

EX-EMPLOYEE v GEDEON RICHTER

Meeting invitation

An ex-employee complained about an invitation to a meeting in Manchester, 6 March 2013, entitled 'Selective Progesterone Receptor Modulators (SPRMs) and a new treatment for uterine fibroids'. The invitation stated that the meeting was supported by an unrestricted educational grant from Gedeon Richter. Gedeon Richter marketed Esmya (ulipristal acetate) which was a synthetic SPRM indicated for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

The complainant noted that the invitation, which referred to SPRMs and a new treatment for uterine fibroids, was publicly available on Gedeon Richter's events company's website. One presentation would cover 'Current treatment options for patients with moderate to severe uterine fibroids' and 'Patient & surgical experience post treatment of ulipristal acetate'. The complainant stated that the invitation would be considered promotional as it contained Esmya branding and an indication. The complainant alleged that prescribing information should have been included.

Prescription only medicines should not be promoted to the public. The complainant noted that the invitation contained the name of the medicine, its indication, had promotional branding (imagery) and was freely accessible to the public.

The detailed response from Gedeon Richter is given below.

The Panel noted that the front page of the invitation featured the brand imagery associated with Esmya. Recipients would immediately associate the meeting with Esmya. According to the invitation the meeting was about SPRMs and a new treatment for uterine fibroids. The invitation referred to a presentation which would cover 'Current treatment options for patients with moderate to severe uterine fibroids' and about 'Patient & surgical experience post treatment of ulipristal acetate'. The Panel considered that the invitation promoted Esmya. As no prescribing information was included a breach of the Code was ruled. This ruling was accepted by Gedeon Richter.

The Panel noted that the invitation had been available on the events company's website. The Panel noted Gedeon Richter's submission that the role of the events company had been entirely passive and that it had facilitated online registration to the meeting. Further, only health professionals who had been invited to the meeting would have known about the website and that no branding or imagery had been used with the public. The Panel did not consider that in these circumstances the availability of the invitation on an events company's website constituted advertising a prescription only

medicine to the public as alleged. No breach of the Code was ruled. This ruling was appealed by the complainant.

The Panel noted its rulings above and did not consider the circumstances warranted a ruling of a breach of Clause 2. No breach of Clause 2 was ruled. This ruling was appealed by the complainant.

The Appeal Board noted that the two tweets provided by the complainant on appeal, did not refer to the meeting at issue.

The Appeal Board noted Gedeon Richter's submission to the Panel that the invitation to the Manchester meeting had been available on the events company's website and only health professionals invited to the meeting would have known of its whereabouts. The Appeal Board noted the tweets from events company about other meetings but considered the complainant had not provided any evidence to show that details of the Manchester meeting had been tweeted. The Appeal Board thus did not consider that, with regard to the meeting at issue, a prescription only medicine had been promoted to the public as alleged. The Appeal Board upheld the Panel's rulings of no breach of the Code including Clause 2. The appeal was thus unsuccessful.

During its consideration of this case, the Appeal Board was extremely concerned that Gedeon Richter had provided the Panel with inaccurate information about the role of the events company. Although no evidence had been produced to show that the events company tweeted information about the meeting at issue, it was clear that it had tweeted details of other meetings to include the name of a medicine and its indication. The events company was thus not entirely passive in relation to meetings and invitations as submitted.

An ex-employee of Preglem UK (a wholly owned subsidiary of Gedeon Richter) complained about an invitation (ref GR-ADV 13/0010) to a meeting in Manchester, 6 March 2013, entitled 'Selective Progesterone Receptor Modulators (SPRMs) and a new treatment for uterine fibroids'. The invitation stated that the meeting was supported by an unrestricted educational grant from Gedeon Richter. Gedeon Richter marketed Esmya (ulipristal acetate).

Esmya 5mg was indicated for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment was limited to 3 months. The summary of product characteristics (SPC) stated that the marketing authorization holder was Gedeon Richter plc Budapest. Esmya was an orally active synthetic SPRM and was first licensed in February 2012.

