

LILLY v BAYER

SortEDin10 campaign

Lilly complained about the promotion of Levitra (vardenafil) by Bayer and alleged that a sponsored 'Erectile Dysfunction' supplement in Practice Nurse and Doctor, an interview for the 'SortEDin10' disease awareness campaign, which appeared in The Daily Mail, the 'SortEDin10' web chat February 2005 and the distribution of Montorsi *et al* (2004) all promoted Levitra as being effective in 10 minutes. Such claims were inconsistent with the Levitra summary of product characteristics (SPC), misleading and exaggerated in a breach of the Code. Unfounded assurances risked alienating men with erectile dysfunction (ED) by creating further barriers to those experiencing success with treatment. Many UK men with ED (23.3%) waited up to five years to tell their doctor about it. ED was a disease with significant psychological impact and Lilly alleged that irresponsible promotion of unsustainable claims lowered the standards of industry as a whole.

Lilly further alleged that Bayer's disease awareness campaign promoted Levitra and its supposed benefits to the public. There was no clear declaration of sponsorship.

The Panel noted that the Levitra SPC stated that the recommended 10mg dose should be taken approximately 25 to 60 minutes before sexual activity. Montorsi *et al* concluded that the onset of action of vardenafil with subsequent intercourse completion was recognised as early as 10 minutes after dosing. The Panel considered that the distribution of Montorsi *et al* by Bayer in effect promoted the efficacy of Levitra 10 minutes after dosing and that the proactive use of the study was inconsistent with the SPC. Breaches of the Code were ruled.

With regard to the supplement 'Erectile Dysfunction' it appeared that the whole supplement was sponsored by Bayer Healthcare. The Panel had only been provided with the article 'Treating the Problem' which included the statement that 'Vardenafil has also been shown to have a fast onset of action; working as quickly as 10 minutes in some men'. No information was given as to the content of the SPC in this regard. The Panel considered that the material in effect promoted Levitra in a manner inconsistent with the SPC and

thus was misleading. Breaches of the Code were ruled.

The article in The Daily Mail was a result of a Bayer global press conference. The associated press release focussed on encouraging those affected by ED to discuss the condition and to take positive steps to seek treatment by visiting their doctor. The press release, which did not refer to any product by name, included quotes by a celebrity including: 'These days there are effective treatments for erectile dysfunction that work as quickly as ten minutes to help you reclaim your sex life'. The article in The Daily Mail quoted the celebrity as mentioning Viagra and Cialis and 'And then [there] are the latest generation of drugs like Levitra which work within ten minutes – so you can keep the all important feeling of spontaneity'.

The Panel considered that the press materials provided by Bayer were misleading regarding the statement that one medicine could work in ten minutes and the materials would encourage patients to ask their doctor to prescribe Levitra. High standards had not been maintained. Breaches of the Code were ruled. On balance, the Panel did not consider that the press materials constituted an advertisement to the public for a prescription only medicine and thus ruled no breach of the Code. The press materials provided by Bayer were clear that the SortEDin10 campaign was sponsored by Bayer and although this was not made clear in The Daily Mail article the Panel did not consider that Bayer was responsible for this. No breach of the Code was ruled.

Lilly noted that the page of the 2006 Levitra calendar for May depicted a solitary sign post stating 'SPEED LIMIT 10' and the claim 'Levitra (10mg) has been shown to start working within 10 minutes'. Lilly alleged that this was an exaggerated and misleading claim, inconsistent with the Levitra SPC in breach of the Code.

The Panel considered that the calendar, by claiming that Levitra started to work within ten minutes, was inconsistent with the Levitra SPC, misleading and not capable of substantiation as ruled above. Breaches of the Code were ruled.

Lilly alleged that the SortEDin10 webchat, where questions from the public were answered by two ambassadors of the disease awareness campaign, a sporting celebrity and a sex expert and relationship guru, advised individuals on personal medical matters and encouraged them to ask for particular prescription only medicines in breach of the Code. In addition, misleading and exaggerated claims of the efficacy of Levitra were made and Bayer's sponsorship was not declared. Lilly alleged that such repeated examples of irresponsible promotion brought the entire industry into disrepute. A breach of Clause 2 was alleged.

