CASE AUTH/2151/7/08

# MEDIA/DIRECTOR v LILLY

## Website and associated TV campaign on erectile dysfunction

**The Financial Times (FT) of 29 July criticised Lilly's 40over40 campaign. In accordance with the Constitution and Procedure this matter was taken up by the Director as a complaint under the Code.**

**The article, 'Sex problems campaign will test rules', alleged that US-style advertising for drugs was coming to Britain in the shape of a television campaign to raise awareness of erectile dysfunction (ED). Lilly had launched a series of television and national newspaper advertisements – the most ambitious to date about ED, accompanied by internet sites and discussion groups, which would run until September. The campaign raised the prospect of Britons for the first time being subject to the kind of widespread advertising for ED medicines that had become so common to US television, particularly during sporting events and other programming that appealed to men.**

**Lilly's product, Cialis, was the most recent of three prescription medicines launched in the competitive ED market. The advertisements did not directly name any of the prescription medicines available for the condition, but stressed that leading treatment options included the use of three different medicines, and Lilly used its own corporate logo prominently.**

**The article noted that consumer advertising of prescription medicines in the US had been criticised for disease mongering.**

**The UK campaign, 40over40, referred to the claim that 40 per cent of men over 40 years old suffer from ED – included a table that listed three anonymous oral tablets as the most prominent form of treatment. While not naming Cialis or its rivals Viagra and Levitra, the first entry in the table was identifiable as Cialis through a description of its unique characteristics and side-effects. Lilly also placed its own logo at the foot of the web page next to another website sponsored by the company. The advertisements marked a sharp advance in a trend for medicines marketing in the UK, at a time when pharmaceutical companies were struggling to bolster revenues.**

**The detailed response from Lilly is given below.**

**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 Panel noted that 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; others were listed as 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 noted that a similar chart was also included in a leaflet, 'Bring back the spontaneity into your love life'; this chart gave the brand names and non-proprietary names for each treatment choice. The leaflet was intended to be placed in surgery waiting rooms and pharmacies for ED sufferers to take. Other materials also referred to spontaneity and the Panel considered that this together with naming Cialis and the details of its duration of effect given in the chart as 'Up to 36 hours after dosing' would lead patients to ask for a prescription for Cialis. A breach of the Code was ruled.**

**All the items clearly stated that they were sponsored by Lilly as required by the Code. The Panel did not accept that the campaign was disease mongering as stated in the article.**

**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 contra-indications. 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 Financial Times (FT) of 29 July carried an article entitled 'Sex problems campaign will test rules' which criticised Eli Lilly and Company Limited's 40over40 campaign. In accordance with Paragraph 6 of the 2008 Constitution and Procedure this matter was taken up by the Director as a complaint under the Code.

Lilly's product, Cialis (tadalafil) was a PDE5 inhibitor for the treatment of erectile dysfunction (ED).

## COMPLAINT

The article alleged that US-style advertising for drugs was coming to Britain in the shape of a television campaign to raise awareness of ED. Lilly had launched a series of television and national newspaper advertisements – the most ambitious to date about ED, accompanied by internet sites and discussion groups, which would run until September.

The campaign raised the prospect of Britons for the first time being subject to the kind of widespread advertising for Viagra and other ED medicines that had become so common to US television, particularly during sporting events and other programming that appealed to men.

It would be closely scrutinised by regulators and competitors for any potential breach of European rules, which forbade companies to advertise prescription medicines directly to patients.

Lilly insisted its campaign respected UK and EU rules that allowed general education about a disease so long as there was no specific promotion of its own medicines.

The company produced Cialis, the most recent of three prescription medicines launched in the competitive ED market. The advertisements, which included short broadcasts after the 9pm watershed for adults on ITV and Channel 4, did not directly name any of the prescription medicine brands available for the condition, but stressed that leading treatment options included the use of three different medicines, and Lilly used its own corporate logo prominently.