COMPLAINT

The complainant noted that the invitation was publicly available on an events management company website. The complainant further noted that the invitation referred to SPRMs and a new treatment for uterine fibroids. On page 2 of the invitation, which detailed the presentations to be given, the complainant noted that one of the speakers would talk about 'Current treatment options for patients with moderate to severe uterine fibroids' and 'Patient & surgical experience post treatment of ulipristal acetate'.

The complainant stated that the invitation would be considered promotional under Clause 1.2 as the meeting was sponsored by a pharmaceutical company and contained branding (imagery) particular to Esmya. As noted above, the name of the medicine and its indication were also stated.

The complainant alleged that under Clause 4.1 prescribing information should have been included on the invitation.

The complainant noted that under Clause 22.1, a prescription only medicine should not be promoted to the public. The complainant submitted that the invitation contained the name of the medicine, its indication, had promotional branding (imagery) and was freely accessible to the public.

When writing to Gedeon Richter the Authority asked it to respond in relation to Clause 2, in addition to Clauses 4.1 and 22.2 cited by the complainant.

RESPONSE

Gedeon Richter noted that Clause 4.1 stated 'The prescribing information listed in Clause 4.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 5)'. The invitation at issue was to a scientific symposium about uterine fibroids entitled 'Selective Progesterone Receptor Modulators (SPRMs) and a new treatment for uterine fibroids'. There was no mention of ulipristal acetate or Esmya (the brand name) on the front of the invitation. On the back of the invitation ulipristal acetate was only mentioned in the context of 'Patient & surgical experience post treatment of ulipristal acetate'. Gedeon Richter submitted that there were clearly no claims made or elements of the therapeutic indication mentioned in the invitation. Gedeon Richter thus did not consider that the invitation promoted ulipristal acetate; the invitation represented an opportunity for clinicians to engage in appropriate scientific discussion about the therapies available for use in the overall treatment of uterine fibroids. Gedeon Richter did not consider that the invitation promoted a medicine and therefore there was no requirement to include the prescribing information. As such the company denied a breach of Clause 4.1.

The invitation to the symposium was available on the website for the events management company. The events management company acted in an entirely passive role on behalf of Gedeon Richter

to facilitate the online registration of invitees to meetings that the company had developed. The events management company did not engage in active promotion, nor did it employ search engine optimisation techniques and so to find the site would require very specific knowledge such as having been given a hard copy of an invitation on which the registration website details could be found. Without this knowledge, which was not publicly available, it was extraordinarily unlikely that a member of the public could gain access to the invitation. The complainant could find the website and invitation as he/she had been previously privy to this specific information. The only people who knew about the location of the invitation and registration details for the meeting were health professionals who had been given an invitation following interaction with a Gedeon Richter representative. Gedeon Richter stated that it, and the many other pharmaceutical companies that used the services of the events management company, considered the entirely passive nature of the events management company in relation to meetings and invitations was sufficient to ensure that members of the public were not exposed to information that might be construed as being promotional. As such the company denied a breach of Clause 22.1.

Gedeon Richter stated that given the above it strongly considered that it had not brought discredit upon, or reduced confidence in, the pharmaceutical industry and it thus strongly refuted any suggestion that it had breached Clause 2.

In response to a request for further information, Gedeon Richter submitted that the invitations to the meeting in Manchester were distributed to local gynaecologists with an interest in the treatment of uterine fibroids. The invitations were distributed by the field-based key account managers either as a hard copy or by email.

Although the approval certificate could imply that the email could be sent directly by the events management company, the statement (assumed to be 'hand-out or via email by KAMS/[events management company]') was intended to refer to the fact that the layout and artwork of the email was created by the events management company but it was to be sent by the key account managers. The events management company did not send out the meeting invitation directly.

Gedeon Richter provided a pad of tear-off patient information sheets designed to support clinicians treating uterine fibroids. The text provided brief information and instructions for the patient and an image of the female reproductive system which was intended to facilitate discussion between the clinician and the patient. This was the only material that was for use by or with the patient; there was no branding or imagery and the general appearance was entirely functional.

