CASE AUTH/2163/8/08

CONSUMERS INTERNATIONAL v LILLY

Website and associated TV campaign on erectile dysfunction

Consumers International was concerned that a website www.40over40.com and associated TV campaign about erectile dysfunction (ED), sponsored by Lilly, promoted that company's medicine Cialis (tadalafil), in breach of the Code as prescription only medicines must not be promoted to the public.

One page of the website contained a table that listed the treatment types available. 'Product 1' in the list was clearly Cialis. Any member of the public that entered 'erectile dysfunction' and 'Eli Lilly' into a search engine could make this discovery in less than 30 seconds. (The name of the company appeared in the TV campaign and on every website page).

Naming Cialis 'product 1' and placing it at the top of the table effectively promoted this treatment over other options; information relating to 'product 1' was more likely to be read compared with information about other products and the positioning was, in itself, likely to give the impression that this treatment was preferable to others. Further, the information given in the table was also likely to steer members of the public towards thinking that 'product 1' was preferable to other treatments because across three of the five criteria (time to become effective, duration of effect and food interactions) it was preferable to the other products listed (on the remaining two criteria it was equivalent).

Consumers International believed that this contravened guidance that: 'A company may conduct a disease awareness or public health campaign provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine'. The guidance 'Particular care must be taken where the company's product, even though not named, is the only product relevant to the disease or symptoms in question' was also relevant.

Even though Cialis was clearly not the only relevant product, given the information in the table it appeared to be preferable, in several respects, to the other treatments. Consumers International believed that equal 'care' should be taken in these circumstances.

Members of the public were told 'You can discuss these options and your preferences with your doctor'. Given the way in which this information was presented Consumers International believed it was highly likely that members of the public would approach doctors stating a preference for Cialis or 'product 1.' This meant that this disease awareness campaign was effectively promotion. Given the link to the TV campaign Consumers International considered that this was a high profile abuse of the Code that would reach an unusually high number of people.

The detailed response from Lilly is given below.

The Panel noted that as part of Case AUTH/2151/7/08 it had already considered an allegation that the website and TV campaign promoted a prescription only medicine to the public.

In Case AUTH/2151/7/08, the Panel considered that patient education programmes were a legitimate activity for a pharmaceutical company to undertake provided that they were in accordance with the Code. Such activities might facilitate the market development of the sponsoring company's products but this was not necessarily in breach of the Code. Each case would need to be judged on its merits.

The supplementary information to the Code stated that a company might conduct a disease awareness or public health campaign provided that the purpose was to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, was the only medicine relevant to the disease or symptoms in question.

The Panel considered that the campaign was within the scope of the Code as it could not take the benefit of the exemption for information relating to human health or diseases provided there was no reference either direct or indirect to specific medicines.

The television advertisement did not refer to medicines other than a general statement that there was a range of treatments that could help. It gave details of the website 40over40.com. The Panel did not consider that the television advertisement *per se* constituted an advertisement to the public for a prescription only medicine nor would it encourage a patient to ask their health professional to prescribe a specific medicine. No breach of the Code was ruled.

The 40over40.com website gave detailed information set out under four sections 'talk', 'test',

'treat' and 'today'. In the Panel's view the sections 'talk', 'test' and 'today' gave helpful information about ED. The 'treat' section included a chart setting out various features about the medicines and devices available. The chart was also included in the 4t Action Plan for patients to download and discuss with their doctor. Neither the treatment chart on the website nor the 4t Action Plan named any of the products. The sections were divided into oral treatments where details of products 1, 2 and 3 were given, injections or insertions which gave details of three products and vacuum pumps and constriction rings which stated that ten different types were available. The features compared for each product were 'How long does it take to work', 'Duration of effect', 'Maximum recommended dosing', 'Most common side effects (over 10%) and 'Food interactions'. Below the chart there was brief mention of hormone treatment and surgery. Information was also given about counselling which, it was stated, should be an integral part of treatment. Only the section describing injections or insertions included the advice to '… discuss all possible side effects with your doctor/nurse'. Only the section describing surgery stated that your doctor would be the best person to advise as to whether it was a suitable option. Although not named the first oral treatment (product 1) listed in the chart was Cialis.

