

EX-EMPLOYEE v GEDEON RICHTER

Meeting tweets

An ex-employee complained about two tweets sent by an events company engaged by Gedeon Richter. Gedeon Richter marketed Esmya (ulipristal acetate) for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

The first tweet sent on 9 November 2012 read 'Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"', and a second tweet, sent on 22 November read 'Places available at the Nottingham symposium on uterine fibroids'. The complainant referred to these tweets in his/her appeal in Case AUTH/2580/2/13. That case was about whether an invitation published on the events company's website constituted promotion of a prescription only medicine to the public. The Appeal Board rejected the appeal in that case and upheld the Panel's ruling of no breach of the Code; the complainant had not provided any evidence to show that the details of the meeting at issue in that case had been tweeted. The tweets of 9 and 22 November related to different meetings. During its consideration of Case AUTH/2580/2/13, the Appeal Board was concerned that given the two tweets referred to by the complainant and contrary to Gedeon Richter's submission to the Panel, it was clear that details of other meetings, including the name of a medicine and its indication, had been tweeted.

The complainant noted the Appeal Board's concerns in Case AUTH/2580/2/13 and alleged that the tweets of 9 and 22 November promoted a prescription only medicine to the public.

The detailed response from Gedeon Richter is given below.

The Panel noted that it was not entirely clear whether the complainant's allegation was solely based on the wording of the tweets in question or encompassed the relevant invitations and meetings. It was not the Panel's role to infer details of a complainant's allegation. After careful consideration the Panel concluded that the complaint was about whether the tweets *per se* promoted a prescription only medicine to the public.

The Panel noted Gedeon Richter's submission that the 22 November tweet did not mention the name of a medicine or a company and referred only to spaces being available at the Nottingham symposium on uterine fibroids. The Panel did not consider that the tweet advertised a prescription only medicine to the public as alleged. No breach of the Code was ruled.

Conversely, the Panel considered that the tweet of 9 November was promotional because it named a prescription only medicine (ulipristal acetate) and

referred to a potential use (in fibroid patients). The meeting referred to was a Gedeon Richter meeting. The Panel did not consider that Gedeon Richter's submission that the tweet would not have been seen by a wide audience based on the low number of followers the events company had on twitter (55) and the time that the tweet was released (1:37am) was relevant in relation to the requirements of the Code. The Panel noted that the nature of twitter was such that tweets could be broadly and quickly disseminated making them available in the public domain and so in that regard the Panel considered that a prescription only medicine had been advertised to the public. A breach of the Code was ruled.

The Panel noted Gedeon Richter's submission that the tweets were sent by the events company without its knowledge or authority. It was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. High standards had not been maintained. A breach of the Code was ruled.

The Panel noted that promoting a prescription only medicine to the public was a serious matter. In addition, the Panel was concerned that Gedeon Richter could not identify a contract or similar material which set out the role and responsibilities of the events company in relation to the materials at issue. The Panel was very concerned that Gedeon Richter had failed to establish a compliance infrastructure for the relationship. The Panel further noted that the lack of any formal agreement between the two parties was only brought to Gedeon Richter's attention by the events company which, following a request from Gedeon Richter in relation to this case for any agreements that were in place between the two, stated that there were no formal documents outlining Gedeon Richter's expectations. The Panel considered that Gedeon Richter had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

An ex-employee of Preglem UK (a wholly owned subsidiary of Gedeon Richter) complained about two tweets sent by an events company engaged by Gedeon Richter. The first tweet, sent on 9 November 2012 read 'Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"' and the second tweet, sent on 22 November read 'Places available at the Nottingham symposium on uterine fibroids'. The complainant referred to these tweets in his/her appeal in Case AUTH/2580/2/13. That case was about whether an invitation published on the events company's website constituted promotion of a prescription only medicine to the public. The Appeal Board rejected

the appeal in that case and upheld the Panel's ruling of no breach of the Code; the complainant had not provided any evidence to show that the details of the meeting at issue in that case had been tweeted. The tweets of 9 and 22 November related to different meetings. During its consideration of Case AUTH/2580/2/13, the Appeal Board was concerned that given the two tweets referred to by the complainant and contrary to Gedeon Richter's submission to the Panel, it was clear that details of other meetings, including the name of a medicine and its indication, had been tweeted.

Gedeon Richter marketed Esmya (ulipristal acetate) which was indicated for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

COMPLAINT

The complainant noted the Appeal Board's concerns in Case AUTH/2580/2/13 and alleged that two tweets sent by an events company engaged by Gedeon Richter promoted a prescription only medicine to the public. The first tweet, sent on 9 November 2012 read 'Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"' and the second tweet, sent on 22 November read 'Places available at the Nottingham symposium on uterine fibroids'.

When writing to Gedeon Richter, the Authority asked it to respond in relation to Clauses 2, 9.1 and 22.1.

RESPONSE

Gedeon Richter strongly refuted any suggestion that it had intentionally deceived the Panel. The information provided during communications with the Panel, had been open, honest and always what Gedeon Richter believed to be the absolute truth without exception.

The events company had not been as passive as initially thought and unbeknownst to Gedeon Richter and some of the events company employees, tweets in relation to Gedeon Richter meetings had been released.

Gedeon Richter noted that the complaint was about whether tweets released by the events company, engaged by Gedeon Richter, on 9 and 22 November promoted a prescription only medicine to the public. Gedeon Richter first became aware of these tweets when the complainant provided them to the Appeal Board in relation to Case AUTH/2580/2/13.

Gedeon Richter submitted that the tweet released by the events company on 22 November 2012, 'Places available at the Nottingham symposium on uterine fibroids', did not mention the name of a medicine nor the name of a company. It merely referred to a disease area and as such the company denied a breach of Clause 22.1.

