sent to representatives as a password-protected link embedded in an email. The video itself was hosted on a secure site not accessible via Internet searches
- 26 January 2015: Follow-up quiz on 2015 brand plan content sent to field-based personnel with the objective of encouraging engagement.

Grünenthal noted that when viewing the video it was important to keep in mind the context in which it was used ie as a concluding part of a multi-faceted, internal campaign to communicate the product brand plan and the intentional use of humour to drive memorability. Whilst on one level the video referred to interactions with members of the medical profession, the content and delivery was so far removed from the professional reality of the current pharmaceutical industry that the intended audience could never be expected to interpret the content literally and/or adopt the behaviours of the central character.

Having presented the way in which the video was used internally at Grünenthal, the company fully accepted that it was wholly inappropriate for it to appear on a publicly accessible Internet site. In mitigation, this was done by a third party contractor without Grünenthal's or its advertising agency's knowledge and, when informed, the company acted immediately to have the content taken down. It was, however, clear that the video was viewed 330 times in the nine months it was available on YouTube, presumably by members of the public. The content of the video was such that Grünenthal considered it constituted promoting a prescription only medicine

to the public and it acknowledged a breach of Clause 26.1 in this regard. Grünenthal noted that it might also constitute statements that could be seen as encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine, contrary to the requirements of Clause 26.2, although this was never the intention.

Grünenthal also accepted that it was ultimately responsible for the activities undertaken by third party service providers working on its behalf even when these occurred without its knowledge or instruction and constituted activities that the company would never sanction. In this case this would also include the actions of the freelance actor engaged by the video production company on behalf of Grünenthal's advertising agency. Grünenthal therefore also accepted that on this occasion high standards had not been met and it was in breach of Clause 9.1. In view of the fact that information relating to a prescription only medicine, which was intended for internal company use only, had appeared on a publicly accessible Internet site, Grünenthal understood the seriousness of the situation and why the Panel might also wish to consider the requirements of Clause 2.

As a result of this material appearing in the public domain, Grünenthal was reviewing its procedures for monitoring the availability of information on its products in the public domain, including social media platforms. The circumstances associated with this occurrence had also been shared across appropriate teams at Grünenthal and it was in the process of reminding third party service providers of their obligations under the company's master services agreements and, in particular, their responsibility to ensure that any sub-contractors they engaged must adhere to the rigorous requirements of working with the pharmaceutical industry.

Grünenthal was asked to provide the Authority with any further comments in relation to the requirements of Clause 2, 9.1, 26.1 and 26.2.

RESPONSE

Grünenthal stated that it accepted responsibility for Clauses 26.1 and 26.2 and due to the seriousness of the nature of this situation, could understand why the Panel would wish to consider a breach of Clause 2. The company submitted that it had provided a full overview of the situation leading up to the voluntary admission and had nothing further to add.

PANEL RULING

The Panel noted that the original video (ref UK/P15 0001) was certified for internal use in January 2015 to reinforce to the sales force, key aspects about the Palexia SR 2015 brand plan. The video had been developed with an advertising agency with which Grünenthal had a master services agreement in place to cover the project. The agency in turn sub-contracted a production company.

The Panel noted that Grünenthal agreed that the advertising agency could submit a shortened version

of the video (with specific references to actual sales targets and promotional material omitted) for a pharmaceutical marketing award in January 2016 where it received a Gold Award in the category for Corporate Communications.

It appeared that in response to a request from the actor, after informing him of the award, the director of the production company forwarded him a copy of the shortened video. This was done without Grünenthal's or the agency's knowledge. The actor uploaded the video to YouTube, presumably as an illustration of his work.

The Panel understood that creative agencies and individuals would want to be able to show examples of their work. The Panel noted that the master service agreement between Grünenthal and its agency referred to the use of third parties and that all parties were bound by confidentiality obligations no less onerous than those set forth in the agreement. The Panel did not know what agreement was in place between the agency and the production company. Whilst the video had not been uploaded by Grünenthal or its agency, it had been sent and uploaded by contractors of the agency. 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 Grünenthal had been let down by the third party working on its behalf.

The Panel noted that the shortened video was presented as a broadcast from 'Arthur Tapentadol' from the 'Ministry of Chronic Pain Control' who described Palexia as 'a jolly good medicine' and 'a darned good product'. It was also stated that Tapentadol was 'just the ticket' and that persuading a doctor to prescribe it would be a 'piece of cake'.

The Panel noted that YouTube 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 YouTube. The Panel considered that placing a video on YouTube which referred to Palexia as, *inter alia*, 'a jolly good medicine', 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 Palexia. 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 did not consider, however, that there had been a breach of Clause 2. Such a ruling was the sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

During the consideration of this case the Panel was concerned to note Grünenthal's submission that as a stand alone item, the video would not be appropriate as a representative briefing document. The company

had submitted that the content and delivery were so far removed from reality that the audience would not be expected to interpret the content literally and/or adopt the behaviour of the central character. Nonetheless, the Panel noted that although the video was one of a number of pieces of communication to the representatives about the 2015 Palexia SR brand plan, all material subject to the Code must be capable of standing alone in relation to compliance

with the Code. Certification for promotional material must certify that the signatory believed that the material, *inter alia*, complied with the Code. The Panel requested that Grünenthal be advised of its concerns in this regard.

Complaint received **20 December 2016**

Case completed **30 January 2017**