A spokeswoman for Lilly said all guidelines had been rigorously respected and the campaign stressed the risk of underlying illness behind ED.

Consumer advertising of prescription medicines had been widespread over the past decade in the US, but had been criticised for disease mongering – encouraging patients to press doctors to prescribe medicines excessively and irresponsibly. A number of pharmaceutical companies had cut back on the practice in an attempt to regain public trust.

The UK campaign, 40over40, referred to the claim that 40 per cent of men over 40 years old suffer from ED – included a table that listed three anonymous oral tablets as the most prominent form of treatment.

While not naming Cialis or its rivals Viagra and Levitra, the first entry in the treatment table was identifiable as Cialis through a description of its unique characteristics and side-effects. Lilly also placed its own logo at the foot of the web page next to another website sponsored by the company. The advertisements marked a sharp advance in a trend for medicines marketing in the UK, at a time when pharmaceutical companies were struggling to bolster revenues.

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 numbered differently. The case was considered under the 2008 Constitution and Procedure.

## RESPONSE

Lilly refuted any allegation reported in this article in relation to its ED disease awareness campaign. Lilly submitted that 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 submitted that ED was a distressing condition for both sufferers and their partners (Fisher *et al* 2005), and one with which many men tended to suffer in silence for prolonged periods of time. In the UK, 2.3 million men suffered from ED, up to 80% of whom had an underlying illness such as diabetes or heart disease (Sullivan *et al* 2001 and Sexual Dysfunction Association 2007). ED could be a warning sign of such conditions (Feldman *et al* 1994 and Journal of Community Nursing on line). Lilly's ED disease awareness campaign was designed to raise awareness among sufferers of the condition, its prevalence, link to underlying illnesses as well as the treatment options available.

Lilly submitted that essential to the success of the campaign over previous disease awareness campaigns conducted by both it and other companies with interest in the disease area, was the need to deliver a strong and memorable consumer-orientated campaign (the name 40over40 was chosen for ease of recall and because it reflected the evidence of prevalence of the condition) designed to effectively deliver the following messages in a non-promotional manner.

- ED was common – 40% of men over 40 suffered from some degree of ED (Feldman *et al*).

  Knowing that other men suffered from this distressing and embarrassing condition was considered by Lilly to be empowering and would reduce the sense of isolation felt by sufferers.

- ED was treatable – 95% of sufferers could be treated (Journal of Community Nursing online).

  A wide array of modern treatments for ED now existed, encompassing first-line (principally oral PDE5 inhibitors), second-line (principally intra-urethral or intra-cavernosal alprostadil) and third-line treatments (penile implant surgery). Together with psychosexual counselling, few, if any patients experienced no improvement in their ED.

- ED sufferers could enjoy their love life again – once diagnosed and appropriate treatment prescribed by their GP, sufferers had the possibility of again reacting spontaneously to their partners.

**Elements of campaign**

Lilly submitted that the 40over40 campaign comprised non-promotional materials delivered through various form of media (including TV, internet and print) and was directed to the public and health professionals. Consistent with the Code, all the materials associated with the campaign identified Lilly as sponsor of the campaign.

- **40over40 television advertisement**

Lilly submitted that television advertising was a powerful tool in bringing messages to the public's attention and such media was considered an

important element of the 40over40 campaign to effectively deliver the campaign to the widest audience of sufferers and raise awareness of the disease. The television advertisement, which was subject to pre-vetting and approval of Clearcast (the broadcast industry's pre-transmission clearance body) was therefore scheduled to be broadcast during programmes that were of most interest to men and, in light of the subject matter, and with agreement of Clearcast, was given a post-9pm broadcast restriction.

Lilly submitted that television advertisements for disease awareness campaigns, which it and other pharmaceutical companies had conducted in the past, for a variety of diseases and conditions, such as ED itself, were not prohibited by the Code or the MHRA. Lilly did not accept the suggestion that the 40over40 television advertisement amounted to a US style advertisement for medicines. The campaign as a whole, including the television advertisement, had been conceived and developed entirely by Lilly's UK company and the television advertisement, as well as all other materials of the campaign, certified in accordance with the requirements of the Code.