The Panel considered that much information had been provided about the treatment for ED. All possible treatments were mentioned. The question was whether the information constituted an advertisement to the public for a prescription only medicine or would encourage a patient to ask their health professional to prescribe a specific medicine. The Panel did not consider that the chart on the website nor its inclusion in the 4t Action Plan constituted an advertisement to the public for a prescription only medicine and no breach of the Code was ruled.

The Panel considered that the features used to describe the products in the chart would result in patients asking their health professionals to prescribe a specific medicine. In addition the Panel was concerned as to whether the information presented was balanced particularly with regard to the presentation of data about side effects. The chart detailed the 'Most common side effects (over 10%)' and listed 'headache and indigestion' for product 1 (Cialis). These were the side effects listed in the Cialis summary of product characteristics (SPC) as very common. The Panel considered that to list only two side effects, albeit at a stated frequency of ≥1/10, would give an unbalanced view of the safety of the product to a potential patient. There was no indication that other side effects were possible. The Panel had similar concerns regarding the data given for products 2 and 3. The Panel was also concerned that there was no mention of contraindications for oral treatments. There was an implication that any of the products could be used successfully to treat ED. This was not necessarily so. In the Panel's view it was to be expected that a potential patient would read the pros and cons for each treatment choice and form an opinion as to which they wanted. Patients were encouraged to take the 4t Action Plan, which included the chart to discuss the options and their preferences with their doctor. The Panel considered that the chart was not factual and balanced. It would encourage a member of the public to request a specific prescription only medicine. Thus the Panel ruled a breach of the Code with regard to the information on the website including the 4t Action Plan.

The Panel considered that by naming medicines and/or giving very specific details about their advantages and certain disadvantages, Lilly had not maintained high standards and a breach of the Code was ruled.

The Panel noted that the treatment option chart gave a clear account of the positive characteristics of each oral tablet whilst very limited information had been given about side effects and none about possible contraindications. Whilst patients were advised to discuss the treatment options with their doctor the website also encouraged them to decide what their preferences might be and to discuss these with their doctor. There was an implication that choosing a medicine to treat ED was straightforward which was not so. It was inappropriate to encourage patients to ask a health professional to prescribe a specific prescription only medicine. The Panel considered that on the facts of this case such action brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel considered that the rulings in Case AUTH/2151/7/08 as set out above applied in the case now before it, Case AUTH/2163/8/08.

The Panel did not accept that placing the information about Lilly's product Cialis as product 1 in the table was necessarily unacceptable. This did not in itself promote product 1 above other products. Thus on this narrow point no breach of the Code was ruled.

COMPLAINT

Consumers International was concerned that the website www.40over40.com and associated TV campaign about erectile dysfunction (ED), sponsored by Lilly, promoted the company's medicine Cialis (tadalafil), in breach of Clause 22 of the Code that stated that prescription only medicines must not be promoted to the public.

The website page relating to treatment http://www.40over40.com/erectile-dysfunction-drugs.html contained a table that listed the treatment types available. 'Product 1' in the list was clearly Cialis, produced by Lilly.

Any member of the public that entered 'erectile

dysfunction' and 'Eli Lilly' into a search engine could make this discovery in less than 30 seconds. (The name of the company appeared in the TV campaign and on every website page.) Naming Cialis 'product 1' and placing it at the top of the table effectively promoted this treatment over other options. This placement meant that information relating to 'product 1' was more likely to be read compared with information about other products and the positioning was, in itself, likely to give the impression that this treatment was preferable to others.

The information given in the table was also likely to steer members of the public towards thinking that 'product 1' was preferable to other treatments, because across three of the five criteria (time to become effective, duration of effect and food interactions) it was preferable to the other products listed (on the remaining two criteria it was equivalent).

Consumers International believed that this contravened guidance that: 'A company may conduct a disease awareness or public health campaign provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine'.

Consumers International stated that the following guidance was also relevant: 'Particular care must be taken where the company's product, even though not named, is the only product relevant to the disease or symptoms in question'.

Even though Cialis was clearly not the only product relevant to this condition, given the information in the table it appeared to be preferable, in several respects, to the other treatments. Consumers International believed that equal 'care' should be taken in these circumstances.