Gedeon Richter stated that it was important to consider whether the text of the tweet released on 9 November 2012 'Register for the event "Sharing

surgical experience after the use of ulipristal acetate in fibroid patients"' could be considered promotional in breach of Clause 22.1 as well as the likely audience. The tweet did not mention the clinical benefits or therapeutic indication of ulipristal acetate nor did it mention the brand name or dosage. Gedeon Richter noted that another formulation of ulipristal acetate at a different dosage was an entirely different medicine marketed by another manufacturer for a different indication. Gedeon Richter submitted that given the lack of therapeutic indication or any claim, the tweet did not promote a prescription only medicine to the public and it thus denied a breach of Clause 22.1.

Gedeon Richter further noted that the events company had 55 followers as of 2 July 2013 and its tweets were only visible to the events company's followers or those who actively sought out the events company's twitter feed. The tweet was sent at 1.37am therefore Gedeon Richter considered it was extremely unlikely that it would have been received and read by a wide audience.

Gedeon Richter refuted the allegation that the tweet sent on 9 November was in breach of Clause 22.1 given that the content of the tweet was not overtly promotional, the low number of the events company twitter followers and the early hour at which the tweet was released. Gedeon Richter thus disagreed that it had failed to maintain high standards or had brought discredit upon or reduced confidence in the industry. The company denied breaches of Clauses 9.1 and 2.

Gedeon Richter further noted that its relationship with the events company had evolved over time and lengthy discussions outlining the specific details of each project took place prior to implementation all with the expectation that the support provided by the events company would be passive and in line with the Code.

Gedeon Richter enclosed copies of correspondence with the events company which it submitted confirmed that the events company had not been instructed by Gedeon Richter to release tweets about its events.

In summary, Gedeon Richter had not known about the tweets released by the events company until they had been provided to the Appeal Board by the complainant as evidence in an earlier complaint. The tweets had been removed as soon as Gedeon Richter knew about them and to avoid any further difficulties, no tweets relating to Gedeon Richter events had been issued since.

PANEL RULING

The complaints procedure relied upon complainants providing comprehensive details about their complaint. It was not the Panel's role to infer details of a complainant's allegation. The Panel noted that the scope of the complaint was such that it was not entirely clear whether the allegation was solely based on the wording of the tweets in question or encompassed the relevant invitations and meetings.

The Panel noted that the previous case, Case AUTH/2580/2/13, concerned the invitation.

The Panel considered the matter carefully and decided that as the complaint explicitly referred to the tweets and did not mention the invitations or meetings, it would consider the complaint on that narrow basis. The Panel thus understood the basis of the current complaint to be about the wording of the tweets and whether they promoted a prescription only medicine to the public. The meetings or material linked to the tweets were not considered during the Panel's consideration of this case.

The Panel noted that Clause 22.1 prohibited the advertising of prescription only medicines to the public.

In its guidance on digital communications (updated October 2012) and in relation to twitter, the Authority had stated that 'If a company wanted to promote a medicine via twitter it would have to ensure that if the medicine was prescription only, the audience was restricted to health professionals and that the message, in addition to any link to further information, complied with the Code. In addition companies would also have to ensure that recipients had agreed to receive the information. Given these restrictions and the character limit on twitter, it is highly unlikely that the use of this medium to promote prescription only medicines would meet the requirements of the Code'.

The Panel considered each tweet separately.

- 'Places available at the Nottingham symposium on uterine fibroids'

The Panel noted Gedeon Richter's submission that the 22 November tweet did not mention the name of a medicine or a company and referred only to spaces being available at the Nottingham symposium on uterine fibroids. The Panel did not consider that the content of the tweet constituted advertising a prescription only medicine to the public as alleged. No breach of Clause 22.1 was ruled. Given this ruling no breaches of Clauses 2 and 9.1 were also ruled.

- 'Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"'

The Panel disagreed with Gedeon Richter's submission that the content of the 9 November tweet was not overtly promotional. The Panel noted

that the tweet named a prescription only medicine (ulipristal acetate) and referred to a potential use (in fibroid patients) and thus considered that it was promotional. The meeting referred to was a Gedeon Richter meeting. The Panel noted Gedeon Richter's submission that the tweet would not have been seen by a wide audience based on the number of the events company's twitter followers and the time at which it was released but did not consider that this was relevant in relation to the requirements of Clause 22.1. Gedeon Richter submitted that the tweet would only be visible to those who either followed the events company on twitter or sought its twitter feed. However, the Panel noted that the nature of twitter was such that tweets could be broadly and quickly disseminated making them available in the public domain and so in that regard the Panel considered that a prescription only medicine had been advertised to the public. A breach of Clause 22.1 was ruled.

The Panel noted Gedeon Richter's submission that the tweets were sent by the events company without its knowledge or authority. It was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. High standards had not been maintained. A breach of Clauses 9.1 was ruled.

The Panel noted that promoting a prescription only medicine to the public, contrary to Clause 22.1, was a serious matter. In addition, the Panel was concerned that Gedeon Richter could not identify a contract or other material which clearly set out the role and responsibilities of the events company in relation to the materials at issue. Whilst the Panel accepted that Gedeon Richter had, to a degree, been let down by the third party, it was very concerned that Gedeon Richter had failed to establish a compliance infrastructure for the relationship. The Panel further noted that the lack of any formal agreement between the two parties was only brought to Gedeon Richter's attention by the events company which, following a request from Gideon Richter in relation to this case for any agreements that were in place between the two, stated that there were no formal documents outlining Gedeon Richter's expectations. The Panel considered that Gedeon Richter had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received

18 June 2013

Case completed

5 August 2013