CASE AUTH/2579/2/13

GENERAL PRACTITIONER v BAYER

Weblink to training workshop

A general practitioner complained that he had had his time wasted by being misled into attending what he thought was a workshop to learn how to use the new EvoInserter, the insertion device for Mirena, an intrauterine contraceptive marketed by Bayer.

The detailed response from Bayer is given below.

The Panel noted that the Mirena on-line training material stated that one way to become familiar with the technique required to use the EvoInserter was to attend a Mirena training workshop. Delegates could find out about the workshops via the 'Mirena training workshop' link. The Panel noted Bayer's submission that such workshops were held in May/June 2012, leading up to the launch of the EvoInserter, and that as each workshop took place the date was removed from the website. The Panel noted, however, that all Mirena meetings throughout the year were accessed through the 'Mirena training workshop' link regardless of title or content. Health professionals were provided with a link to fulfil a specific training need (ie to learn how to use the EvoInserter) and so it was not unreasonable to assume that training dates/events offered through that link would fulfil that need. The Panel considered that the website was misleading in that regard and ruled a breach of the Code.

The complainant provided a copy of an email to him from the agency managing the logistics for the meeting which he had decided to attend. The email referred to the 'Mirena Education Programme' and a copy of the agenda was attached which detailed two presentations; 'What's topical in contraception' and 'How to optimise counselling in intrauterine contraception (workshop)'. Bayer submitted information to show that the complainant had been sent an invitation and agenda by post. This invitation stated that the programme aimed to give delegates the optimum opportunity for an educational experience with a view to: update on what was topical in contraception, a workshop on counselling women for intrauterine contraception and holding a local fitters forum to discuss current issues. The Panel considered that although the meeting incorporated a workshop, it was clear from both the invitation and the agenda that it would be about counselling, not the practical use of the EvoInserter. The Panel noted Bayer's submission that in any event, two of its employees had been at the meeting to demonstrate the EvoInserter from the promotional stand and that demonstrator Mirenas and models were available for practice.

The Panel noted that the meetings were aimed at current fitters. It might have been helpful if the agenda had made this point clear, particularly as the link to register for these meetings was the same as the link to meetings to learn how to use the EvoInserter. However, the Panel considered that the invitation and the agenda for the meeting at issue were clear as to the content and that once in receipt of these, the complainant should have realised that the meeting was not the training workshop he had imagined it to be. The Panel considered that in that regard the nature of the meeting had not been disguised. No breach of the Code was ruled.

The Panel did not consider that the circumstances meant that high standards had not been maintained. No breach of the Code was ruled.

A general practitioner complained about a training workshop on Mirena (an intrauterine contraceptive containing levonorgestrel) organised by Bayer HealthCare.

COMPLAINT

The complainant noted that Bayer advertised a training workshop for health professionals to fit Mirena using its new EvoInserter. As the company was to provide the training, the complainant decided to attend the January training workshop in Leicester. The complainant noted that in an email from an events management agency to a GP colleague, dated 26 April 2012, it was stated 'The workshop will be led by a local trainer and delegates will be given the opportunity to use a demo EvoInserter'. The complainant noted, however, that no such hands-on training took place. The complainant considered that he had been misled in attending an event which he believed was training to fit Mirena using the new EvoInserter, but was not.

The complainant provided his email communication with the same events management agency. He noticed the title of 'Mirena Medical Education Programme' was different from the on-line title of 'Mirena training workshop'.

The complainant was not happy that Bayer had behaved improperly and wasted his time.

When writing to Bayer, the Authority asked it to respond in relation to Clauses 7.2, 9.1 and 12.1 of the Code.

RESPONSE

Bayer explained that in 2012 it introduced an improved insertion device, the EvoInserter, for the Mirena Intrauterine System (IUS). Mirena was the only IUS currently available in the UK. The changes were relatively minor and ergonomic. In granting the licence the Medicines and Healthcare products Regulatory Agency (MHRA) did not require Bayer to inform health professionals about the changes. However, Bayer developed a communication plan to inform health professionals about the new insertion device and used a variety of channels, including face-

to-face meetings and an on-line training programme. Bayer considered as the communications on the changes were about the benefits of the product, they were treated as promotional activities. Before the launch of the EvoInserter, Bayer also developed a series of promotional/educational meetings on Mirena which incorporated a workshop on the new inserter. Each workshop was led by health professionals who were experienced trainers in intrauterine techniques. Invitations to these events were sent in April 2012 and the meetings ran from 8 May to 19 June. The invitation and agenda for these meetings was provided.