Lilly submitted that the television advertisement was non-promotional and in accordance with the Code and the MHRA Guidelines for conducting Disease Awareness Campaigns. Indeed, the FT article conceded that the advertisement did not name any of the ED prescription brands. Contrary to the assertion that the television advertisement stressed that leading treatment options included the use of three different medicines, the advertisement invited the viewer to consider that there existed a 'range of treatments that could help you' – with no greater level of specificity than that. Further, consistent with the Code, the advertisement also identified Lilly as sponsor of the campaign.

- **40over40.com**

Lilly submitted that the ED disease awareness campaign website, www.40over40.com, contained a comprehensive overview of the disease. There were four sections directed at ED sufferers: Talk; Test; Treat; Today; these comprised the 4T Action Plan (see below). A section to be directed to health professionals was currently under construction (see 'Health professionals materials' below). Contrary to the FT article, the campaign did not include any discussion groups or forums connected to the website or otherwise.

**Talk:** This section outlined the basics of ED, its prevalence, the importance of sufferers to be able to talk to their GP and their partner, as well as helpful tips on how to raise this sensitive topic.

**Test:** This section contained the International Index of Erectile Function (IIEF) questionnaire for sufferers to rate their severity of ED. It also contained information about the tests that a GP might carry out to determine any underlying conditions as well as a section on ED and diabetes as ED could be associated with diabetes.

**Treat:** This section contained a thorough, fair and balanced list of all of the treatment options available for ED, including oral PDE5 inhibitors, injections, pumps, counselling, hormone treatment and surgery.

**Today:** This section contained a series of links to advocacy group websites related to ED. There was also a series of videos of a media GP with an expert interest in ED, talking to viewers on similar topics that were covered throughout the website.

Lilly refuted any implication that the website constituted the advertising of prescription only medicines to the public. The table of treatments referred to comprised a fair and balanced list of the whole range of options available for the management of ED. Within the table oral treatments were listed first because they were generally the first-line treatment option for ED; hence their logical place was first in the list rather than as suggested by the article as the most prominent form of treatment. The information contained in this website was designed to be used by sufferers in discussion with their doctor and any consideration of the relative merits of the treatment options mentioned remained the responsibility of the health professional.

Lilly submitted that again, consistent with the Code, the 40over40.com website identified Lilly as the campaign sponsor. Amongst six other websites offering advice and support in this and other related areas, it also correctly identified www.lovelifematters.co.uk, a website directed to the partners of those suffering from ED, as sponsored by Lilly.

- **Consumer print materials**

Lilly submitted that the most effective way of raising ED disease awareness was through a variety of media channels. Therefore, in addition to the television advertisement and the 40over40 website, the campaign comprised printed materials directed to ED sufferers (a full list was provided). Such non-promotional materials were available in the healthcare setting, such as surgeries and pharmacies, and provided ED sufferers with information on the condition in order to enable them to discuss their problems with their GP and obtain appropriate advice.

- **Health professional materials**

Lilly submitted that the role of the health professional was an important one, as they would discuss, diagnose and decide, with the ED sufferer, appropriate management of their problems. The objective of the campaign materials for health

professionals was to inform them that Lilly was raising awareness of ED through a disease awareness campaign and to remind them of the critical role they played in talking about the condition, testing for any underlying conditions which might be causing ED and appropriately treating where necessary.

Lilly planned to launch a health professional section within the www.40over40.com website shortly. A copy of this site was provided. This particular aspect of the Lilly ED disease awareness campaign, whilst certified, was not currently live as it was under construction. Therefore the current homepage did not contain any links to a health professionals section.

- **Public relations**

To coincide with the launch of its campaign Lilly had commissioned a survey of 1,000 men aged over 40; the results highlighted a variance between men's health expectations and reality.