The Panel noted that the briefing for the sporting celebrity stated that he was a Levitra patient; it was further stated that he could respond truthfully in a factual and descriptive way to any questions regarding his treatment as he felt appropriate. The brief included background information on ED and specific treatments including Levitra. One of the broadcast messages for treatment referred to a 'winning formula' being 'fast and effective'.

In response to a question about the lack of spontaneity with Viagra, the celebrity was quoted on the webchat as stating 'If you use what I use you will find it fast. Ten minutes works for me because it takes that long to make a cup of tea! Try it!'

The Panel considered that as the celebrity, a known Levitra patient, had been briefed to talk about his treatment for, and personal experience of, erectile dysfunction, Bayer was responsible for the remarks that he made on the webchat. The celebrity had been briefed by Bayer and the company had facilitated his appearance on the webchat. It was therefore not possible for Bayer to dissociate itself from what he had said in the interview; if it were otherwise then the effect would be for companies to use patients as a means of avoiding the restrictions in the Code. The Panel considered the webchat would encourage patients to ask their doctor to prescribe Levitra. A breach of the Code was ruled.

The Panel did not consider that the circumstances were such as to justify a ruling of a breach of Clause 2 of the Code.

Eli Lilly and Company Limited complained about the promotion of Levitra (vardenafil) by Bayer Health Care Pharmaceutical Division of Bayer plc. The items at issue were a sponsored 'Erectile Dysfunction' supplement in Practice Nurse and Doctor, 'SortEDin10' disease awareness campaign – interview in The Daily Mail, a calendar (5LEVI 142), 'SortEDin10' web chat February 2005 and the distribution of Montorsi *et al* (2004).

1 Distribution of Montorsi *et al* (2004), sponsored 'Erectile Dysfunction' supplement in Practice Nurse and Doctor and 'SortEDin10' disease awareness campaign – interview in The Daily Mail

COMPLAINT

Lilly alleged that the materials contained claims that Levitra was effective in 10 minutes and this was a breach of the Code.

Lilly alleged that claims of efficacy at 10 minutes were inconsistent with the Levitra summary of product characteristics (SPC), misleading and exaggerated in breach of Clauses 3.2, 7.2 and 7.4 respectively. Such unfounded assurances risked alienating men with erectile dysfunction (ED) by creating further barriers to men experiencing success with treatment. Many UK men with ED (23.3%) waited up to five years to tell their doctor about it. ED was a disease with significant psychological impact and Lilly alleged that irresponsible promotion of unsustainable claims lowered the standards of industry as a whole. A breach of Clause 9.1 was also alleged.

In addition, Lilly alleged that Bayer's disease awareness campaign 'SortEDin10' contravened the Code. In the examples above, ambassadors of Bayer's disease awareness campaign clearly promoted Levitra and its supposed benefits to the public in breach of Clauses 3.2, 7.2, 7.4, 20.1 and 20.2. Furthermore, there was no clear declaration of sponsorship in breach of Clauses 9.10 and 10.1.

RESPONSE

Bayer submitted separate responses to each allegation as follows.

Distribution of Montorsi *et al*

Bayer submitted that it was not only reasonable but obligatory to make the results of all *bona fide* clinical trials available to health professionals to enable them to make an up-to-date full evaluation of the product. When referring to time to onset of activity the SPC was no more specific than 'approximately 25 to 60 minutes before sexual activity' because at the time of regulatory submission no clinical study had specifically examined this parameter and so it was only possible to give dosing instructions compatible with the registration trial results which were based upon pharmacokinetics and predicted pharmacodynamics.

Bayer submitted that the fact that data were derived from clinical trials performed after marketing authorization, and therefore additional to that within the SPC, did not constitute sufficient grounds for Lilly's consideration that the results presented in Montorsi *et al* were not consistent with the SPC. The dosing instructions suggested in the SPC remained entirely appropriate for most men but Montorsi *et al* showed that some might experience a therapeutic effect as early as 10 minutes.

Bayer agreed that health professionals should not be given the impression that all patients responded to Levitra as early as 10 minutes and consequently no such claim was made. Montorsi *et al* made it quite clear that not all patients responded as early as 10 minutes. This was precisely the manner in which Bayer used this paper.

Bayer submitted that Montorsi *et al* described the patient population, methodology and results to the

extent that health professionals could make their own judgement as to the limitations or otherwise of the study. In this peer reviewed publication the authors made no attempt to misrepresent the data. Bayer did not agree that use of the paper was misleading or that its conclusions were misleading.