Bayer submitted that practices and/or clinics tended to hold low numbers of Mirena as stock; consequently those individuals who fitted Mirena were likely to encounter the new inserter soon after it became available. All the training was therefore planned to take place before the EvoInserter was launched in June 2012. In addition to the meetings programme, an on-line training programme was available which was widely advertised and communicated to health professionals involved in family planning.

To attend a Mirena educational meeting heath professionals had to register via the Mirena website when the dates, locations and agenda were available.

Bayer stated that from the evidence submitted, a GP was forwarded, from a colleague, an email on 26 July 2012 which had originally been sent by Bayer in April 2012; the email outlined a meetings programme which included the EvoInserter workshop which had ended in mid-June 2012. As each meeting happened it was removed from the website thus if the recipient had gone on the Mirena website in July 2012 no meetings or workshop dates were listed.

Bayer ran a number of educational meetings/workshops, relevant to those health professionals who were involved in providing Mirena, throughout the year. Bayer's Spring/Summer meetings programme ended on 19 June, these included the EvoInserter workshops. From 11 October the dates of an Autumn/Winter meetings programme could be accessed from the website. All meetings throughout the year were accessed from the 'Mirena training workshops' link on the website but the specific title and content of each meeting series changed.

Invitations to the Autumn meetings programme were posted on 16 October and emailed (with permission) on 22 October. The agenda clearly stated the titles of the talks. The talks were relevant to those interested in contraception, in particular intrauterine contraception. The meetings were Mirena branded and all communication was accompanied by prescribing information. Furthermore, registration for the meetings could only be achieved by registering on the promotional website Mirena.co.uk. As there was no attempt to disguise the promotion of Mirena Bayer rejected the alleged breach of Clause 12.1.

The invitations were targeted at those heath professionals Bayer had identified as qualified to fit long acting reversible contraception (LARC) or intrauterine contraception (IUC) and all were sent the invitation by post. Bayer considered that these heath professionals specifically would be interested in the content of the meetings.

A leavepiece was also distributed via Bayer's sales force with a reply paid card to register interest.

Once someone registered interest in a meeting via the Mirena website, the events management agency Bayer contracted to handle the logistics of the meeting programme confirmed attendance by email. The agenda for the meeting was provided.

The Leicester meeting was originally scheduled for December but moved for logistical reasons. All those registered were informed of the postponement. The new date was communicated in early January and was again accompanied by the meeting agenda.

A final reminder to those registered was emailed the day before the meeting with directions to the venue and the agenda attached. Bayer provided a list of those who had attended the Leicester meeting and details as to how they were informed of the meeting. A separate list of when they registered to attend was also provided.

Bayer submitted that those who attended the Leicester meeting were sent the agenda on at least three occasions. The content of the meeting was clear from the agenda. There was no suggestion that there would be an EvoInserter training workshop, it was clearly stated that the subject of the workshop was on counselling in intrauterine contraception.

With regard to the lack of hands-on EvoInserter training which the complainant had wanted, Bayer noted that at the meetings held from November to January at least two of its employees were present and available to demonstrate the EvoInserter from a promotional stand. Demonstrator Mirenas (no active ingredient and clearly labelled) and model uteruses were available for anyone to practice with. Demonstration/training devices and uterus models could be requested and sent or delivered to any health professional who requested them. All of the speakers were experienced in intrauterine contraception and Faculty of Sexual and Reproductive Health accredited trainers in intrauterine techniques. Bayer submitted that there was ample time for discussion and questions on any topic including the EvoInserter. Discussion was encouraged at all of the meetings to share best practice amongst this group of health professionals who could fit intrauterine contraception.

Bayer stated that it held meetings with the same programme in 16 locations between November 2012 and January 2013 and 299 health professionals had attended. Bayer had reviewed the feedback forms from all the meetings and no-one rated the information received before and during the meeting as below expectation. Nationally most rated the

content as useful. The feedback forms for the Leicester meeting were provided.