Members of the public were told 'You can discuss these options and your preferences with your doctor'. Given the way in which this information was presented Consumers International believed it was highly likely that members of the public would approach doctors stating a preference for Cialis or 'product 1.' This meant that this disease awareness campaign was effectively promotion. Given the link to the TV campaign Consumers International considered that this was a high profile abuse of the Code that would reach an unusually high number of people.

When writing to Lilly, the Authority asked it to respond in relation to Clauses 2, 9.1, 22.1 and 22.2 of the 2008 Code which were the same as in the 2006 Code though differently numbered.

RESPONSE

Lilly refuted any suggestion that it had breached Clauses 2, 9.1, 22.1 and/or 22.2 of the 2008 Code; the campaign was non-promotional and in accordance with the Code and the Medicines and Healthcare products Regulatory Agency (MHRA) Guidelines for conducting disease awareness campaigns.

Background and design of campaign

Lilly explained that erectile dysfunction was a common condition, with 40% of men over the age of 40 suffering from it to some degree. It was a distressing condition for both sufferers and their partners. Many men tended to suffer in silence for prolonged periods of time due to the taboo surrounding the condition. Moreover, ED was often an early warning sign of serious, potentially life-threatening conditions, such as diabetes or heart disease.

However, ED was treatable in 95% of all patients. With the wide array of modern treatments, encompassing first-line (principally oral PDE5 inhibitors), second-line (principally intra-urethral or intra-cavernosal alprostadil) and third-line treatments (penile implant surgery), and psychosexual counselling, few if any patients would experience no improvement in their ED.

The disease awareness campaign at issue was designed to raise awareness of the prevalence of ED, its link to underlying illness and the range of treatment options available. Knowing that others suffered from this distressing and embarrassing condition was empowering and reduced the sense of shame and isolation felt by many men with ED, which negatively impacted on their ability to seek medical attention. Knowing that the condition was treatable was also empowering for ED sufferers, as many believed that the condition was a part of ageing and could not be treated.

In addition, Lilly considered that essential to the success of the current campaign over previous disease awareness campaigns, conducted by both Lilly and others, was the need to deliver a strong and memorable consumer-orientated campaign. The name '40over40' was chosen for its ease of recall, as well as reflecting the evidence of prevalence of this condition. The various elements of the campaign were designed to effectively deliver this and the other key messages in a non-promotional manner.

Elements of the campaign

The 40over40 campaign comprised non-promotional materials delivered through various forms of media, including TV, internet and print, and was directed to both the public and to health professionals. The campaign was non-promotional and in accordance with the Code and with the MHRA Guidelines for conducting disease awareness campaigns. Consistent with the Code, all the materials associated with the campaign identified Lilly as its sponsor.

40over40 TV advertisement

Television was a powerful tool to bring messages to the public's attention and, as such, was considered an important element of the 40over40 campaign, to effectively deliver the campaign to the widest audience of sufferers. The advertisement was subject to pre-vetting and approval by Clearcast and was scheduled to be broadcast during programmes of most interest to men and, in light of the subject matter, after the 9pm watershed.

Television advertisements for disease awareness campaigns had been conducted in the past by Lilly and others, for a variety of conditions including ED, and were not prohibited by the Code or by the MHRA.

40over40.com website

The disease awareness campaign website, www.40over40.com contained four sections directed at ED sufferers: 'talk' included a comprehensive overview of the disease and helpful tips on how to raise this sensitive topic with partner and GP; 'test' included a questionnaire for sufferers to rate their severity of ED and information about tests that GPs might perform to determine any underlying conditions; 'treat' was a thorough, fair and balanced list of all of the treatment options available for ED; and 'today' linked to advocacy group websites that related to ED; these together comprised the '4t Action Plan'.

The table of treatments in the 'treat' section, http://www.40over40.com/erectile-dysfunction-drugs.html, referred to by the complainant, comprised a fair and balanced list of the whole range of options available for management of ED. Within this table 'oral tablets' were listed first, since oral treatment represented the first-line treatment option for ED, hence this was its logical place.