Lilly's public/media relations media releases highlighted the survey data plus the launch of the campaign. The media releases were tailored to audiences comprising men with ED, GPs, nurses, pharmacists and media correspondents. A full list of the media releases and other PR materials was provided.

In addition, as part of the public relations campaign associated with the launch of the disease awareness campaign, a media Doctor conducted interviews with regional and local radio stations. The approved radio script and cue sheet were provided.

**FT article entitled 'Sex problems campaign will test rules'**

With regard to the allegations reported in the FT article, in addition to its comments above, Lilly specifically addressed the following comments:

Allegation of advertising prescription medicines directly to the public

- The 40over40 campaign sought to educate sufferers that ED could be managed effectively. The campaign materials provided a balance of information with respect to ED as a disease, how its management could be broached and discussed with health professionals and the broad range of treatments available. Raising awareness of ED was responsible and the campaign was consistent with the Code. Lilly categorically refuted the allegation that the campaign was aimed at advertising prescription medicines directly to the public.

**Implication of disease mongering**

- Lilly refuted any suggestions, implied or otherwise, that the 40over40 campaign could be considered to be disease mongering. As stated above, ED was recognised as a serious condition with considerable implications to both the sufferer and their partner. Indeed, research had shown that ED was an indicator of other serious health issues, such as diabetes and cardiovascular disease; in one report the majority of men seeking ED treatment were newly diagnosed with hypertension, diabetes, dyslipidemia (high cholesterol) or angina (Sadovsky, 2007).

**Specific identification of Cialis**

- Lilly submitted that with specific regard to the treatment table that appeared in the 40over40 website, the article stated that whilst Cialis was not named, the first entry was identifiable as Cialis through a description of its unique characteristics and side-effects. Lilly did not accept that there was any basis for the assertion that a member of the public would be able to identify any particular PDE5 inhibitor (including Cialis) by reference to the characteristics of Product 1, 2 or 3 as set out in this website treatment table. Therefore, Lilly did not accept the suggestion that this treatment table constituted the promotion of Cialis to the general public or was likely to bias either the ED sufferer or their doctor towards consideration of Cialis. The treatment table presented all treatment options available for ED in a fair and balanced manner, and such presentation would not in any event restrict the naming of such treatment options, as long as such a treatment table was fair and balanced. The fact that treatments, named or anonymised, might have unique characteristics and/or side effects did not in itself preclude presentation of treatment options in the context of a fair and balanced discussion. Lilly therefore refuted any allegation that the treatment table promoted Cialis. Lilly was aware of its responsibilities with respect to the Code and had ensured that all aspects of the 40over40 campaign were consistent with this and of the highest standards and quality.

## PANEL RULING

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 summary of product characteristics (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 noted that a similar chart was also included in a leaflet (ref CI1534), 'Bring back the spontaneity into your love life'; this chart gave the brand names and non-proprietary names for each treatment choice. The leaflet was intended to be placed in surgery waiting rooms and pharmacies for ED sufferers to take. Many of the other materials referred to spontaneity; for example the web banner advertisements (CI 1540), one of which started 'Go back to loving spontaneously' followed by '95% of erectile dysfunction can be treated' and 'Go to **www.40over40.com** and Talk-Test-Treat-Today'. The consumer print advertisement (CI 1536) included the statement 'Bring back spontaneity into your love life' as did the surgery poster (CI 1533) and the leaflet card dispenser (CI 1539). The Panel considered that the call to bring back spontaneity together with naming Cialis and the details of its duration of effect given in the chart as 'Up to 36 hours after dosing' would lead patients to ask for a

prescription for Cialis. A breach of Clause 22.2 was ruled.

All the items clearly stated that they were sponsored by Lilly as required by the Code. The Panel did not accept that the campaign was disease mongering as stated in the article.

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 contra-indications. 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.

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| **Proceedings commenced** | **30 July 2008** |
| **Case completed** | **10 October 2008** |