Bayer did not believe it had made an irresponsible or unsustainable claim, and therefore denied a breach of Clause 9.1.

Sponsored article in Erectile Dysfunction supplement in Practice Nurse and Doctor

Bayer did not consider that Lilly was entirely clear as to which clauses of the Code were alleged to be in breach in relation to this article for health professionals. Therefore, Bayer addressed the three clauses cited by Lilly. Bayer emphasised that this article was directed solely towards health professionals.

Bayer submitted that the question of promotion being consistent with the SPC, covered by Clause 3.2, had been addressed above.

Bayer noted that Lilly had asserted part of this article was in breach of Clauses 7.2 and 7.4. During intercompany correspondence Lilly had referred to the statement 'Vardenafil has also been shown to have a fast onset of action; working as quickly as 10 minutes for some men' and the company assumed that it was this statement that was now at issue. The statement did not claim, however, that vardenafil worked after 10 minutes in all men. Therefore there could be no question that it was misleading or exaggerated.

SortEDin10 Disease Awareness Campaign – interview in The Daily Mail

Bayer noted that the interview that appeared in the Daily Mail on 6 December 2005 was written as a result of a global press conference that took place at the European Society of Sexual Medicine in Copenhagen. The press conference was attended by journalists from all over the world.

A media celebrity was fronting an international disease awareness campaign for ED. Her role was to provide a platform for women to identify with and convince their partners that it was important that they should go to their doctor for advice and potential treatment.

Bayer submitted that all materials provided to the UK journalists were approved according to the Code and the briefing document provided to the media celebrity by Bayer's global team had not referred to Levitra.

Bayer submitted that in all cases Bayer's declaration as sponsor of a disease awareness programme was made clear. This interview was under the editorial control of the newspaper. Again Bayer did not agree that it was in breach of any of the clauses cited.

PANEL RULING

The Panel noted that the Levitra SPC stated that the recommended 10mg dose should be taken approximately 25 to 60 minutes before sexual activity. Montorsi *et al* concluded that the onset of action of

vardenafil with subsequent intercourse completion was recognised as early as 10 minutes after dosing.

The Panel considered that the distribution of Montorsi *et al* by Bayer in effect promoted the efficacy of Levitra 10 minutes after dosing. The SPC referred to a time period of 25 to 60 minutes for the 10mg dose. The Panel considered that the proactive use of Montorsi *et al* was inconsistent with the SPC. Breaches of Clauses 3.2, 7.2 and 7.4 of the Code were ruled.

With regard to the supplement 'Erectile Dysfunction' it appeared that the whole supplement was sponsored by Bayer Healthcare. The Panel had only been provided with the article 'Treating the Problem' which included the statement that 'Vardenafil has also been shown to have a fast onset of action; working as quickly as 10 minutes in some men'. No information was given as to the content of the SPC in this regard. The Panel considered that the material in effect promoted Levitra in a manner inconsistent with the SPC and thus was misleading. Breaches of Clauses 3.2, 7.2 and 7.4 were ruled.

The article in The Daily Mail was a result of a Bayer global press conference. Interviews with the media celebrity had been arranged and a press release was issued. The press release focussed on encouraging those affected by ED to discuss the condition and to take positive steps to seek treatment by visiting their doctor. The press release included a list of approved quotes by the celebrity including: 'These days there are effective treatments for erectile dysfunction that work as quickly as ten minutes to help you reclaim your sex life'.

The press release and other materials did not mention any product by name. The article in The Daily Mail quoted the celebrity as mentioning Viagra and Cialis and 'And then [there] are the latest generation of drugs like Levitra which work within ten minutes – so you can keep the all important feeling of spontaneity'.

The Panel did not agree with Bayer's submission that the interview was under the editorial control of the newspaper. The article in The Daily Mail was under the editorial control of the newspaper. Bayer had arranged the global press conference and had arranged interviews with the media. It was not known whether The Daily Mail had been one of those given an interview with the celebrity who was acting as a spokesperson for Bayer.

The Panel considered that the press materials provided by Bayer were misleading regarding the statement that one medicine could work in 10 minutes and the materials would encourage patients to ask their doctor to prescribe Levitra. Thus the Panel ruled a breach of Clause 20.2 of the Code.