Although the complainant correctly deduced 'product 1' to be Cialis, Lilly refuted that placing product 1 at the top of the table 'effectively promoted this treatment over other options'. Lilly also did not accept that 'information relating to 'product 1' was more likely to be read compared with information about other products', nor that 'the positioning was, in itself, likely to give the impression that this treatment was preferable to others'. Cialis was denoted as 'product 1' simply because it was first in the alphabetical order of the products, with product 2 being Levitra and product 3 being Viagra. The treatment table presented factual information for all three oral treatments in a fair and balanced manner, consistent with the respective summaries of product characteristics (SPCs). Information regarding other, non-pharmacological treatments for ED was also presented in a similar manner. The fact that some treatments, named or anonymised, might have particular characteristics and/or side effects did not in itself preclude presentation of treatment options in the context of a fair and balanced discussion, and this was consistent with both the MHRA Guidelines and with the Code. Lilly therefore refuted any allegation that the treatment table promoted Cialis.

All materials associated with the campaign were non-promotional and provided ED sufferers with information on the condition in order to help facilitate discussions with their GP, should they wish to do so, and obtain appropriate advice. The campaign clearly indicated that all treatment decisions should be made with the ED sufferer's GP. Since the treatment options presented were all prescription only medicines, or options requiring a medical referral, treatment could only be obtained in conjunction with a consultation with a medical practitioner.

Hence, Lilly did not consider that the way in which the treatment options were presented placed any undue influence on the clinical consultation. Whilst consultations involving well-informed patients were to be welcomed, it remained the responsibility of qualified medical practitioners to decide upon the relative benefit and risks associated with any particular treatment. This involved consideration of information such as potential medicine interactions, side effects and co-morbidities, which could not be appropriately detailed in any disease awareness campaign. Lilly did not accept the assertion that qualified medical practitioners relied on consumer awareness material in order to make prescribing decisions, or allowed patient choice to over-ride the clinical decisions relating to treatment options, particularly if this was not appropriate for the patient.

Similarly, Lilly did not accept the complainant's assertion that the guidance concerning disease awareness campaigns for 'diseases or conditions where there is only one, one leading or few medicinal treatments' to be of relevance with regard to this matter, since there were a number of available treatment options, and hence did not accept that special 'care' should be applied to the current Lilly disease awareness campaign. The modern treatment for ED encompassed a wide range of effective treatments, some pharmacological, some not, as previously noted. Different treatments suited different men, with different lifestyles. Lilly considered that the complainant's assertion that Cialis, or product 1, was a treatment of such clear desirability and preference, over and above all other treatments mentioned, including other PDE5 inhibitors, was subjective and did not necessarily reflect other opinion.

In summary, Lilly was fully cogniscent of its responsibilities with respect to the Code and had ensured that all aspects of the ED disease awareness campaign were of the highest standards and quality.

Lilly categorically rejected the unfounded allegation of the complainant of an abuse of the Code and

trusted that the information provided helped in the Authority's consideration of this matter.

PANEL RULING

The Panel noted that as part of Case AUTH/2151/7/08 it had already considered an allegation that the website and TV campaign promoted a prescription only medicine to the public.

Case AUTH/2151/7/08

The Panel considered that patient education programmes were a legitimate activity for a pharmaceutical company to undertake provided that such programmes were in accordance with the Code. Such activities might facilitate the market development of the sponsoring company's products but this was not necessarily in breach of the Code. Each case would need to be judged on its merits.

The Panel noted that the supplementary information to Clause 22.2 stated that a company might conduct a disease awareness or public health campaign provided that the purpose was to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, was the only medicine relevant to the disease or symptoms in question.

The Panel considered that the campaign was within the scope of the Code as it could not take the benefit of the exemption for information relating to human health or diseases provided there was no reference either direct or indirect to specific medicines (Clause 1.2).

The Panel examined the material in question. The television advertisement did not refer to medicines other than a general statement that there was a range of treatments that could help. The television advertisement gave details of the website 40over40.com. The Panel did not consider that the television advertisement *per se* constituted an advertisement to the public for a prescription only medicine nor would it encourage a patient to ask their health professional to prescribe a specific medicine. No breach of Clauses 22.1 and 22.2 was ruled.