PANEL RULING

The Panel noted that the front page of the meeting invitation featured the brand imagery associated with Esmya. In that regard the Panel considered that

recipients would immediately associate the meeting with Esmya. The invitation stated that the meeting was about SPRMs and a new treatment for uterine fibroids. The second page of the invitation referred to a presentation which would cover 'Current treatment options for patients with moderate to severe uterine fibroids' and about 'Patient & surgical experience post treatment of ulipristal acetate'. The Panel considered that the invitation itself promoted Esmya for the treatment of uterine fibroids and in that regard should have incorporated the prescribing information for the medicine. As no prescribing information was included a breach of Clause 4.1 was ruled. This ruling was accepted by Gedeon Richter.

The Panel noted that the invitation had been available on the events management company website. The events management company was an events management agency. The Panel noted Gedeon Richter's submission that the events management company's role had been entirely passive and that it had acted to facilitate online registration of invitees to the meeting. Further, only health professionals who had been invited to the meeting would have known about the website and that no branding or imagery had been used with the public. The Panel did not consider that in these circumstances the availability of the invitation on an events management company website constituted advertising a prescription only medicine to the public as alleged. No breach of Clause 22.1 was ruled. This ruling was appealed by the complainant.

The Panel noted its rulings above and did not consider the circumstances warranted a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of Clause 2 was ruled. This ruling was appealed by the complainant.

During its consideration of this case, the Panel was concerned that the invitation stated that the meeting was 'Supported by an unrestricted educational grant by the Women's Health Division of Gedeon Richter (UK) Ltd' which it considered might give a misleading impression that Gedeon Richter had given an arm's length grant to a third party for it to organise the meeting. This was not so. The meeting was a Gedeon Richter meeting and this should have been made clear. The Panel was further concerned that the date of first authorization of Esmya was 23 February 2012. The invitation was dated February 2013 and referred to 'a new treatment for uterine fibroids'. The Panel assumed that the new treatment was Esmya but noted that Clause 7.11 stated that 'new' must not be used to describe any products which had been generally available for more than twelve months in the UK. The Panel thus queried whether the invitation met the requirements of that clause.

APPEAL FROM THE COMPLAINANT

The complainant appealed the Panel's ruling of no breach of Clauses 2 and 22.1.

The complainant alleged that Gedeon Richter's submission that the events management company had acted in an entirely passive role on its behalf seemed untrue and that the company had misled the

Panel on this assessment. The events management company had not only produced the promotional items but it had also actively promoted the meeting on its twitter page. A tweet on 9 November stated 'Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"'. The complainant noted the inclusion of the name of the medicine and its use. There was a similar message on 22 of November to register for an event. These twitter messages threw some light on the relationship between Gedeon Richter marketing and the events management company and how the events management company played an active role in marketing the medicine.

The complainant requested that the Appeal Board enquired about the approval of these twitter messages which the complainant was sure the company would be quick to deny.

COMMENTS FROM GEDEON RICHTER

Gedeon Richter submitted that it had been entirely unaware of, and in no way requested or sanctioned the tweet on the events management company twitter feed. Gedeon Richter's discussion with the events management company as to the nature of its activities relating to meetings it sponsored described that its expectations were that the events management company would passively facilitate registration. It appeared that these expectations were not sufficiently transmitted through the management company staff with the outcome being that this tweet appeared on its twitter feed at the time that registration system could be accessed.

Gedeon Richter stressed that it did not request, permit or otherwise agree to the meeting being advertised in this manner and, despite the complainant's view, it did not seek to mislead the Panel. Gedeon Richter understood that it was responsible for the actions of its service providers and that in this case it was clear that a tweet was released into the public domain which mentioned the name of the product and other information about the licensed indication which could therefore be perceived as being promotional.

Gedeon Richter noted that as the current number of followers of the events management company on its twitter feed was very low it was unlikely that many people saw this tweet, particularly as it was broadcast at 1.37am. But the company accepted that the tweet could potentially represent a breach of the Code. Gedeon Richter submitted that given its belief that the likelihood that the audience for the tweet was low and that this specific action was unlikely to bring discredit upon, or reduce confidence, in the pharmaceutical industry, this did not represent a breach of Clause 2 of the Code.