Bayer stated that its employees who attended the Leicester meeting had confirmed that a number of the attendees were shown how to use the EvoInserter on the promotional stand. One employee remembered one doctor saying he/she thought there was going to be something about the EvoInserter; they declined an offer of a one-to-one demonstration and the chance to practice with the demonstrators available.

In Bayer's view, the basis of the complaint was a misunderstanding about an email forwarded by a colleague and the assumption that any meeting Bayer held many months later would have the same content. Additionally despite receiving the agenda on a number of occasions, which included the titles of the talks, the complainant did not realize the content was quite different to the meeting they assumed they were attending.

In summary, Bayer believe the promotional content of the meeting and the nature of the workshop was made very clear from the outset and there was no indication that the meeting would have specific trainer-led use of a demonstrator Mirena EvoInserter. Bayer believed the meeting had good educational content which was delivered by local experts and relevant to the invited audience. Feedback from the meetings was positive. Bayer therefore rejected the alleged breaches of Clauses 12.1, 7.2 and 9.1.

PANEL RULING

The Panel noted that the complainant provided a printed copy of the Mirena on-line training material which stated that the reader could familiarise themselves with the technique required to use the new insertion device, the EvoInserter, either by completing the on-line training module and/or by attending a Mirena training workshop. Delegates could find out about the workshops by clicking on the 'Mirena training workshop' link. The Panel noted Bayer's submission that such workshops were held between 8 May and 19 June 2012, leading up to the launch of the EvoInserter, and that as each workshop took place the date was removed from the website. The Panel noted, however, that all Mirena meetings throughout the year were accessed through the 'Mirena training workshop' link even though the specific title and content of each meeting series changed. The Panel noted Bayer's submission that registration for the meetings could only be achieved by registering on the Mirena website. In the Panel's view the arrangements were misleading. Health professionals were provided with a link to fulfil a specific training need (ie to learn how to use the EvoInserter) and so it was not unreasonable to assume that training dates/events offered through that link would fulfil that need. The Panel considered that the website was misleading in that regard and ruled a breach of Clause 7.2.

The complainant appeared to have decided to attend a Mirena training workshop based on an email originally sent to his colleague in April 2012 and forwarded to him on 26 July 2012 ie when the workshops had already finished. The email stated that 'delegates will be given the opportunity to use a demo EvoInserter'. The complainant also provided a copy of an email to him from the agency managing the logistics for the meeting which he had decided to attend. The email referred to the 'Mirena Education Programme' and the fact that the meeting he had elected to attend had been postponed until January 2013. A copy of the agenda was attached to the email which detailed two presentations; 'What's topical in contraception' and 'How to optimise counselling in intrauterine contraception (workshop)'. The Panel noted that Bayer had submitted a list of those who had attended the meeting and information to show that the complainant had been sent an invitation and agenda by post. The invitation to the Autumn series of the 'Mirena Medical Educational Programme' stated that the programme aimed to give delegates the optimum opportunity for an educational experience with a view to: update on what was topical in contraception, a workshop on counselling women for intrauterine contraception and holding a local fitters forum to discuss current issues. The Panel considered that although the meeting incorporated a workshop, it was clear from both the invitation and the agenda that it would be about counselling, not the practical use of the EvoInserter. The Panel noted Bayer's submission that in any event, two of its employees had been at the meeting to demonstrate the EvoInserter from the promotional stand and that demonstrator Mirenas (with no active ingredient) and model uteruses were available for delegates to practice with.

The Panel noted that the meetings were aimed at current fitters. It might have been helpful if the agenda had made this point clear, particularly as the link to register for these meetings was the same as the link to meetings to learn how to use the EvoInserter. However, the Panel considered that the invitation and the agenda for the meeting at issue were clear as to the content. The Panel noted its ruling above regarding the misleading link to Mirena meetings/events but considered that once in receipt of the invitation and agenda, the complainant should have realised that the meeting was not the Mirena training workshop he had imagined it to be. The Panel considered that in that regard the nature of the meeting had not been disguised. No breach of Clause 12.1 was ruled.

The Panel did not consider that the circumstances meant that high standards had not been maintained. No breach of Clause 9.1 was ruled.

Complaint received **20 February 2013**

Case completed **28 March 2013**