The 40over40.com website gave detailed information set out under four sections 'talk', 'test', 'treat' and 'today'. In the Panel's view the sections 'talk', 'test' and 'today' gave helpful information about ED including possible causes and advice about talking to a health professional. The 'treat' section included a chart setting out various features about the medicines and devices available to treat ED. The chart was also included in the 4t Action Plan for patients to download and discuss with their doctor. Neither the treatment chart on the website nor the 4t Action Plan named any of the products. The sections were divided into oral treatments where details of products 1, 2 and 3 were given, injections or insertions which gave details of three products and vacuum pumps and constriction rings which stated that ten different types were available. The features compared for each product were 'How long does it take to work', 'Duration of effect', 'Maximum recommended dosing', 'Most common side effects (over 10%) and 'Food interactions'. Below the chart there was brief mention of hormone treatment and surgery. Information was also given about counselling which, it was stated, should be an integral part of treatment. Only the section describing injections or insertions included the advice to '… discuss all possible side effects with your doctor/nurse'. Only the section describing surgery stated that your doctor would be the best person to advise as to whether it was a suitable option. Although not named the first oral treatment (product 1) listed in the chart was Cialis.

The Panel considered that much information had been provided about the treatment for ED. All possible treatments were mentioned. The question was whether the information constituted an advertisement to the public for a prescription only medicine or would encourage a patient to ask their health professional to prescribe a specific medicine. The Panel did not consider that the chart on the website nor its inclusion in the 4t Action Plan constituted an advertisement to the public for a prescription only medicine and no breach of Clause 22.1 was ruled.

The Panel considered that the features used to describe the products in the chart would result in patients asking their health professionals to prescribe a specific medicine. In addition the Panel was concerned as to whether the information presented was balanced particularly with regard to the presentation of data about side effects. The chart detailed the 'Most common side effects (over 10%)' and listed 'headache and indigestion' for product 1 (Cialis). These were the side effects listed in the Cialis SPC as very common. The SPC, however, also listed the following common (≥1/100 to <1/10) side effects: dizziness, palpitations, flushing, nasal congestion, abdominal pain, gastro-oesophageal reflux, back pain and myalgia. The Panel considered that to list only two side effects, albeit at a stated frequency of ≥1/10, would give an unbalanced view of the safety of the product to a potential patient. There was no indication that other side effects were possible. The Panel had similar concerns regarding the data given for products 2 and 3. The Panel was also concerned that there was no mention of contraindications for oral treatments. There was an implication that any of the products could be used successfully to treat ED. This was not necessarily so. In the Panel's view it was to be expected that a potential patient would read the pros and cons for each treatment choice and form

an opinion as to which they wanted. Patients were encouraged to take the 4t Action Plan, which included the chart to discuss the options and their preferences with their doctor. The Panel considered that the chart was not factual and balanced. It would encourage a member of the public to request a specific prescription only medicine. Thus the Panel ruled a breach of Clause 22.2 with regard to the information on the website including the 4t Action Plan.

The Panel considered that by naming medicines and/or giving very specific details about their advantages and certain disadvantages, Lilly had not maintained high standards and a breach of Clause 9.1 was ruled.

The Panel noted that the treatment option chart gave a clear account of the positive characteristics of each oral tablet whilst very limited information had been given about side effects and none about possible contraindications. Whilst patients were advised to discuss the treatment options with their doctor the website also encouraged them to decide what their preferences might be and to discuss these with their doctor. There was an implication that choosing a medicine to treat ED was straightforward which was not so. It was inappropriate to encourage patients to ask a health professional to prescribe a specific prescription only medicine. The Panel considered that on the facts of this case such action brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Case AUTH/2163/8/08

The Panel considered that the rulings in Case AUTH/2151/7/08 as set out above applied in the case now before it, Case AUTH/2163/8/08.

The Panel did not accept that placing the information about Cialis as product 1 in the table was necessarily unacceptable. This did not in itself promote product 1 above other products. Thus on this narrow point no breach of Clauses 22.1 and 22.2 was ruled.

Complaint received **20 August 2008**

Case completed **13 October 2008**