The Panel noted its rulings of breaches of Clauses 3.2, 7.2 and 7.4 with regard to promotion of the efficacy of Levitra 10 minutes after dosing; Lilly had alleged breaches of these clauses. The Panel considered that its ruling of a breach of Clause 20.2 with regard to the information to the public covered the point. Clauses 3.2, 7.2 and 7.4 of the 2003 Code related to the promotion of medicines rather than the provision of information to the public. Some changes in this regard had been made to the 2006 Code.

On balance, the Panel did not consider that the press materials regarding the celebrity constituted an advertisement to the public for a prescription only medicine and thus ruled no breach of Clause 20.1. The press materials provided by Bayer were clear that the SortEDin10 campaign was sponsored by Bayer. This was not clear in the Daily Mail article. The Panel considered that Bayer was not responsible for this. Thus no breach of Clauses 9.10 and 10.1 was ruled.

The Panel considered that the misleading nature of the materials that were inconsistent with the Levitra SPC meant that high standards had not been maintained. A breach of Clause 9.1 was ruled.

2 2006 Levitra calendar

COMPLAINT

Lilly noted that each page of this calendar represented a different month which contained a photographic image and a key message associated with Levitra. May depicted an arctic scene with a solitary sign post stating 'SPEED LIMIT 10'. The claim on this page was 'Levitra (10mg) has been shown to start working within 10 minutes'. This was further evidence of the use of an exaggerated and misleading claim, inconsistent with the Levitra SPC in breach of Clauses 3.2, 7.2 and 7.4.

RESPONSE

Bayer submitted that the statement 'Levitra (10mg) has been shown to start working within 10 minutes' was based on Montorsi *et al.* Hence Bayer referred to its response outlined above.

PANEL RULING

The Panel considered that the calendar, by claiming that Levitra started to work within 10 minutes, was inconsistent with the Levitra SPC, misleading and not capable of substantiation as ruled above. Thus the Panel ruled breaches of Clauses 3.2, 7.2 and 7.4.

3 SortEDin10 webchat February 2005

COMPLAINT

Lilly noted that the SortEDin10 webchat, where questions from the public were answered by two ambassadors of the disease awareness campaign, a sporting celebrity and a sex expert and relationship guru, advised individuals on personal medical matters and encouraged them to ask for particular prescription only medicines in breach of Clauses 20.1 and 20.4. In addition, misleading and exaggerated claims of the efficacy of Levitra were made in breach of Clauses 3.2, 7.2 and 7.4. Sponsorship by Bayer was not declared in breach of Clauses 9.10 and 10.1.

Lilly alleged that such repeated examples of irresponsible promotion brought the entire industry into disrepute and a breach of Clause 2 was alleged in relation to the campaign.

RESPONSE

Bayer provided the briefing materials used to prepare

the sporting celebrity and a sex expert and relationship guru, together with press material. Bayer submitted that all materials provided to facilitate the webchat were approved according to the Code and the briefing document provided to the celebrity and the guru by Bayer and its agency referred specifically to the disease awareness campaign, in which Bayer's role as sponsor of this campaign was clearly declared.

Bayer submitted that the interview was under the editorial control of the broadcasters. Again Bayer did not agree that it was in breach of any of the clauses cited.

Bayer submitted that in January 2005, at the launch of SortEDin10, it provided all briefing documents to the MHRA, together with relevant press articles. The MHRA requested no further information and made no comments suggesting that further scrutiny was needed to exclude a breach of the Code.

Bayer submitted that it was important to look at this complaint in the context of the ED market which had exceptionally high brand awareness; 'Viagra' now appeared in at least two English dictionaries, and was common parlance in the English language. Bayer did not intend complaining to the Authority every time the words Viagra or Cialis appeared in the lay press. Some recent examples were provided. Bayer submitted that the remit of a disease awareness campaign, according to the MHRA Blue Guide, was to heighten patient awareness for self help, which included awareness of treatment choices.

Bayer submitted that the SortEDin10 campaign was designed to encourage men with ED to go to their doctor for assessment and potential treatment. The campaign provided essential information to patients, and their partners, about the causes of, and potential treatments available for, ED. It was made clear that the onset of ED might indicate an underlying serious disease, such as diabetes or heart disease, and that consultation with their doctor was all the more important to either exclude these conditions or to start treatment as soon as possible.