Gedeon Richter submitted that the nature of the complaint and the complainant led it to believe that it knew the identity of the complainant. Although the complainant remained anonymous and the nature of the complaint was not material to the case in hand, Gedeon Richter considered that the complaint had been initiated through motives other

than a desire to uphold the letter and spirit of the Code. If the company was correct in its assumption as to the identity of the complainant then it was unable to explain why someone who purported to be a defender of the Code failed to apply the same level of scrutiny to the materials at hand when they were employed. Gedeon Richter surmised that the complainant may have known about the tweet whilst still employed by the company and so it queried why nothing was done about it at the time. Gedeon Richter felt slightly ambushed by the complainant in this regard.

Despite Gedeon Richter's assumptions and beliefs surrounding the case it also recognised that there were remedial actions that it could and should have taken. Gedeon Richter noted that it had initiated a thorough and comprehensive review and update of its promotional activities and it would also review its ongoing working arrangements with the events management company, with particular emphasis on its behaviours relating to future events.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant noted that as expected, Gedeon Richter claimed that it had no knowledge of the twitter messages that the events management company had sent, and that the events management company twitter account had very few followers. The complainant noted that twitter accounts were by default public and visible to anyone with or without a twitter account. Twitter users were aware of this public display hence many companies chose this form of marketing.

The complainant noted that with the provision of free alert tools provided by various search engines, one need not look for the website or twitter messages. The public and patients who looked for new therapies or new medicines could set these alerts to learn about what was available and whenever something was new, an email was automatically sent with the link. This was how the complainant knew about the events management company tweets as the alert had picked up several recent new tweets about the medicines. There was a recent meeting held in Barcelona specifically on this medicine. There were various other tweets available; however it would not be appropriate to provide additional material at this point.

The complainant alleged that the participation of the events management company on twitter was looked at within the alerts when Gedeon Richter claimed that it had instructed the events management company to be a passive participant. There was no element of 'ambush' as claimed by Gedeon Richter.

APPEAL BOARD RULING

The Appeal Board noted that the two tweets from the events management company, cited by the complainant, did not refer to the meeting at issue in this case ie 'Selective Progesterone Receptor Modulators (SPRMs) and a new treatment for uterine fibroids' held in Manchester on 6 March 2013. The tweet of 9 November stated 'Register for the event "Sharing surgical experience after the use of ulipristal acetate in fibroid patients"'. The tweet of 22 November stated 'Places available at the Nottingham symposium on uterine fibroids'.

The Appeal Board noted Gedeon Richter's submission to the Panel that the invitation to the Manchester meeting had been available on the events management company website and only health professionals invited to the meeting would have known of its whereabouts. The Appeal Board noted tweets from the events management company about other meetings but considered the complainant had not provided any evidence to show that details of the Manchester meeting had been tweeted by the events management company. The Appeal Board thus did not consider that, with regard to the meeting at issue, a prescription only medicine had been promoted to the public as alleged. The Appeal Board upheld the Panel's ruling of no breach of Clause 22.1. The Appeal Board consequently also upheld the Panel's ruling of no breach of Clause 2. The appeal was thus unsuccessful.

During its consideration of this case, the Appeal Board was extremely concerned that Gedeon Richter had provided the Panel with inaccurate information about the role of the events management company. Although no evidence had been produced to show that the events management company tweeted information about the meeting at issue, it was clear that it had tweeted details of other meetings to include the name of a medicine and its indication. The events management company was thus not entirely passive in relation to meetings and invitations as submitted. In that regard the Appeal Board noted that companies such as the events management company were usually engaged to maximise attendance at meetings and so were unlikely to be passive.

The Appeal Board further noted that the Authority had issued guidance on digital communications to include the use of social media. Companies must know and control what third parties acting on their behalf might do in that regard.

Complaint received **20 February 2013**

Case completed **30 May 2013**