Bayer submitted that another important objective for the SortEDin10 campaign was to try to alleviate the embarrassment that men might experience when presenting to their doctors with ED. This embarrassment in itself might be enough to stop them seeking help and it was this important point that the campaign tried to address. The involvement of the celebrity had been of considerable help in this regard; he was a prominent public figure who was willing to report that he had experienced ED and that really there was nothing for a man to be embarrassed about when talking to his doctor. The celebrity's passionate belief that all men with this condition should see their doctors to seek advice and help had defined his involvement in the SortEDin10 campaign.

Bayer submitted that although 'Viagra' was now part of the English language and synonymous with the treatment of ED, as with any treatment for ED it did not work for all men. The final objective of the SortEDin10 campaign was, therefore, to tell patients that other treatments existed and to encourage men who might already have been treated for ED to return to their doctor if this treatment had not been satisfactory.

Bayer submitted that SortEDin10 remained a disease awareness programme to encourage men who might be embarrassed to talk about ED to come forward and discuss their condition with a health professional. It was widely acknowledged that men should consult their doctor because ED could be the first sign of a more serious underlying condition. Many patients did not return after failure on their first treatment, and it was important they were made aware there were other options.

Bayer submitted that the Department of Health and medical professionals alike recognised the wider benefits of disease awareness programmes of this kind. Bayer provided some of the extensive work that it had done to heighten disease awareness in this market over the last year as part of the SortEDin10 campaign. Further examples could also be seen on www.sortedin10.co.uk.

Bayer submitted that given what it had set out above, it did not believe it had breached Clause 2 of the Code.

PANEL RULING

The Panel examined the briefing materials for the SortEDin10 campaign. The briefing for the sporting celebrity noted that he was a Levitra patient; it was stated that he could respond truthfully in a factual and descriptive way to any questions regarding his own treatment choice as he felt appropriate. The brief included background information on ED and treatments. A range of treatments were mentioned, injections, vacuum pumps, pellets, counselling, hormone therapy and tablets. More detailed information was given about tablets including the names of the phosphodiesterase type 5 inhibitors Viagra, Cialis and Levitra.

The brief then included background information on Levitra. The broadcast messages were grouped under the headings General, Impact on ED, Involvement in SortEDin10 Campaign, Treatment and Potential Questions. The broadcast message for Treatment was: 'There are a number of highly effective treatments available. I think most men would prefer to take a tablet to other forms of treatment, and preferably one that allows them to respond in a normal, spontaneous way to their partner. In my world, the winning formula is to be fast and effective, so what I wanted

was a treatment that worked fast & I could rely on – a treatment in fact, a bit like me!'

The brief for the sex expert and relationship guru included that five key aims including raising awareness that there is now a range of oral treatments for ED. The guru was not to be encouraged to '...endorse or recommend Levitra as the sponsoring brand of this activity or any other specific treatment'. The webchat page dated 14 February 2005 reported on an interview with the celebrity and the guru.

The webchat reported the celebrity as suggesting mentioning to the doctor 'the treatment I found so good for me...'. It also stated that 'I like to hope that my being connected with SortEDin10 and one of the important treatments to help with erectile dysfunction...'.

In response to a question about the lack of spontaneity with Viagra the guru stated that there were three medicines available for ED and alternatives should be discussed with the doctor. Levitra and Cialis were mentioned. The celebrity stated that Viagra did nothing for him, Cialis worked well but not as fast as he wanted because the lack of spontaneity was difficult to handle. 'If you use what I use you will find it fast. Ten minutes works for me because it takes that long to make a cup of tea! Try it!

The Panel considered that as the celebrity, a known Levitra patient, had been briefed to talk about his treatment for, and personal experience of, erectile dysfunction, Bayer was responsible for the remarks that he made on the webchat. The celebrity had been briefed by Bayer and the company had facilitated his appearance on the webchat. It was therefore not possible for Bayer to dissociate itself from what he had said in the interview; if it were otherwise then the effect would be for companies to use patients as a means of avoiding the restrictions in the Code. The Panel considered the webchat would encourage patients to ask their doctor to prescribe Levitra. A breach of Clause 20.2 was ruled.

The Panel did not consider that the circumstances were such as to justify a ruling of a breach of Clause 2 of the Code which was used as a sign of particular censure and reserved for such use.

Complaint received **15 March 2006**

Case completed **9 June 2006**